Clinical incident management

Factsheet 11 Key information for Board Directors and Executive

The vast majority of care delivered in hospitals and by other health services in Queensland is very safe and effective. However, despite excellent skills and best intentions of our staff, occasionally things do not go as expected. When this happens, it is distressing for patients, families and staff, particularly when the consequence is severe. These events can also cause the community to lose trust in their healthcare system.

Clinical Incident Management (CIM) systems are utilised worldwide for recording, analysing and learning from clinical incidents. Self-reporting incident systems form a foundation of good transparent and accountable patient safety approaches: investigating incidents and implementing recommendations is crucial for improving the care of our patients.

Queensland Health has worked hard to develop a learning system approach, with a patient safety culture that actively encourages staff to report clinical incidents and see these as opportunities to learn from and fix problems. Incident reporting is viewed as an indicator of a good patient safety culture that ultimately leads to better patient care.

What is a clinical incident?

A clinical incident is any unplanned event which causes, or has the potential to cause, harm to a patient. An adverse event is a clinical incident which resulted in unintended or unnecessary harm to the patient.

Queensland Health categorises clinical incidents into four groupings i.e. Severity Assessment Codes (SACs) according to the level of harm experienced.

- SAC1: Death or likely permanent harm which is not reasonably expected as an outcome of healthcare.
- SAC2: Temporary harm which is not reasonably expected as an outcome of healthcare.
- SAC3: Minimal or no harm which is not reasonably expected as an outcome of healthcare.
- SAC4: No harm or near miss.

NB *A SAC 1 event does not automatically mean that there is an act or omission by the health service that contributed to the outcome.*

Background of patient harm and the effectiveness of CIM

Patient harm rates remain at unacceptably high levels around the world: between 6-16% of hospital inpatients will experience an adverse event with approximately 0.5% of hospital inpatients having an adverse event, resulting in permanent harm or death.[1] About half of these harms are deemed preventable. Health systems are still learning how best to further reduce this preventable harm.

Why is there so much risk and harm in healthcare?

Providing health care on a daily basis is the single most complex undertaking for the clinical / health workforce within organisations:

- Each patient requires a myriad of interrelated considerations and care, depending on their diagnosis, comorbidities, complications; the interactions of these can result in complex care.
- Equipment and computer systems failures can cause vulnerabilities, impacting on staff and patients.
- The care is provided and coordinated by a team of different professions, working, for patients, on a 24 hour a day, 7 days a week basis.
- Staff shortages can present a challenge to providing safe health care (due to availability of experienced skilled staff and/or unexpected leave).

[1] National Patient Safety Foundation. *Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after* To Err Is Human. Boston, MA: National Patient Safety Foundation; 2015.

- There are thousands of guidelines, protocols and procedures for these staff to follow.
- Improvement and streamlining processes in healthcare lags other industries, so healthcare has not been good at making it easier for staff to navigate this complexity and always do the right thing for patients. This complexity is growing.[2]
- Many of the risks encountered in healthcare are unique for which there are no correct and agreed rules, procedures and precedents for management.

What is *Work-as-done* versus *work-as-imagined* and why it is important?[2]

"Work as imagined" describes what should happen under normal working conditions. Unfortunately, it doesn't take account that those performing the task performance have to adjust to constantly changing conditions of work. "Work as done", on the other hand, describes what actually happens, over time, in the complex reality of health services. Unless what is really happening on the clinical floor is known, the response to clinical incidents is likely to be mis-directed.

Effectiveness of CIM

CIM has resulted in significant gains for patient care.[3] [4] It has helped lead to local improvement initiatives, Clinical Standards and National Standards; there are now successful state-wide systems for alerts and communiques to assist hospitals address emerging issues.

Moving forward however, realising further patient safety gains from clinical incident management is becoming harder. There are other concerns regarding the effectiveness of the current CIM processes globally, that include the following:

- the significant evidence gap in the effectiveness of the various investigative methods used in reducing patient harm.[5]
- the collection of too much information and doing too little with it.[6] There are often insufficient resources to deal with the volume of reports, leaving reports inadequately analysed or acted upon.[7]
- Root Cause Analyses (RCA) focused on the single incident in isolation and not assessing the wider system in which the event occurred[8] or help with highly preventable recurrent incidents.[9]
- weak RCA recommendations i.e. less than 1 out of 10, produce recommendations that are strong enough to prevent recurrence of the incident.[10]
- low implementation rates of recommendations, varying from 45%-70%.[8]
- engagement of patients and families is variable.[8]
- lack of human factors expertise and application leads to attribution of blame.[11]

The high rates of patient harm make essential the Board / Executive / Manager's role in setting the moral compass of the organisation and ensuring a just culture and ethical decision making: **a blame culture is detrimental to patient safety.**

Restorative Just Culture – the foundation

Every Board Director and Executive needs to cultivate a culture that leads to improved patient care by avoiding blaming behaviours and by assigning roles and responsibilities to support patients, families, and staff, as well learning from and implementing improvements. This is a **Restorative Just Culture.**

If we are to reduce the extent of harm in healthcare, it is crucial that we learn from adverse events to help reduce future harm to patients. The reaction of leaders to an adverse event is crucial in determining if the heath service learns from the incident or not, and hence, if future harm to patients is reduced. Patient harm is distressing to the staff who have cared for them: staff are often the second victim of an adverse event.[12]

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[2] Hollnagel, E., Braithwaite, J. & Wears, R. L. (Eds.) (2013). Resilient Health Care. Farnham, UK: Ashgate.
[3] Bromiley M. *RCoA Bulletin* 2008;48:2442-5
[4] National Patient Safety Agency, 2008
[5] Harrison et al. An evidence Check rapid review brokered by the Sax Institute for the Clinical Excellence Commission 2019.
[6] Macrae C. *BMJ Qual Saf* 2016; 25:71–75.
[7] Mitchell et al. BMJ Qual Saf doi:10.1136/bmjqs-2015-004405
[8] Peerally MF,Carr S, Waring J, *et al. BMJ Qual Saf* 2017;**26:**417-422
[9] Card et al Risk Anal 2014;34:1469-81
[10] Hibbert et al. *INT J QUAL HEALTH C*, 2016, 28(6), 640–649
[11] Makeham et Sydney: Australian Commission on Safety and Quality in Healthcare 2017.
[12] Sirriyeh et al. Quality and Safety in Health Care. 2010;19(6):e43.

A reaction to an adverse event that is based on hindsight, that focus on the individual care giver rather than the system of care and that focus on what people should have done, rather than understanding why they did it, will not help reduce future harm: a blame culture is detrimental to patient safety. It can have devastating effects on staff and on the broader healthcare community.

As an alternative, a restorative just culture replaces this backward-looking determination of blame with a focus on learning and support for all the people affected by the adverse event.[13]

A restorative just culture asks "what" is responsible not "who" is responsible. It is very action oriented and assigns roles and responsibilities for all who have a stake in the event. Everyone accepts forward-looking accountability. Staff have accountability to support families, learn from incidents and be part of the improvement process. Board Directors and Executives have accountability for ensuring systems are in place to support consumers and families after an event, to provide evidence-based support for staff; to learn from and implement improvements. They have accountability for modulating their responses to an event to ensure these processes occur without the detrimental impact of hindsight bias.

Key roles for Board Directors

The two key roles for Board Directors in clinical incident management are:

1. Monitor the CIM performance of the Hospital and Health Service (HHS) and in particular, the governance and legislation requirements (see below).
2. Monitor the recommendations arising from CIM including the *implementation* of these recommendations and the *sustaining* of the resultant patient care gains.

In fulfilling these roles, Board Directors will:

- Respect the confidentiality of patients and staff information involved in incidents.
- Hold themselves accountable for cultivating a restorative just and learning culture.
- Acknowledge the high-risk nature of healthcare and the extent of patient harm.
- Acknowledge the complexity of the system within which staff strive to provide consistent high-quality care and prevent patient harm.
- Pay particular focus to the key aspects of CIM as outlined in this Factsheet.
- Seek assurance on the issues/risks arising from CIM by asking questions of Executive, while acknowledging that it is the role of Executive to manage CIM: "noses in, fingers out" is the appropriate Board Director mindset.[14]

Key roles for Executive

The two key roles Executive play in clinical incident management include:

1. Board engagement:
    a. Report to the Board in a manner that is candid in so far as CIM issues/risks, compliance and improvement. The Executive should provide expert narrative from the perspective of "what does the Board need to know to make a decision".
    b. Answer with candour the questions that the Board needs to ask to fulfil its roles in CIM.
2. Management of CIM and in particular:
    a. Ensure governance and legislation requirements are met (see below).
    b. Provide leadership in the process of developing recommendations including the implementation of these recommendations and the sustaining of the resultant patient care gains.

In fulfilling these roles, Executive will:

- Respect the confidentiality of patients and staff information involved in incidents
- Acknowledge the importance of supporting the clinical/health workforce to mitigate the recurrence of similar incidents.
- Hold themselves accountable for cultivating a restorative just and learning culture.
- Acknowledge the high-risk nature of

[13] Turner et al. ANZJP.2020: 54(6):000486742091865
[14] Australian Institute of Company Directors (AICD), Company Director Magazine, 01 Dec 2015. Accessed 29 September 2020. <http://www.companydirectors.com.au/director-resource-centre/publications/company-director-magazine/2015-back-editions/december?page=2>

healthcare and the extent of patient harm.

- Ensure staff have access to critical incident debriefing to support their health and wellbeing.
- Acknowledge the complexity of the system within which staff strive to provide consistent high-quality care and prevent harm to patients.
- Pay particular focus to the key aspects of CIM as outlined in this Factsheet.

Key governance and legislation information

There is no legislation or binding policy in Queensland that prescribes which form of analysis HHS must undertake for SAC 1 events.

The requirements for a SAC1, under the Patient Safety Health Service Directive [15], requires:

- HHS to report all SAC1 incident in RiskMan within one business day of becoming aware of the SAC1 event.
- HHS to conduct an analysis of all SAC1 clinical incidents containing a factual description of the event, the factors contributing to the event and recommendations to prevent or reduce the likelihood of a similar event.
- HHS are to submit a report to the Patient Safety and Quality Improvement Service (PSQIS) within 90 calendar days.

There are no legislative requirements for SAC 2, 3 or 4 incident management.

Key areas to focus on to increase the effectiveness of clinical incident management

1. Analysing incidents

As identified above HHSs are required to conduct an analysis of SAC 1 clinical incidents, selection of the type of analysis is up to the HHS. HHSs may also choose to undertake an analysis on other incidents that may have led to more serious harm or require a detailed analysis.

There are at least 35 different analysis methods for serious incidents, each with their strengths and weaknesses.[5] In QH, the main analysis tools are RCA, Human Error and Patient Safety and Clinical Review. There are decision support tools to help guide which analysis to use. For example, where there are indications that the incident has systems causes that are highly preventable, a systems analysis and improvement tool results in stronger recommendations and sustainable changes.[16]

2. Effective recommendations

Recommendations need to be based on both their strength in preventing recurrence and for their achievability. Recommendations such as procedure writing and education, which currently dominate recommendations, are unlikely to prevent the event reoccurring.[17]

Getting the right stakeholders involved, knowing what "good" looks like, brainstorming findings, and prioritising recommendations based on *both impact and achievability* will help recommendations to be more effective in improving patient care.

Recommendations made in conjunction with the treating clinicians (particularly those involved in the clinical incident) are more powerful and likely to be sustained long-term.

Refer to *Factsheet 6: Effective recommendations*

3. Implementing and sustaining the improvements

All improvement involves change. Implementing of recommendations and sustaining the gains has been a weak link in global incident management processes. Implementation is hard in the face of system complexity.[18] Yet to impact patient care, monitoring the implementation of changes resulting from investigations, and their impact needs to happen.[5] Before widespread implementation, changes may need to be tested at small scale to check if they work and to learn from those tests.[19]

Refer to *Factsheet 8: Implementing and sustaining the improvements*

[15] *Health Service Directive # QH-HSD-032:2014*
[16] Dixon-Woods M, Martin GP. Future Hospital Journal 2016 Vol 3, No 3: 191–4
[17] Kellogg et al. BMJ Qual Saf.2017;26(5):381-7
[18] Vincent et al. Implementation Science: IS.2017;12 (1):151
[19] Harvard Business Review. Accessed 30 March 2020. <https://hbr.org/2016/11/4-steps-to-sustaining-improvement-in-health-care>

4. The role of the patient/family/ carer in incident management

A key principle of good clinical incident management is the transparent involvement of patients/families/carers. Their key concerns must be identified at the commencement of the process and the report must address their concerns. For SAC1 incidents, patients /families /carers should be offered formal open disclosure and the *review report* should be offered to them. For RCA, this release needs to be approved by the Commissioning Authority.

Refer to *Factsheet 2: Supporting the patient/family/carer when a serious incident occurs*.

5. The use of clinical incident data

The global evidence says that only 2-8% of all clinical incidents are reported.[10] So, numbers or rates of reported incidents offer a poor way of measuring safety performance.[1]

In the complexity of healthcare, there is rarely a single piece of information that gives the answer. Mostly, there are multiple, interacting contributory factors to an issue.

Given this reality, using clinical incident *rates* to assess clinical performance is not advised.

Refer to *Factsheet 10: Using incident numbers and rates.*

Conclusion

Clinical Incident Management systems are a basic and valued foundation of patient safety. They have resulted in many improvements in patient care at a local, nationally and international level.

The continuing high rates of harm to patients and the growing complexity of healthcare highlights the need for health care systems to better utilise CIM systems to improve patient care.

Globally, opportunities to improve the effectiveness of these systems have become apparent. This Factsheet summarises the Queensland Health Clinical Incident Management system and outlines five (5) key areas for the consideration of Board Directors, Executive and Managers to improve the care of our patients as well as providing support for the wellbeing of our health workforce.

Note: Human Rights Act 2019

Due consideration must be given under the *Human Rights Act 2019* to undertake public functions in a principled way that places individuals at the centre of decision making and service delivery, ensuring that all have their human rights respected, protected and promoted.

For further information on clinical incident management in your Hospital and Health Service, please contact your local Clinical Governance Unit.

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