Serious Adverse Event Review

Incident analysis-

Immediacy, Accountability, Kindness

NSW GOVERNMENT | CLINICAL EXCELLENCE COMMISSION

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Background

Everyday thousands of patients in New South Wales (NSW) are treated safely and compassionately by highly skilled healthcare professionals. On occasion things go wrong that result in poor outcomes for patients, carers and their families. When a serious incident occurs, action is taken to reduce or prevent the likelihood of future harm.

Serious clinical incidents undergo a serious adverse event review. The Chief Executive determines the review methodology for each incident.

Regardless of methodology used, an incident review focuses on answering:

- What happened?

- Why did it happen?

- What action can we take to prevent it happening again?

Serious adverse event reviews in NSW are underpinned by:

- Just culture – when an incident occurs, individuals are treated fairly and not held accountable for system failings over which they have no control

- Focus on systems and not people – review processes consider the conditions under which individuals work, taking into account the complexity and interdependencies

- Human factors – action is taken to improve the interaction of staff with one another and the environment in which they work

- Learning – outcomes are shared to generate insights for action

This toolkit provides guidance for teams undertaking an Incident analysis (IA) review. It includes the tools and processes that will assist a team in answering the three questions. It is divided into two sections:

1. Concise incident analysis

2. Comprehensive incident analysis

Each section / methodology has a different approach to answering the questions:

- What happened?

- Why did it happen?

However, the response to "What action can we take to prevent it happening again?" is consistent with no difference in the approach. This guidance can be found at the end of this toolkit.

The Incident analysis workbooks act as a compendium to this toolkit and should be used by teams to ensure that all necessary steps have been completed.

Acronyms

ASE	Australian Sentinel Event
CE	Chief Executive
DFC	Dedicated family contact
PRA	Preliminary risk assessment
RCA	Root cause analysis
RIB	Reportable incident brief
SAER	Serious adverse event review

Serious adverse event reviews

A serious adverse event review (SAER) is required for reportable incidents (clinical Harm Score 1) or clinical incidents that the Chief Executive determines may be due to serious systemic problems.

Approved SAER review methods are outlined in the *Health Administration Regulation 2020*. The Chief Executive determines the review method for each incident.

- Root cause analysis (RCA)

- Systems Analysis of Clinical Incidents – London Protocol

- Concise incident analysis

- Comprehensive incident analysis

Privilege

Statutory privilege applies from the time a SAER team is appointed. It protects team members and documents produced as part of the review from use as admissible evidence in any legal proceedings. It does not apply to documents produced previously including the incident report or medical record.

SAER team members maintain privilege by not disclosing any information obtained during the investigation, unless it is for a purpose that is part of the SAER process.

The Incident Management Policy provides further guidance on privilege.

Before the team is appointed

When a serious incident occurs there are a series of processes that take place prior to the commencement of a SAER.

These include:

1) Clinician disclosure – staff share what they know about the incident with the patient, care and family

2) The incident is notified in ims[+] and relevant staff are informed

3) The CE appoints a team of staff to undertake a preliminary risk assessment (PRA) to ensure that people and the environment are sate and supported

4) A Reportable Incident Brief (RIB) is submitted to the Ministry of Health

5) A dedicated family contact is appointed. This staff member is the main contact for the family during the SAER process

6) The Open Disclosure team meet with the family and share the findings of the PRA

Team composition

The Chief Executive (CE) appoints a concise IA team composed of 2 members:

- One team member (usually team leader) has SAER expertise

- One has essential knowledge of the care processes where the incident occurred

- No team member should have been directly involved in the incident or patient's care

Team members should not:

- Have any personal connection with clinicians involved in the incident

- Have a conflict of interest

- Be the manager of the department or unit where the incident occurred

Team appointment

Team members receive a CE letter of appointment and are informed of their roles and responsibilities.

Training team members

IA team members will come from different backgrounds. Some may have extensive knowledge and experience in SAER processes. For others, the foundational concepts of IA may be totally new.

The team leader will have experience and training with IA. Other team members require a basic understanding of IA process. They are encouraged to access IA Just in time training that are available on the Clinical Excellence Commission (CEC) website.

www.cec.health.nsw.gov.au/

Issues with individual clinicians

If the SAER team forms the opinion that an incident may involve professional misconduct, unsatisfactory professional conduct or impairment by an individual clinician/s, they **must** notify the CE in writing. The CE will determine appropriate action in accordance with PD2018_032 Managing Complaints and Concerns about Clinicians with support from Human Resources as required.

SAER teams can use decision trees to help determine individual versus systemic issues The CEC website contains a number of tools that the team may wish to apply. www.cec.health.nsw.gov.au/Review-incidents/Upcoming-changes-to-incident-management

The SAER team take no further action on the matter that relates to the individual.

The team may continue to review the **systems issues** in the incident. This may include exploring why staff involved in incidents acted as they did, and to pose appropriate questions to explore the human factors aspects of an incident (e.g. communication processes).

Incident analysis

Incident analysis (IA) is an incident review methodology that has been developed based on learning gained from the Canadian experience with incident analysis[1]. The methods and resources are designed to support organisational learning, quality improvement, a safe and just culture and improve the success of analysis in enhancing the safety of patient care.

One of the key differences in this methodology is the discontinuation of the use of the term "root cause analysis"(RCA), as there was a misperception by some that the RCA only generated one "root cause". The approach also moves beyond a linear representation of patient safety incident analysis by introducing concepts related to complexity theory and depicting contributing factors as clusters within a constellation, rather than as part of direct one-to-one cause-and-effect relationships.

IA highlights the importance of recognising that there are many sources of information flowing through a healthcare organisation that can clarify risks to the safety of patients (e.g. recommendations from accreditation, complaints, global trigger tool data, etc.). It provides resources to assist organisations to synthesize the findings from incident analysis with these other recommendations in a coordinated manner.

The resources and tools presented in this toolkit are largely based on the original Canadian Incident Analysis Framework[1] IA but have been adapted for use in the New South Wales (NSW) context. Some of the tools and processes have been amended.

IA methodology provides two approaches for reviewing incidents: a concise and comprehensive incident analysis. The approach to be used is determined by advice to the Chief Executive from the PRA team. However, in some instances a concise event analysis may generate information that prompts the need for a comprehensive event analysis.

1. **Concise incident analysis** is a succinct, yet systematic way to review incidents. The sources of information consulted are the available reports, supplemented with a small number of select interviews and a targeted review of other sources of information. The analysis is completed in a short interval of time by two individuals.

2. **Comprehensive incident analysis** is used for complicated and complex incidents. Multiple sources of information are consulted, including interviews with those directly or indirectly involved in the incident as well as experts, and may be supplemented by a literature review. A significant amount of time and resources (human and financial) can be invested to conduct the analysis.

IA is one of the approved methods outlined in the Regulations. The Chief Executive (CE) determines the appropriate review method for each incident, however in general IAs are the preferred approach for community mental health Harm Score 1 incidents

The Chief Executive determines the review method for each Harm Score 1 incident. Findings from the preliminary risk assessment will provide guidance for the decision.

In Mental Health settings, Incident Analysis is used to review community suicides as follows:

- The review of community suicides that occurred within 2-7 days of last contact with a community mental health commence with a NSW Health Concise incident analysis.

- If issues of complexity arise during the data gathering stage a discussion should occur with Director Clinical Governance to determine if transition to Comprehensive incident analysis is indicated.

* Refer to guidance on page 17 regarding the process for transitioning form a concise to comprehensive incident analysis.

High level overview IA process and tools

What happened?	Why did it happen?	What action can we take to prevent it happening again?
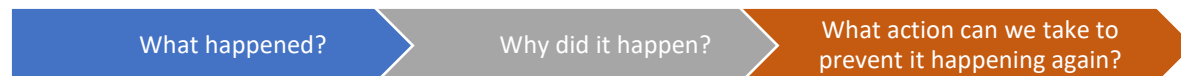
Phase	Process / tools used
Gather information	Review of incident report, medical record, and PRA Family and staff interviews Literature review Review of documents e.g. standards, policies Equipment or other artefacts Site visits
Construct a timeline	Detailed incident chronology
Identify factors that caused or contributed to the incident	Guiding questions Constellation diagram
Link factors to the outcome	Statements of findings
Develop findings	Findings worksheet
Make recommendations	Action hierarchy worksheet IA Action Planning worksheet

Differences between concise and comprehensive incident analysis

Characteristic	Concise	Comprehensive
Review team	2 people	3-5 people
Review team includes people with knowledge of incident review, human factors, systems approach, and effective solutions development	Yes	Yes
Family interviews completed	Yes	Yes
Time taken for review	30 days	60 days
Complexity level	Complicated	Complicated, complex
Resources required / available	Moderate	Moderate to extensive

Tools used	Concise	Comprehensive
Review of incident report, PRA and medical record	Yes	Yes
Staff interviews	Small number – max 30 minutes duration	All staff involved
Site visits	Where appropriate	Yes (if possible, simulate incident)
Detailed incident chronology	Yes	Yes
Guiding questions	Categories reviewed for appropriateness. Review of questions in relevant categories only	All questions reviewed
Constellation diagram	Yes	Yes

Concise incident analysis

IA flow – Concise incident analysis

The following describes the recommended flow for conducting a concise IA review. The flow and process may vary depending on the complexity of the case.

Before the first meeting

The team leader:

- Sends the medical record and any other relevant documentation to the other team member
- Begins to construct the incident chronology
- Communicates with the other team member and determines the staff members to be interviewed

Team members:

- Review medical record and any other relevant documentation and makes notes of about potential human factors, context and complexity and potential questions
- Undertakes family and staff interviews

Meeting 1

1. Incident chronology is finalised and confirmed.
2. The team review the domains of the guiding questions to identify relevant ones.
3. The team review the guiding questions for all relevant domains.
4. A constellation diagram is developed by identifying contributing factors and their inter-relationships
5. Findings are identified and confirmed.
6. Findings are summarised as a series of statements of fact.
7. The team sense-check findings with family and clinical team.

After the first meeting

The Findings Report is written and is shared with the family following CE approval. Additional experts are appointed to the team to assist with developing recommendations if indicated.

Meeting 2

1. Any new team members are briefed.
2. Statements of findings are reviewed.
3. Actions and recommendations and key outcome measures are written.

After the second meeting

The Recommendations Report is finalised and submitted to the CE for approval. The approved Findings and Recommendations Reports are submitted to the Ministry of Health and shared with the family.

Timeline for completion of review: ~ 30 days

What happned?		Why did it happen?		What action can we take to prevent it happening again?
• Completed within 2-3 weeks	→	• Completed within 3-4 weeks	→	• Completed within 4-5 weeks
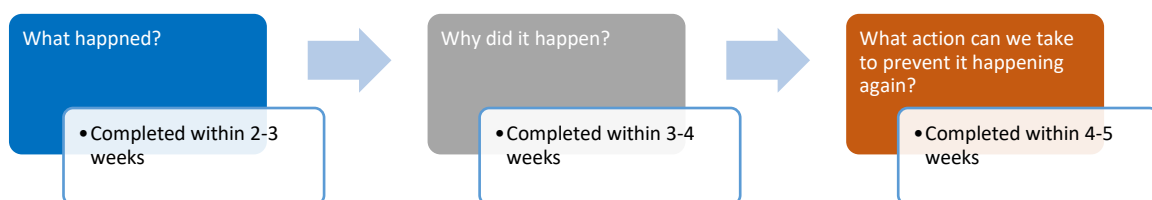
Section one: What happened?

> For a concise IA team to understand what happened they:
>
> Step 1:   Gather information
>
> Step 2:   Construct incident chronology

Preparation

The team leader provides team members with access to the incident report, medical record, preliminary risk assessment (PRA) and any other relevant documentation to review prior to the first meeting.

Step 1: Gather information

The concise IA team gather sufficient information in order to understand how and why the incident occurred. The reviewer may have informal discussions with the family, healthcare providers, managers and / or experts in the process and examine any equipment involved in the incident. Open ended questions are used to elicit the 'story' from the individual's perspective. The IA team ask about any factors that contributed to the incident as well as factors that mitigated the outcome of the incident (what went well?).

Instructions
   I.   The team gather and review all relevant information including the incident report, PRA report, medical record, policies.
   II. Any material that have directly or indirectly contributed to the circumstances such as equipment and any product / care items. Photographs of workspaces may also be helpful
   III. Informal discussions (interviews) are held with families and a small number of staff and managers. Interviews last approximately 30 minutes with the following questions asked:
        a. What happened?
        b. What factors may have contributed to the incident?
        c. What factors may have mitigated the severity of the incident?
        d. How might an incident like this be prevented in the future?

Step 2: Construct incident chronology

Once all the information has been gathered, the concise IA team can construct an incident chronology. This provides a detailed timeline of the steps leading to the event. This information is provided in the form of a narrative chronological description.

Because the team will use the detailed timeline as a starting point for identifying system-based factors underlying the incident, it is crucial that the timeline include only the actual facts or processes as they occurred, and not what was supposed to happen.

Instructions

    I.   The team review information gathered and document in a chronological narrative

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The following incident will be used to demonstrate the application of the tools during a concise incident analysis during the remainder of this section.

Client was found in bathroom by RN on arrival at 0900 for dressing change. Moderate amount of bright red blood in toilet and floor. Ambulance called and transferred to Emergency Dept. Incident notifier called ED and spoke with Nurse looking after patient. Patient's INR 5.8. Upon review of medication bottles it was determined that patient was unintentionally taking 5 mg of Warfarin daily as he did not know that Coumadin was the same medication as Warfarin so took "previously"ordered dose of 3 mg (Warfarin) and "newly" prescribed dose of 2 mg(Coumadin) as well. The patient's condition was unable to be stabilised. He died in the Intensive Care Unit surrounded by family

Date / time	Information item	Comment / source
History	Client receiving weekly home care visit by RN for leg ulcer dressing change every five to seven days for approximately six weeks. Occasionally forgetful about caring for dressing and short-term memory mildly impaired, however able to manage own medications.	
Friday – 14 days prior to incident	RN makes home visit to change client's leg dressing. She notes that he is feverish and short of breath with congested cough. RN contacts client's GP and transfer to hospital is arranged. Patient is admitted community acquired pneumonia.	Community health record
5 days prior to incident	Patient is discharged from hospital and returns to apartment. INR testing during hospital stay resulted in Warfarin dose being reduced to 2 mg OD. Physician referral lists medications Nifedipine 10mg TID (calcium channel blocker), Atenolol 50 mg BID (betablocker), Coumadin 2 mg OD (anticoagulant), ASA 81 mg OD(antiplatelet), Doxycycline 100mg OD x 6 days (antibiotic),Nitrospray prn and DuoDERMR dressing to leg ulcer weekly and request to resume dressing change schedule as well as request for assistance with weekly bath. Referral received by fax on Saturday. RN responsible for that area of the community on the weekend does not know the client however she reviewed referral and home care record. Minimal changes noted so slotted for RN visit for dressing change in five days (Thursday) and personal carer booked to make home visit for assistance with bath in six days (Friday). She leaves a voice mail for the regularly scheduled RN in the area to advise her of the client's return home however that RN is off work for several days before receiving the message. She has significant backlog of messages and workload so does not take any action with this information.	Hospital electronic medical record and referral form RN interview (regularly scheduled in the area)
5 days prior to incident	At the Pharmacy: • Pharmacy technician processes filling the prescription in computer. • Pharmacist notes the change in Warfarin/Coumadin dose from 3mg OD to 2mg OD so ensures that new bottle of tablets provided for ease of self-administration. All medications are filled for dispensing to ensure that patient has sufficient supply for upcoming month. • Pharmacist attempts to explain dosing information to neighbour. Highlights the dose change on the patient information sheets as well as the potential of increased anticoagulant effect with the combination of Doxycycline and Warfarin.	Pharmacist interview

Date / time	Information item	Comment / source
4 days prior to incident	Client continues to feel tired and not eating or drinking very much. Spends much of the day resting in bed or watching TV.	Client interview
2 days prior to incident	Client indicates he felt weak and was also a bit concerned about the colour of his urine. He was also a bit embarrassed about seeing some blood on the toilet paper after he moved his bowels. He assumed it was his haemorrhoids giving him trouble again.	Client interview
2 days prior to incident	Client feeling weaker and more concerned about colour of urine and more blood in stool. Doesn't want to bother neighbour so decides to wait until nurse visits in two days for dressing change.	Client interview
1 day prior to incident	Slept in bed most of day and doesn't recall many other details.	Staff interviews
Day of incident 0900	Client was found in bathroom by RN on arrival at 0900 for dressing change. Moderate amount of bright red blood in toilet and floor. Ambulance called and transferred to Emergency Dept.	RN interview
Day of incident 1400 .	RN called ED and spoke with Nurse looking after patient. Patient's INR 5.8. Upon review of medication bottles, it was determined that patient was unintentionally taking 5 mg of Warfarin daily as he did not know that Coumadin was the same medication as Warfarin so took previously ordered dose of 3mg and newly prescribed dose of 2 mg as well.	RN interview
2 days after incident	The patient's condition was unable to be stabilised. He died in the Intensive Care Unit surrounded by family.	Medical record

Transition to Comprehensive Analysis

If during the step of understanding what happened there is some indication that a concise incident analysis may not be appropriate, consult with Director Clinical Governance to decide if a comprehensive approach to the analysis is needed. If yes, the facts collected so far can be used for the comprehensive analysis. Factors that may be considered:

- Increased need of resources for investigation to effectively identify contributing factors and/or develop high leverage interventions
- Significant risk to organisation (for example, reputation, liability)
- Patterns of similar incidents in other work areas

Tips for transitioning to a Comprehensive Analysis

- Document findings arising from the Concise Incident Analysis and identify key additional sources of information to fully understand what happened.
- Formalise a team for the comprehensive analysis (with original team members).

Section two: Why did it happen?

For the concise IA team to understand why an incident happened they:

Step 3:   Apply guiding questions

Step 4:   Develop a constellation diagram

Step 5:   Write up factors linking them to outcome

Step 5:   Identify any practices

Step 6:   Write findings report

Step 3: Apply guiding questions

The information gathered is used to identify key factors that contributed to the incident. Two key questions that will help this process are: "how did this happen?" and "what else influenced the circumstances?" The facilitator should continue to ask "how" and "what influenced it" questions until no further information can be generated for the key contributing factors.

A set of guiding questions is provided below to guide the identification of contributing factors, hazards and mitigating factors during the "how and why did it happen" stage of incident analysis. They are intended to assist with checking the availability and strength of safeguards at all levels in the organization and guide the analysis towards the identification of system vulnerabilities that aligned in such a way that allowed for the incident to take place. Teams are encouraged to note, analyse and report the system barriers that worked well (mitigating factors) and therefore should be reinforced and recognised so they will continue to prevent future harm.

The questions are grouped around categories of factors designed to focus the analysis on the interaction between humans and the system, and in this way help identify system-level contributing factors at various levels in the organisation.

Use the guiding questions in the table below to briefly explore each domain (task, equipment, work environment, patient characteristics, care team, organization, other) of factors that may have contributed to this incident. For domains that are relevant to the incident, further explore each specific question.

When identifying potential contributing factors, focus on systems-based factors, and not people-focused ones to ensure that likewise, the recommended actions are not people focused. Keeping in mind human factors principles and systems theory, analysis should focus on "how" certain human actions occurred, not just that they occurred.

For example, in the course of analysing an incident in which an incorrect medication was administered, it was determined that the nurse was in a hurry. The fact that the nurse was in a hurry is a factual detail of what happened, and not a contributing factor. The contributing factor(s) are those that may have caused them to be in a hurry. Examples could include: too many tasks were assigned (the nurse was assigned too many complex patients); or the patient's medication needs conflicted with shift change (the patient was admitted right before the shift ended and the nurse wanted to give the patient their pain medications so that they did not have to wait until after the shift change). By focusing on the systems-based contributing factors, the analysis team will be able to identify higher leverage solutions. Recommended actions should be consistent with one of the main tenets of human factors: fit the task or system to the human, not the other way around.

Instructions

I. The IA team review each domain of the guiding questions and determine if it is relevant to the incident

II. For domains that have been identified as relevant, the team explore each question to identify contributing factors

Domains of factors in guiding questions

Patient(s) characteristics: (Considered in the context of how well the system identified, understood, and acted upon these factors. It should not be the only factor considered.)
Task (care/work process)
Care team – Caregiver(s)
Care team – Supporting team (all involved in care process)
Equipment (including materials, fixtures, information and communication systems)
Work environment
Organisation – Policies and priorities
Organisation – Culture
Organisation – Capacity (resources)

Guiding questions

Domain / category of contributing factors	Relevant?	
Patient(s) characteristics: (Considered in the context of how well the system identified, understood, and acted upon these factors. It should not be the only factor considered)		
Did the patient (s) have the information to assist in avoiding the incident?		
If not, what would have supported the patient in assisting their care team?		
Did factors like age, sex, medications, allergies, diagnosis, other medical conditions, contribute to the incident? How did they contribute?		
Did any social or cultural factors contribute to the incident?		
Was language a barrier?		
Other?		
Task (care/work process)		
Were there previous or predicted failures for this task or process?		
Were specialised skills required to perform the task?		

Domain / category of contributing factors	Relevant?
Was a fixed process or sequence of steps required (e.g. order sets, checklists)?	
If a fixed process existed, was it followed?	
Was a protocol available, was it up-to-date, and was it followed in this case?	
Were there constraints or pressures (e.g. time, resources) when performing the task?	
Was the information required to make care decisions available and up-to-date (e.g. test results, documentation, patient identification)?	
Was there a risk assessment/audit/quality control program and in place for the task/process?	
Other?	
Care team – Caregiver(s)	
Were the education, experience, training and skill level appropriate?	
Was fatigue, stressors, health or health factors an issue?	
Was the workload appropriate?	
Was appropriate and timely help or supervision available?	
Other?	
Care team – Supporting team (all involved in care process)	
Was there a clear understanding of roles and responsibilities?	
Was the quality and quantity of communication (verbal and/or written) between team members appropriate (clear, accurate, free of jargon, relevant, complete, and timely)?	
Were there regular team briefings/debriefings about important care issues?	
Was team morale good? Did team members support each other?	
Were the communication channels available and appropriate to support the needs of the team (e.g., email, pager, and phone)?	
Other?	
Equipment (including materials, fixtures, information and communication systems)	
Were the displays and controls understandable?	
Did the equipment automatically detect and display problems?	
Was the display functional?	
Were the warning labels, reference guide, and safety mechanisms functional and readily visible/accessible?	
Were the maintenance and upgrades up-to-date?	
Was the equipment standardised?	
Would the users describe this equipment as easy to use?	
Were the communication systems (phone, pager, software, hardware, etc.) available and operational?	
Other?	
Organisation - Policies and priorities	
Were the relevant policies and procedures available, known, and accessible, and did they meet the needs of users?	
Were there workarounds to the documented policy/procedure?	
Was there a mechanism in place to identify and resolve gaps between policy and practice?	
Were the strategic priorities of the organisation clear to all?	
Other?	
Organisation – Culture	

Domain / category of contributing factors	Relevant?
Was everyone (patients, clinicians, other staff) comfortable to speak-up about safety concerns?	
Was there visible support from leadership and the board for safe patient care?	
Was communication between staff and management supportive of day-to-day safe patient care?	
Were incidents viewed as system failures with a mechanism/transparent process for fair and just review of actions by individuals where indicated?	
Other?	
Organisation – Capacity (resources)	
Did scheduling influence the staffing level, or cause stress, or fatigue?	
Was there sufficient capacity in the system to perform effectively (e.g., access to resources)?	
Other?	
Other – consider	
Are there any factors that prevented this event from happening on a more regular basis?	
Where there any factors or actions taken that mitigated the severity of the event?	
Were there any local conditions or circumstances that may have influenced the incident and/or an outcome?	
Were there any other contextual conditions or circumstances that may have influenced the incident and/or outcome?	
Other?	

Step 4: Develop a constellation diagram

A constellation diagram provides a visual description of the non-linear cascading aspects of each contributing factor. In addition, the unique visual representation of the constellation diagram encourages and facilitates the identification of inter-connections and the sphere of influence among contributing factors, which will assist in identifying the contributing factors with the biggest impact on patient safety.

Improving safety and quality of care in complex adaptive healthcare systems is dependent on the ability to see how the parts of the system influence each other so the limited resources available can be focused with more precision to where the greatest risks are identified.

Instructions

I. Describe the incident. Briefly summarize the incident and harm/potential harm in the centre of the diagram (typically fewer than 10 words).

II. Identify potential contributing factors

   a. Add the contributing factor categories (task, equipment, work environment, patient, care team, organization, etc.) to the diagram in a circle around the incident/outcome description

b. Use the guiding questions provided identify potential contributing factors.

c. Place each potential contributing factor on a sticky note and group the factors near the category title

III. Define inter-relationships between and among contributing factors.
   a. For each potential contributing factor ask, "How and why did this happen?;"What was this influenced by?"; and "What else influenced the circumstances.
   b. Add the answers to these questions to develop "relational chains". Some contributing factors may be directly linked with each other, within the same category to create a chain. Some answers may come from different contributing factor categories; if so, show the linkage by drawing lines.
   c. Continue to ask "why" and "what influenced it" questions until no further information can be generated.

IV. Identify the findings that are central to the incident. The team should expect to identify several findings – there is seldom, if ever, only a single reason why an incident occurred.

Findings will be identified in three categories:

a. Factors that, if corrected, would likely have prevented the incident or mitigated the harm – these will be the basis for developing recommended actions (note that these factors may require actions at different levels of the system).

The question to be asked is: "If this factor was eliminated or corrected, would it have likely reduced the risk of incident recurrence and/or harm?" While it is possible that many contributing factors will be identified in the analysis, certain factors, if corrected, have the greatest probability to prevent the incident altogether, or mitigate harm from the incident. It is common for these factors to be "**highly relational**"; in other words, relationships or potential relationships between a number of the identified factors appear to have combined to enable an incident to occur, there is a sphere of influence amongst them. These findings will be the basis for developing recommended actions (note that actions may be required at different levels of the system).

b. Factors that if corrected, would not have prevented the incident or mitigated the harm, but are important for patient/staff safety or safe patient care in general. These issues should be included in the team's findings and brought to the attention of the appropriate individuals for follow-up and documented in the analysis report for future review and action as appropriate.

c. Mitigating factors – factors that didn't allow the incident to have more serious consequences and represent solid safeguards that should be kept in place. An example of a completed constellation diagram is illustrated in the figure below.

V. Confirm the findings with the team. The team should agree on the findings before moving forward to develop recommended actions.

INCIDENT: Anticoagulant overdose
OUTCOME: Client experienced rectal bleeding and hospitalization

ORGANIZATION
CARE TEAM
PATIENT
WORK ENVIRONMENT
EQUIPMENT
TASK
OTHER

No systems approach to MedRec and/or single source of truth for up to date Best Possible Medication History

No Med Rec/ communication process for patients returning home from hospital with new prescriptions

Pharmacy/ Pharmacist did not communicate no change to home care service

Pharmacy/ Pharmacist did not confirm Client's understanding of new start/stop anticoagulant dose

Discharge MedRec not routinely completed for patients leaving hospital

Hospital care team did not complete discharge MedRec and/ or provide an updated BPMH to pharmacy, patient or home care service

Client and home care service not aware of anticoagulant dose change

Client unintentionally self administered Coumadin and Warfarin

Client did not know that Coumadin and Warfarin were the same drug

Client unable to interact directly with the pharmacist or review drug information

Client recently unable to obtain and manage anticoagulants independently

Reduced physical & cognitive abilities related to age and medical condition

Deterioration in Client's medical condition (and ability for self care) not detected upon discharge home

Client not identified by hospital, MD or home care as requiring nursing assessment

Weekend RN and regularly assigned RN did not have time to call or visit Client soon after discharge from hospital

There are no guidelines/ protocols or risk assessment tools to guide the identification of at risk patients leaving hospital

Step 5: Write up factors linking them to outcome

A summary of what was found is prepared to define the contributing factors related to the incident. This summary is provided as a series of "statements of findings. (The statements of findings have been adapted from "causal statements")

The statements of findings describe the relationships between the contributing factors and the incident and/or outcome. The statements focus on the contributing factors and should be as specific as possible (note that there could be a group of factors that together contributed to the incident or outcome).

The suggested statement format is as follows: *The contributing factor(s), within the context of the incident, increased/decreased the likelihood that this outcome would occur.* A well-constructed constellation diagram will assist in the development of summary statements, working from the outside of the diagram back towards the centre.

Formulation of the statements of findings may be assigned to a sub-group of the SAER team and reviewed with the full team at a subsequent meeting. Another approach is to develop draft statements at a team meeting, which are subsequently finalised by the facilitator and clinical lead.

Instructions

The team review the constellation diagram and work from the outside of the diagram back towards the centre to develop draft summary statements

The SAER team identified the following findings:

Task

No key findings

Equipment

No key findings

Work environment

The lack of a standardised community health risk assessment tool or protocol increased the likelihood that clients discharged from hospital back to the community would not be accurately triaged to ensure appropriate and timely home care services are provided.

Patient
The deterioration in the client's physical and cognitive abilities increased the likelihood of a medication error in his self-medication management.

Care team and organisation
The lack of a formalised, system-wide and communicated Discharge Medication Reconciliation process (including an updated Best Possible Medication History) decreased the likelihood that the client would receive the appropriate and timely support required for safe medication management.

Step 6: Identify any practices, process or systems that could be reviewed

Having identified the factors that caused or contributed to an incident, the team determine the practices, processes or systems that could be reviewed. This will be documented in the "Areas for review" section of the Findings Report

Instructions

I. The team review the causation statements and discuss the practices, processes or systems that could be reviewed.

II. The agreed areas are documented in preparation for the writing of the Findings Report

#	Area for review
1	Handover processes from hospital back to community health
2	Process for assessing patient suitability to self-medicate
3	Discharge medication reconciliation processes

Step 7: Write findings report

The IA team write up the Findings Report and submit to the Chief Executive (CE).

Instructions

The team:

I.   Agree on the findings at a meeting or via email confirmation to the team leader
II.   Submit the findings to the CE or nominated officer for approval

The findings of the IA can be shared verbally with the family following approval by the CE or nominated officer. The dedicated family contact speaks with the family to arrange a meeting with the Open Disclosure team.

The family are invited to suggest recommendations to prevent future incidents from recurring. Any proposals are relayed to the IA team for consideration

The CE or nominated officer determines on the next stage of the review. They decide whether to appoint additional members to the team. Expertise may include:

Clinician with knowledge of the service

• Quality improvement (QI) expert

• Human factors expert

• Redesign expert

• Senior manager

• Manager/leader from another service/facility/agency to support feasibility e.g. eHealth NSW for digital health tools such as the eMR

• Manager/leader from another service/facility/agency responsible for implementing a recommendation e.g. NSW Ambulance, Ministry of Health, eHealth NSW.

More detailed information about appointing additional team members to develop recommendations can be found on the Clinical Excellence Commission internet.

Resources include:

- *Separation of recommendations and findings* webinar
- Fact sheet: *Information for clinicians*: *Separation of recommendations and findings for serious adverse event reviews*

Having answered What Happened? And Why did it happen?, the IA team move on to answer What action can we take to prevent it happening again? (section 3 of this document)

Comprehensive incident analysis

IA flow – Comprehensive incident analysis

The following describes the recommended flow for conducting a comprehensive IA review. The flow and process may vary depending on the complexity of the case.

Before the first meeting

The team leader:

- Sends the medical record and any other relevant documentation to the other team member
- Begins to construct the incident chronology

Team members:

- Review medical record and any other relevant documentation, making note of any issues requiring further clarification.

Meeting 1

1. An overview of the case is provided by the team leader.
2. Draft incident chronology and factor analysis tool are discussed.
3. Guiding Questions are applied.
4. The team determine the information to be collected through speaking with people, gathering relevant documents and looking at the literature when applicable

After the first meeting

Relevant information is gathered through meetings with patients, carers and families, staff interviews and the collation and review of documents and literature.

Meeting 2

1. Team members provide feedback on information obtained.
2. Incident chronology is reviewed and confirmed.
3. A constellation diagram is developed by identifying contributing factors and their inter-relationships.
4. Findings are identified and confirmed.
5. Findings are summarised as a series of statements of fact.

After the second meeting

The Findings Report is written and is shared with the family following CE approval. Additional experts are appointed to the team to assist with developing recommendations if indicated
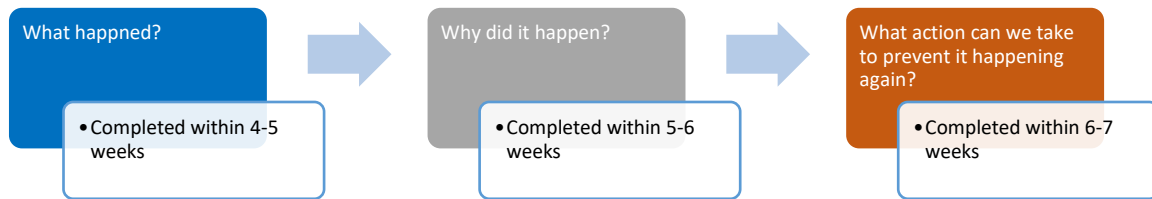
Meeting 3

1. Any new team members are briefed.
2. Statements of findings are reviewed.
3. Actions and recommendations and key outcome measures are written.

After the third meeting

The Recommendations Report is finalised and submitted to the CE for approval. The approved Findings and Recommendations Reports are submitted to the Ministry of Health and shared with the family.

Timeline for completion of review: 60 days

What happned?		Why did it happen?		What action can we take to prevent it happening again?
• Completed within 4-5 weeks	→	• Completed within 5-6 weeks	→	• Completed within 6-7 weeks

Team composition

The Chief Executive (CE) appoints a comprehensive IA team composed of 3-5 members:

- One team member (usually team leader) has SAER expertise

- One has essential knowledge of the care processes where the incident occurred

- One team member is external to the unit where the incident occurred.

- No team member should have been directly involved in the incident or patient's care

Team members should not:

- Have any personal connection with clinicians involved in the incident

- Have a conflict of interest

- Be the manager of the department or unit where the incident occurred

Team appointment

Team members receive a CE letter of appointment and are informed of their roles and responsibilities.

Training team members

IA team members will come from different backgrounds. Some may have extensive knowledge and experience in SAER processes. For others, the foundational concepts of IA may be totally new.

The team leader will have experience and training with IA. Other team members, require a basic understanding of IA process. They are encouraged to access IA Just in time training that are available on the Clinical Excellence Commission Internet Page

Section one: What happened?

For a comprehensive IA team to understand what happened they:

Step 1:   Gather information

Step 2:   Construct an incident chronology

The IA team leader ensures the other team member with access to the medical record to review prior to the first meeting.

Step 1: Gather information

The comprehensive IA team gather information to understand how and why the incident occurred. The importance of a thorough review phase cannot be overstated. A process is followed for assessing information needs and gathering information to ensure the analysis is thorough and credible. Sources of information include the medical record, incident report and PRA report. Interviews are conducted with family members and staff involved in the incident. Consideration is given to relevant literature and policy documents. Where possible, the team visit the location where the incident occurred and may simulate the events.

Instructions
I. The team gather and review all relevant information including the incident report, PRA report, medical record, policies.
II. Any material that have directly or indirectly contributed to the circumstances such as equipment and any product / care items. Photographs of workspaces may also be helpful
III. Informal discussions (interviews) are held with families and relevant staff and managers. Interviews last approximately 30 minutes with the following questions asked:
   a. What happened?
   b. What factors may have contributed to the incident?
   c. What factors may have mitigated the severity of the incident?
   d. How might an incident like this be prevented in the future

Step 2: Construct an incident chronology

Once all the information has been gathered, the IA team can construct an incident chronology. This provides a detailed timeline of the steps leading to the event. This information is provided in the form of a narrative chronological description.

Because the team will use the detailed timeline as a starting point for identifying system-based factors underlying the incident, it is crucial that the timeline include only the actual facts or processes as they occurred, and not what was supposed to happen.

Instructions
The team review information gathered and document in a chronological narrative

> The following incident will be used to demonstrate the application of the tools during a comprehensive incident analysis during the remainder of this section.
>
> *76-year-old female resident cared for on secured dementia wing found by police walking along the highway approximately two km from the home*
>
> *Resident found cold (dressed only in light clothing and slippers on a cool evening [temperature 10˚C]) and appeared confused. Noted to have deep lacerations and a fractured humerus. Taken to hospital by police - treated with warm blankets and given IV fluids. Patient died post-operatively*

Date / time	Information item	Comment / source
4 months prior to incident	75-year-old female resident admitted to the secured dementia unit of the home • Medical history: Type II diabetes, dementia • Admission medications: Metformin 500 mg three times daily, Donepeziil 5 mg daily, and multiple vitamin daily • Initial nursing assessment: impaired cognition, poor decision-making skills, mild confusion, walks independently with a cane • Assessed as at risk of wondering and an electronic monitoring bracelet was placed on her right wrist	Health record; staff interviews
6 weeks prior to incident	Resident has become increasingly confused and agitated. Assessed by physician who ordered Risperidone 0.25 mg at bedtime	Nursing progress notes
4 weeks prior to incident	Resident found outside the home in the early evening. Resident was in the staff parking lot at the back of the building and was found by a staff member coming in for the evening shift. Staff on duty did not recall hearing any alarms sound. The resident's electronic bracelet was tested and found to be working.	Nursing progress notes; staff interviews

Date / time	Information item	Comment / source
2 weeks prior to incident	Resident very confused and attempting to leave unit; redirected numerous times by staff. Physician contacted; order received to increase Risperidone to 0.25 mg twice daily	Nursing progress notes
Day of incident 1145	Resident told nurse who gave noon medications that she "was going home". Staff planned for resident to eat lunch in the dining room and then nap in her room per her usual routine. She was last observed eating lunch	Staff interviews
1305	Back door alarm sounded; reset by staff without checking as one staff member had just left the desk on lunch break and usual practice was to exit through back door to gain easy access to the parking lot.	Staff interviews
1600	Assistant in Nursing (AIN) went to check on resident to get her ready for supper but did not find her in her room; assumed she was already in the common room watching TV.	Staff interviews
1730 .	Kitchen staff noticed that resident was not in the dining room. Discussed with AIN who went to check her room	Staff interviews
1740	AIN unable to locate resident. Checked other care units and walked around perimeter of building but could not locate her.	Health record; staff interviews
1755 .	AIN reported to charge nurse that resident is missing. Full search of entire facility initiated	Health record; staff interviews
1840	Staff unable to locate resident on the grounds. Resident's family contacted. Evening staff are arriving so three of the day shift staff get in their personal vehicles and begin searching the surrounding area. Call made to local police. Police advise that an elderly woman was found walking on the highway two km from the home at approximately 1800 and that she has been transported to hospital for assessment as she was cold (dressed only in light clothing and slippers, temperature 10˚C) dehydrated and appeared confused. She has a large laceration on her forehead and upper arm.	Health record; staff interviews
1845 .	Resident's family contacted to advise that resident has been found and is at local emergency department	Health record; staff interviews
1850	Facility Manager contacts local emergency department for report on resident condition. Resident has had wounds dressed, IV fluids initiated and has been given warm blankets. She sustained a fractured humerus and is booked for surgery.	Health record; staff interviews
1900	Nurse Unit Manager contacts Facility Manager to provide report of situation. Plan to transfer back to Residential Aged Care Facility following day	Health record; staff interviews

Date / time	Information item	Comment / source
Day after incident 0930	Patient arrested during surgery for fixation of humerus but was successfully resuscitated.	Health record
1115	Patient arrested in Recovery and was unable to be resuscitated	Health record; staff interviews
Two days after incident. 1030	Electronic alert bracelet tested. Found not to be working. It was later determined that the resident had been fitted with a 90-day device, rather than a 12-month device as intended.	Health record

Section two: Why did it happen?

For a comprehensive IA team to understand why an incident happened they:

Step 3:   Apply guiding questions

Step 4:   Develop a constellation diagram

Step 5:   Write up factors linking them to outcome

Step 6:   Identify any practices, processes or systems for review

Step 7:   Write findings report

Step 3: Apply guiding questions

The information gathered is used to identify key factors that contributed to the incident. Two key questions that will help this process are: "how did this happen?" and "what else influenced the circumstances?" The facilitator should continue to ask "how" and "what influenced it" questions until no further information can be generated for the key contributing factors.

A set of guiding questions is provided below to guide the identification of contributing factors, hazards and mitigating factors during the "how and why did it happen" stage of incident analysis. They are intended to assist with checking the availability and strength of safeguards at all levels in the organization and guide the analysis towards the identification of system vulnerabilities that aligned in such a way that allowed for the incident to take place. Teams are encouraged to note, analyse and report the system barriers that worked well (mitigating factors) and therefore should be reinforced and recognized so they will continue to prevent future harm.

The questions are grouped around categories of factors designed to focus the analysis on the interaction between humans and the system, and in this way help identify system-level contributing factors at various levels in the organisation.

Use the guiding questions in the table below to briefly explore each domain (task, equipment, work environment, patient characteristics, care team, organization, other) of factors that may have contributed to this incident. For domains that are relevant to the incident, further explore each specific question.

When identifying potential contributing factors, focus on systems-based factors, and not people-focused ones to ensure that likewise, the recommended actions are not people focused. Keeping in mind human factors principles and systems theory, analysis should focus on "how" certain human actions occurred, not just that they occurred.

For example, in the course of analysing an incident in which an incorrect medication was administered, it was determined that the nurse was in a hurry. The fact that the nurse was in a hurry is a factual detail of what happened, and not a contributing factor. The contributing factor(s) are those that may have caused them to be in a hurry. Examples could include: too many tasks were assigned (the nurse was assigned too many complex patients); or the patient's medication needs conflicted with shift change (the patient was admitted right before the shift ended and the nurse wanted to give the patient their pain medications so that they did not have to wait until after the shift change). By focusing on the systems-based contributing factors, the analysis team will be able to identify higher leverage solutions. Recommended actions should be consistent with one of the main tenets of human factors: fit the task or system to the human, not the other way around.

Instructions

    I.   The team explore each question and ask how it impacted the incident.

    II.   If the answer to a guiding question suggests that a safeguard was not in place or did not work, additional questions are asked to delve deeper e.g. why is this the case, if so, how did this contribute to or impact on the incident?

Guiding questions

Domain / category of contributing factors	Relevant?
Patient(s) characteristics: (Considered in the context of how well the system identified, understood, and acted upon these factors. It should not be the only factor considered)	
Did the patient (s) have the information to assist in avoiding the incident?	
If not, what would have supported the patient in assisting their care team?	
Did factors like age, sex, medications, allergies, diagnosis, other medical conditions, contribute to the incident? How did they contribute?	
Did any social or cultural factors contribute to the incident?	
Was language a barrier?	
Other?	
Task (care/work process)	
Were there previous or predicted failures for this task or process?	
Were specialised skills required to perform the task?	
Was a fixed process or sequence of steps required (e.g. order sets, checklists)?	
If a fixed process existed, was it followed?	
Was a protocol available, was it up-to-date, and was it followed in this case?	
Were there constraints or pressures (e.g. time, resources) when performing the task?	

Domain / category of contributing factors	Relevant?
Was the information required to make care decisions available and up-to-date (e.g. test results, documentation, patient identification)?	
Was there a risk assessment/audit/quality control program and in place for the task/process?	
Other?	
Care team – Caregiver(s)	
Were the education, experience, training and skill level appropriate?	
Was fatigue, stressors, health or health factors an issue?	
Was the workload appropriate?	
Was appropriate and timely help or supervision available?	
Other?	
Care team – Supporting team (all involved in care process)	
Was there a clear understanding of roles and responsibilities?	
Was the quality and quantity of communication (verbal and/or written) between team members appropriate (clear, accurate, free of jargon, relevant, complete, and timely)?	
Were there regular team briefings/debriefings about important care issues?	
Was team morale good? Did team members support each other?	
Were the communication channels available and appropriate to support the needs of the team (e.g., email, pager, and phone)?	
Other?	
Equipment (including materials, fixtures, information and communication systems)	
Were the displays and controls understandable?	
Did the equipment automatically detect and display problems?	
Was the display functional?	
Were the warning labels, reference guide, and safety mechanisms functional and readily visible/accessible?	
Were the maintenance and upgrades up-to-date?	
Was the equipment standardised?	
Would the users describe this equipment as easy to use?	
Were the communication systems (phone, pager, software, hardware, etc.) available and operational?	
Other	
Organisation - Policies and procedures	
Were the relevant policies and procedures available, known, and accessible, and did they meet the needs of users?	
Were there workarounds to the documented policy/procedure?	
Was there a mechanism in place to identify and resolve gaps between policy and practice?	
Were the strategic priorities of the organisation clear to all?	
Other?	
Organisation – Culture	
Was everyone (patients, clinicians, other staff) comfortable to speak-up about safety concerns?	
Was there visible support from leadership and the board for safe patient care?	
Was communication between staff and management supportive of day-to-day safe patient care?	

Domain / category of contributing factors	Relevant?
Were incidents viewed as system failures with a mechanism/transparent process for fair and just review of actions by individuals where indicated?	
Other?	
Organisation – Capacity (resources)	
Did scheduling influence the staffing level, or cause stress, or fatigue?	
Was there sufficient capacity in the system to perform effectively (e.g., access to resources)?	
Other?	
Other – consider	
Are there any factors that prevented this event from happening on a more regular basis?	
Where there any factors or actions taken that mitigated the severity of the event?	
Were there any local conditions or circumstances that may have influenced the incident and/or an outcome?	
Were there any other contextual conditions or circumstances that may have influenced the incident and/or outcome?	
Other?	

Step 4: Develop a constellation diagram

A constellation diagram provides a visual description of the non-linear cascading aspects of each contributing factor. In addition, the unique visual representation of the constellation diagram encourages and facilitates the identification of inter-connections and the sphere of influence among contributing factors, which will assist in identifying the contributing factors with the biggest impact on patient safety.

Improving safety and quality of care in complex adaptive healthcare systems is dependent on the ability to see how the parts of the system influence each other so the limited resources available can be focused with more precision to where the greatest risks are identified.

Instructions

I.   Describe the incident. Briefly summarize the incident and harm/potential harm in the centre of the diagram (typically fewer than 10 words).

II.   Identify potential contributing factors

a.   Add the contributing factor categories (task, equipment, work environment, patient, care team, organization, etc.) to the diagram in a circle around the incident/outcome description
b. Use the guiding questions provided identify potential contributing factors. Place each potential contributing factor on a sticky note and group the factors near the category title

III. Define inter-relationships between and among contributing factors.
   a. For each potential contributing factor ask, "How and why did this happen?;"What was this influenced by?"; and "What else influenced the circumstances?

   b. Add the answers to these questions to develop "relational chains". Some contributing factors may be directly linked with each other, within the same category to create a chain. Some answers may come from different contributing factor categories; if so, show the linkage by drawing lines.

   c. Continue to ask "why" and "what influenced it" questions until no further information can be generated.

IV. Identify the findings that are central to the incident. The team should expect to identify several findings – there is seldom, if ever, only a single reason why an incident occurred.

   Findings will be identified in three categories:

   a. The question to be asked is: "If this factor was eliminated or corrected, would it have likely reduced the risk of incident recurrence and/or harm?" While it is possible that many contributing factors will be identified in the analysis, certain factors, if corrected, have the greatest probability to prevent the incident altogether, or mitigate harm from the incident. It is common for these factors to be "**highly relational**"; in other words, relationships or potential relationships between a number of the identified factors appear to have combined to enable an incident to occur, there is a sphere of influence amongst them. These findings will be the basis for developing recommended actions (note that actions may be required at different levels of the system).

   b. Factors that if corrected, would not have prevented the incident or mitigated the harm, but are important for patient/staff safety or safe patient care in general. These issues should be included in the team's findings and brought to the attention of the appropriate individuals for follow-up and documented in the analysis report for future review and action as appropriate.

   c. Mitigating factors – factors that didn't allow the incident to have more serious consequences and represent solid safeguards that should be kept in place. An example of a completed constellation diagram is illustrated in the figure below.

I. Confirm the findings with the team. The team should agree on the findings before moving forward to develop recommended actions.

INCIDENT: Resident elopement
OUTCOME: Resident found cold and dehydrated 2 km from LTC home

ORGANIZATION
CARE TEAM
OTHER
PATIENT
WORK ENVIRONMENT
EQUIPMENT
TASK

Staff unfamiliar with Code Yellow procedures

Close call charted but not formally reported or investigated

Process changes not implemented after previous elopement

No standardized process for "mock" codes

Code Yellow not fully implemented when resident first identified as missing

Caregivers initially worked independently to try to find resident

Communication lacking between team members when resident first identified as missing

Cognitively impaired; elopement risk

Fire alarm not "heard" or responded to

Electronic bracelet not tested daily per instructions provided with device

No internal process to ensure device testing and accompanying documentation

Electronic bracelet failed to alarm

Code Yellow not called when resident not in room

Assumptions made re resident's whereabouts

Lack of clarity around when to call a Code Yellow

Lack of standard expectations re resident status checks

Fire alarm sounds frequently staff are "desensitized"

Monitoring bracelet was expired

3 month device used instead of 12 month

Routine use of an emergency exit to access the staff parking lot

Similar appearance of devices

Two types of bracelets stocked

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

Step 5: Write up factors linking them to outcome

A summary of what was found is prepared to define the contributing factors related to the incident. This summary is provided as a series of "statements of findings. (The statements of findings have been adapted from "causal statements").

The statements of findings describe the relationships between the contributing factors and the incident and/or outcome. The statements focus on the contributing factors and should be as specific as possible (note that there could be a group of factors that together contributed to the incident or outcome).

The suggested statement format is as follows: *The contributing factor(s), within the context of the incident, increased/decreased the likelihood that this outcome would occur.* A well-constructed constellation diagram will assist in the development of summary statements, working from the outside of the diagram back towards the centre.

Formulation of the statements may be assigned to a sub-group of the analysis team and reviewed with the full team at a subsequent meeting. Another approach is to develop draft statements at a team meeting, which are subsequently finalized by the facilitator and clinical lead.

Instructions

The team review the constellation diagram and work from the outside of the diagram back towards the centre to develop draft summary statements

The IA team identified the following findings:

Task

Lack of standard expectations regarding resident status checks decreased the likelihood that the resident absconding from facility would be detected in a timely way.

Equipment

Two types of electronic monitoring bracelets with similar appearance stocked in the home increased the likelihood that the incorrect device would be selected and applied.

No standardised internal process to ensure testing of electronic monitoring bracelets with accompanying documentation decreased the likelihood that the bracelet would be identified as non-functioning prior to an elopement incident.

Work environment

Routine use of an emergency exit to access the staff parking lot decreased the likelihood that the alarm function would be effective as staff became "desensitized" to frequent alarms.

Patient

The resident's cognitive impairment decreased the likelihood that she would be aware of the risk of leaving the facility.

Care team

Communication lacking between team members when resident first identified as missing, combined with lack of familiarity with procedures decreased the likelihood that an appropriate response would be initiated immediately.

Organisation

Lack of a formal process to report and investigate close calls decreased the likelihood that the previous incident in which the resident left the home but was found immediately, would be followed-up to identify process changes to prevent future occurrences.

Lack of a standardized process for regular"mock" scenarios to provide ongoing training and assess staff understanding of processes decreased the likelihood that staff would be familiar procedures.

Other

No other factors identified.

Step 6: Identify any practices, process or systems that could be reviewed

Having identified the factors that caused or contributed to an incident, the team determine the practices, processes or systems that could be reviewed. This will be documented in the "Areas for review" section of the Findings Report.

Instructions
  I.   The team review the causation statements and discuss the practices, processes or systems that could be reviewed.
  II. The agreed areas are documented in preparation for the writing of the Findings Report

#	Area for review
1	Process for resident status checking
2	Storage of electronic monitoring bracelets
3	Testing of electronic monitoring bracelets
4	Staff awareness of emergency procedures
5	Reporting and review of near misses

Step 7: Write findings report

The IA team write up the findings report and submit to the Chief Executive (CE).

Instructions

The team:

III.   Agree on the findings at a meeting or via email confirmation to the team leader
IV.   Submit the findings to the CE or nominated officer for approval

---

The findings of the IA can be shared verbally with the family following approval by the CE or nominated officer. The dedicated family contact speaks with the family to arrange a meeting with the Open Disclosure team.

The family are invited to suggest recommendations to prevent future incidents from recurring. Any proposals are relayed to the IA team for consideration

---

The CE or nominated officer determines on the next stage of the RCA. They decide whether to appoint additional members to the team. Expertise may include:

Clinician with knowledge of the service

• Quality improvement (QI) expert

• Human factors expert

• Redesign expert

• Senior manager

• Manager/leader from another service/facility/agency to support feasibility e.g. eHealth NSW for digital health tools such as the eMR

• Manager/leader from another service/facility/agency responsible for implementing a recommendation e.g. NSW Ambulance, Ministry of Health, eHealth NSW.

More detailed information about appointing additional team members to develop recommendations can be found on the Clinical Excellence Commission internet.

Resources include:

- *Separation of recommendations and findings* webinar
- Fact sheet: *Information for clinicians*: *Separation of recommendations and findings for serious adverse event reviews*

Section three: What action can we take to prevent it happening again?

For an IA team to develop actions they:

Step 8:   Recommend actions

Step 9:   Develop action plan

Step 10:   Write recommendations report

Step 11:   Submit Recommendations Report to CE for approval

Step 8: Recommend actions

The team recommend actions aimed at preventing or mitigating the factors that caused or contributed to the incident.

The success of the recommended actions is dependent on

- the quality of findings (how and why it happened)

  Using human factors identify contributing factors facilitates the identification and evaluation of the effectiveness of recommended actions. In other words, identifying systems-based contributing factors correctly should lead to systems-based solutions

- the strength and combination of recommendations

  The action hierarchy is used to ensure recommendations developed provide effective and sustained improvement. A recommendation may address more than one factor that caused or contributed to the incident. The SAER team ensure that at least one strong or intermediate action is recommended.

- how well recommendations are implemented.

SAER teams can identify system improvements unrelated to the incident.

In some instances review processes may not generate any new recommended actions.

Instructions

The team:

I.   Examine the findings report, particularly factors that caused or contributed to an incident and the areas for review findings.

II. Brainstorm actions that could prevent the incident or mitigate the harm should a similar incident occur.

III. Consider any suggested recommendations from the family.

IV. Assess the strength of each action against the Action Hierarchy. Ensure at least one strong or intermediate action relevant to each factor.

V. For each proposed action, the team ask if this recommendation was implemented would it have prevented the incident or mitigated the harm?

VI. Consult if required –The team consult with another service if actions are recommended for a service not represented on the SAER team. An interview letter is issued beforehand.

VII. Consult with another organisation if actions are recommended for an organisation not represented on the SAER team (issue interview letter beforehand) and ensure CE from other organisation approves the recommendation/s

Action Hierarchy

	Action Category	Example
Stronger actions (these tasks require less reliance on humans to remember to perform the task correctly)	Architectural / physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g. IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).
	Simplify the process	Remove unnecessary steps
	Standardise on equipment or process or care maps	Standardise on the make and model of medication pumps used throughout the organisation. Use bar coding for medication administration.
	Tangible involvement and action by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA process; purchase needed equipment; ensure staffing and workload are balanced.
Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.

	Action Category	Example
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
	Education using simulation based training, with periodic refresher sessions and observations	Conduct patient handovers in a simulation lab/environment, with after action critiques and debriefing.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fibre optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the medication room.
	Standardised communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardised patient handover format e.g. ISBAR.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	Double checks	One person calculates dosage, another person reviews their calculation.
	Warnings	Add audible alarms or caution labels.
	New procedure/ memorandum/policy	Remember to check IV sites every 2 hours.
	Training	Demonstrate correct usage of hard-to-use medical equipment.

Action hierarchy levels and examples adapted from National Patient Safety Foundation[4].

Step 9: Develop action plan

All recommendations need a due date and a plan. The plan needs to be specific and the outcomes quantifiable. The strategy is defined with a timeframe, person responsible and oversight committee.

Instructions

I. The team define an outcome measure for each recommendation. The measure needs to specify what is being measured and include a numerator and denominator. The measure should evaluate the effectiveness of actions not just whether they have been completed.

II. Determine a length of time to implement the recommendation and a due date.

III. Assign one person with responsibility for each recommendation. This should be someone with the right level of authority to effect change and the resources to implement the action.

IV. Specify an oversight committee. Regular updates and evidence of implementation will be sent to this group by the person responsible.

V. The team follow the same process for any recommendations for system issues identified during the review but unrelated to the factors that caused or contributed to the incident. This is documented in Table 2 of the SAER report.

Example action plan

#	Recommendations	Link to underlying factors statement /s (A,B,C etc.)	Outcome measure	Timeframe	Oversight Committee	Position responsible for implementation
1	A checklist for patient handovers between Cardiology staff be developed to ensure ordered pathology and medical images are review after hours and at weekends.	A	Audit of medical handover checklists show 95% use-compliance Audit conducted 3 monthly for 1 week.	November 2020	Patient Safety and Clinical Quality	Cardiology Head of Department
2	Develop a process to ensure that all patients who	B	Audit of patients who fell	October 2020	Patient Safety and	Director Clinical Services

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	experience a fall after hours are reassessed for falls related injuries by the admitting team		after hours shows 95% compliance with review by admitting team		Clinical Quality	

Step 10: Write Recommendations Report

The team finalise the recommendations report and submit to the CE for approval. When the report is approved it is submitted to the Ministry of Health (MoH) with the findings report.

Instructions

The team:

I.   Agree on the recommendations at a meeting or via email confirmation to the team leader
II. Follow local processes for submission of the Recommendations Report to the CE. This often includes a sign off meeting with the team leader, senior clinicians +/- Director Clinical Governance.

The CE may:

- consult with other staff members and provide feedback to the team regarding the proposed recommendations
- approve recommendations and sign report
- choose to not endorse one or more of the recommendations. If this occurs, they will need to document with the reasons and the proposed alternative action
- add recommendations to the report

The recommendations report can be shared with the family following approval by the CE. The dedicated family contact speaks with the family to arrange a meeting with the Open Disclosure team.

The outcome of the SAER is also shared with staff who work in the clinical area where the incident occurred as well as other relevant stakeholders.

Glossary

Action hierarchy	A tool that assists teams in identifying which actions will have the strongest effect for successful and sustained system improvement.
Australian Sentinel Event	An Australian Sentinel Event (ASE) is • A wholly preventable patient safety incident resulting in death or serious patient harm. • Defined by the Australian Commission on Safety and Quality in Health Care and approved by the Health Ministers www.safetyandquality.gov.au/our-work/indicators/australian-sentinel-events-list
Cause and effect diagram	A graphic representation of an incident and the factors that caused or contributed to the outcome. It assists in analysing the relationships between an incident and its causes.
Constellation diagram	A visual representation of the non-linear cascading aspects of each contributing factor. It facilitates the identification of inter-connections and the sphere of influence among contributing factors, which assists in identifying the contributing factors with the biggest impact on patient safety
Contributing factor	The influencing and causal factors that contributed to an incident.
Incident review	A structured process to identify • What happened • How and why it happened • What could be done to make care safer and reduce risk • What was learned.
Just culture	A concept related to systems thinking which suggests that incidents are usually a product of organisational culture rather than the individual practitioner. After an incident the question asked is 'What went wrong' rather than 'Who caused the problem?' A just culture helps create an environment where individuals feel free to report errors and help the organisation to learn. It supports a culture of fairness, openness and learning.
Open Disclosure	Ongoing communication process with a patient, carer or family about an incident and its management. Formal Open Disclosure involves multidisciplinary discussion/s with the patient, carer or family and senior clinical leaders and/or hospital executive.
Dedicated family contact	A staff member who is the primary contact for the patient, carer and family for a serious incident review and sometimes beyond. They are appointed during the Preliminary Risk Assessment and liaise between the patient, carer and family, review team and Open Disclosure team.

Findings report	The SAER team produce a findings report that describes what happened, how it happened and any practices, processes or systems that could be reviewed
Incident management	Actions and processes for immediate and ongoing activities following an incident. Review is part of incident management[1].
Preliminary Risk Assessment (PRA)	A PRA must occur as soon as possible after a reportable incident or a clinical incident which may due to serious systemic problems. PRA assessors assist the Health Service to understand the events and identify immediate risks for action to ensure people and the environment are safe and supported. They complete a privileged PRA report for the Chief Executive.
Privilege	Preliminary Risk Assessment (PRA) and serious incident reviews for reportable incidents or clinical incidents due to serious systemic problems are privileged. People who are members of privileged processes must not share any documents or discussions with other people and cannot be compelled to give evidence about the documents and discussions. Some committees are privileged e.g. Collaborating Hospitals' Audit of Surgical Mortality (CHASM).
Psychological safety	A belief that an individual will not be punished or humiliated for speaking up with ideas, questions, concerns or mistakes.
Recommendations report	The SAER team prepare a recommendations report which specifies actions to address the systems issues identified in the Findings report
Reportable incident (clinical Harm Score 1)	- Unexpected death - Suspected suicide - Suspected homicide - Unexpected intrapartum stillbirth - Australian Sentinel Event (ASE)
Serious adverse event review (SAER)	A SAER is undertaken for clinical Harm Score 1 incidents. It includes root cause analysis (RCA) and other types of review prescribed by the Regulations undertaken by a review team for a serious incident.
Statement of findings	A statement that articulates the relationship between the contributing factors and the incidents and / or outcome. The suggested statement format is as follows: *The contributing factor(s), within the context of the incident, increased/decreased the likelihood that this outcome would occur*

References

1. Incident Analysis Collaborating Parties 2012. *Canadian Incident Analysis Framework*. Edmonton, AB: Canadian www.patientsafetyinstitute.ca

2. US Department of Veterans Affairs (VA) National Center for Patient Safety (2015). *Root cause analysis tools.* www.patientsafety.va.gov/professionals/onthejob/rca.asp