Serious Adverse Event Review

Comprehensive Incident Analysis workbook for teams

Immediacy, Accountability, Kindness

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

Background

The Incident analysis – Canadian framework (IA) workbook has been developed to support IA teams to complete all the necessary steps of the review process. It contains instructions and templates for the team to work through during each of their meetings.

The IA process focuses on answering these three questions:

- What happened?
- Why did it happen?
- What action can we take to prevent it happening again?

In general, IA teams completing a **comprehensive incident analysis** can address these questions over three meetings. This workbook provides guidance on the tasks for completion at each of the meetings.

This document acts as compendium to the *Serious adverse event review: Incident analysis toolkit.* Teams are encouraged to consult the toolkit for additional guidance.

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IA flow – Comprehensive incident analysis

The following flow is 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

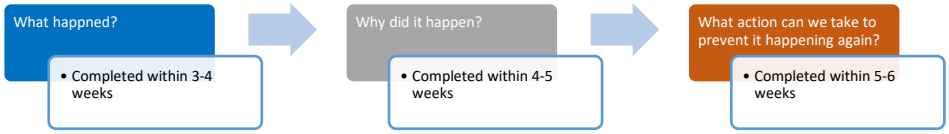
Meeting 3

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



Planning Calendar / Gantt Chart / Checklist

Instructions for using template

1 Review task list and modify to suit local processes
2 Enter dates into Week ending column
3 Determine the date the Recommendations report is due to CE +/- date for CE Sign off / endorsement. Ensure you allow enough time for CE to review and consult with stakeholders. Highlight these dates using shading tool (NB SAER reports need to be completed within 60 days of incident notification. This is a little over 8 weeks)
4 Work backwards to ensure that all tasks are sign posted for completion prior to due date. Use shading tool in Home ribbon to highlight dates
5 As tasks are completed tick them off in the 'tick box' column

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Team appointed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Additional meeting dates scheduled including date for CE sign off meeting (as appropriate).	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Team leader sends medical records & other documentation to team for review prior to first meeting	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Team leader constructs incident chronology	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	First team meeting held	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending										
	Draft Incident chronology										
	Guiding questions applied										
	Planning for staff and family interviews +/- other information gathering										
	Family and staff interviews +/- other information gathering undertaken										
	Second meeting held										
	Constellation diagram developed										
	Incident chronology reviewed, updated and confirmed										
	Identify factors which caused or contributed to the incident and link to the outcome by developing statements of fact										
	Identify areas for review (practices, processes and systems)										
	Team leader finalises draft findings report										
	Circulate draft findings report to team for approval										
	Submit findings report to CE for approval										

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	CE appoints additional team members to team, if required, to prepare recommendations	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Brief new team members on findings of RCA	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Develop recommendations	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Specify an outcome measure, timeframe, person responsible and oversight committee for each recommendation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Team leader finalises draft recommendations report	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Circulate draft recommendations report to team for approval	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Submit recommendations report to CE	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	CE endorsement meeting / sign off	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Section one: What happened?

The comprehensive IA team begin the task of working out ‘what happened’ prior to coming together for the first team meeting

Task for completion before meeting one

- ☐ Team leader sends incident report, PRA report and medical record to team members
- ☐ Site visit considered and completed if considered appropriate
- ☐ Team leader constructs draft incident chronology
- ☐ Team members review incident report, PRA report and medical record

Step 1: Gather information

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. Site visits are completed if necessary
IV. 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

Interviewing staff, patients, carers and families

Name of individual to be interviewed	Who will set up interview	Meeting time, date and venue

Interview sheet

Interviewee	Date of interview
What happened?	
Factors that may have contributed to the incident	
Factors that may have mitigated the severity of the incident	
How might an incident like this be prevented in the future?	

Step 2: Construct an incident chronology

Instructions

The team review information gathered and document in a chronological narrative

Date / time	Information item	Comment / source

Section two: Why did it happen?

Meeting one tasks

- ☐ Introductions
- ☐ Overview of tasks to be achieved this meeting
- ☐ Review of information gathered including incident report, PRA report, medical record and site visits
- ☐ Incident chronology and factor analysis reviewed and discussed
- ☐ Guiding questions applied
- ☐ The team determine the information to be collected through speaking with people, gathering relevant documents and looking at the literature when applicable
- ☐ Action plan developed for tasks to be completed prior to meeting two

Step 3: Identify contributing factors

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)?	

Domain / category of contributing factors	Relevant?
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	
Was everyone (patients, clinicians, other staff) comfortable to speak-up about safety concerns?	

Domain / category of contributing factors	Relevant?
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?	

Meeting two tasks

- ☐ Overview of tasks to be achieved this meeting
- ☐ Review of information gathered including feedback from interviews,
- ☐ Incident chronology finalised
- ☐ Constellation diagram developed
- ☐ Findings identified and confirmed
- ☐ Findings summarised as statements of fact developed
- ☐ Discussion about whether to add any team members to assist with development of recommendations
- ☐ Agreement on next steps including process for writing and approval of Findings Report

Step 4: Develop a constellation diagram

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.

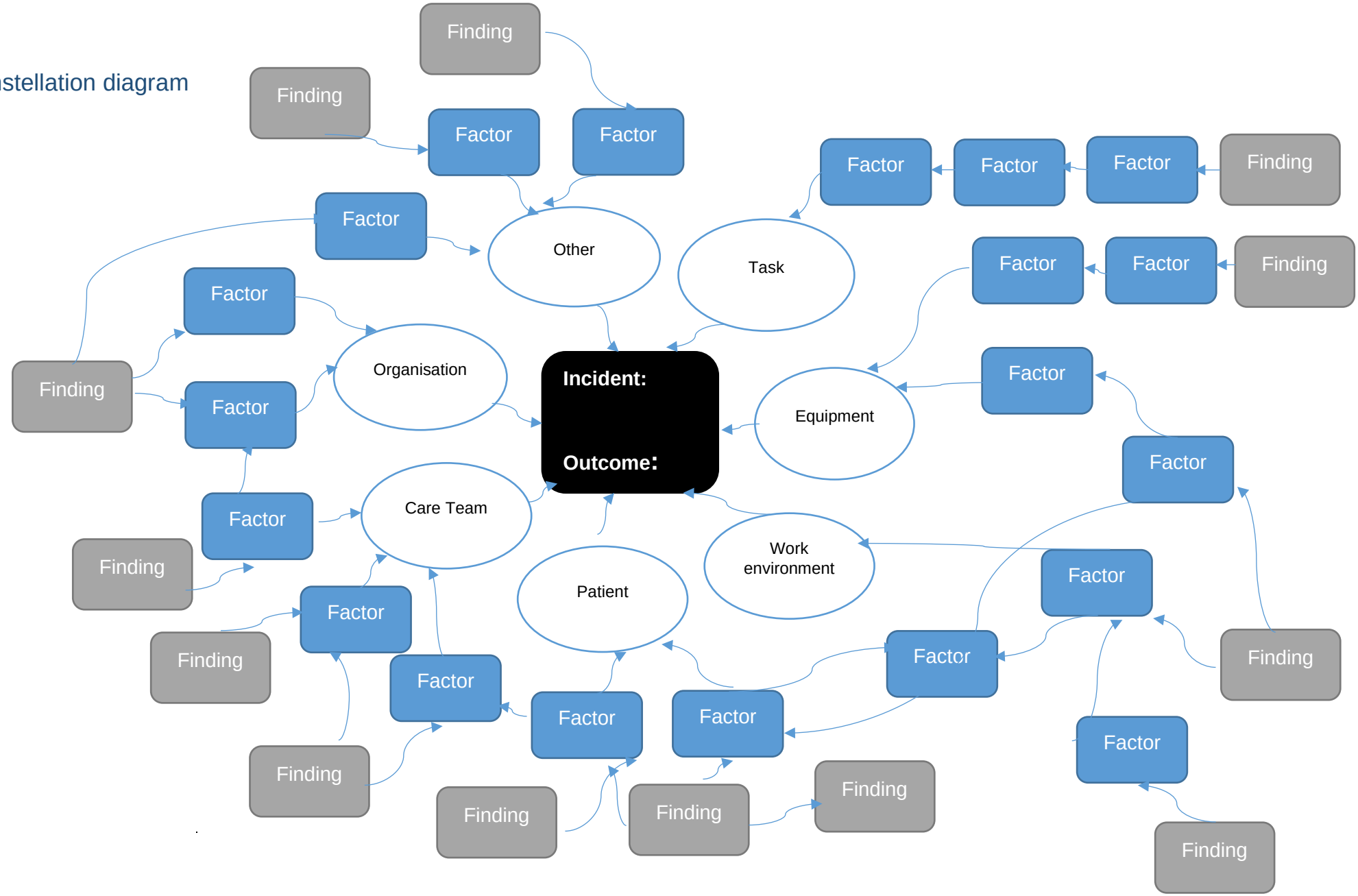
c. Mitigating factors – factors that didn't allow the incident to have more serious consequences and represent solid safeguards that should be kept in place.
An example of a completed constellation diagram is illustrated in the figure below.

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

Instructions for using constellation diagram template

1. The black box in the middle should have a very brief summary of the incident. Limit to 10 words if possible.
2. The blue circles around the black box represent the domains and should not be edited. However, if some of the domains aren't relevant to the incident under review then these may be deleted.
3. The blue boxes represent factors and the team should type in any factors relating to a domain.
4. Arrows should be moved around the template to represent the relationships between factors and domains.

Constellation diagram



Step 5: Write up factors linking them to outcome

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 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. e.g.* 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.

Findings worksheet

Domain	Finding
Task	1. 2.
Equipment	1. 2.
Work environment	1. 2.
Patient	1. 2.
Care team	1. 2.
Organisation	1. 2.
Other	1. 2.

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

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	
2	
3	

Step 7: Write findings report

Instructions

The team:

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

#	Statement of findings	Could the team benefit from additional expertise to develop recommendations?	Suggested expertise	Name and details of possible experts
1		☐ / ☐		
2		☐ / ☐		
3		☐ / ☐		
4		☐ / ☐		

Findings report checklist		
Element of the final report	**Needs to include**	**Avoid**
Description of Reportable incident	☐ less than one page in length Includes: ☐ Patient's age, sex, ☐ diagnosis, reason for admission, co-morbidities, ☐ relevant dates, planned or actual procedure, ☐ key points related to the patient's course of care.	☐ Dot points ☐ Non-factual information – not assumptions ☐ Identifying information such as hospital name, service, initials or locations titles to be referred to by function e.g. JMO ☐ Irrelevant information
Report Summary	☐ Demonstrate the team's comprehensive analysis ☐ Clear statements in regard to the appropriateness of deficiencies of policy or guidelines ☐ System vulnerabilities and the associated risks identified	☐ Repeating statements or opinions obtained from staff interviewed under privilege such as the nurse stated "…" to ensure that the requirements of the privilege applied to the process are not breached ☐ - Repeating the narrative – rather comment on the inter-relationship of interventions in the course of care
Element of the final report	**Needs to include / consider**	**Example**
Causation Statements / Factors Linked to Outcome	☐ Clearly convey the contributing system vulnerabilities identified by the team and clearly demonstrate how each of these factors contributed to the incident. ☐ Must demonstrate the cause and effect relationship ☐ Must meet the five rules of causation ☐ Have you got to the contributing factors?	"The lack of an effective process in the allocation of casual staff that takes into consideration the skill level of a staff member resulted in a staff member functioning beyond their level of experience. This resulted in the administration of a rectal medication being administered orally". Are you able to ask a why question against your causal statement / factor linked to outcome and get an answer? - If so, it is likely that the root cause / contributing factor has not been determined.

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

Meeting three tasks

- ☐ Overview of tasks to be achieved this meeting
- ☐ Orientation of any new team members
- ☐ Feedback from findings report e.g. CE or delegate, family
- ☐ Review of statements of findings
- ☐ Recommendations developed
- ☐ Action plans developed
- ☐ Summary of next steps including process for writing, approval and submission of Recommendations report

Step 8: Recommend 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	Recommended action/s
Stronger actions (these tasks require less reliance on humans to remember to perform the task correctly)	• Architectural / physical plant changes • New devices with usability testing • Engineering control (forcing function) • Simplify the process • Standardise on equipment or process or care maps • Tangible involvement and action by leadership	
Intermediate Actions	• Redundancy • Increase in staffing/decrease • in workload • Software enhancements, • Modifications • Eliminate/reduce • Distractions • Education using simulation based • training, with periodic • refresher sessions and • observations • Checklist/cognitive aids • Eliminate look- and • sound-alikes • Standardised communication • tools • Enhanced documentation, • communication	

	Action Category	Recommended action/s
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	• Double checks • Warnings • New procedure/ • memorandum/policy • Training	

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

Step 9: Develop action plan

Instructions

I. For each recommendation, the team define a measurement plan that details what is being measured and includes a numerator and denominator. Measurement plans need to be specific and measure the effectiveness of actions not just whether they have been completed.

II. A length of time to implement the recommendation is documented.

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

IV. An oversight committee is named. 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 contributing factors

VI. #	Recommendations	Link to underlying factors statement /s (A,B,C etc.)	Outcome measure	Timeframe	Oversight Committee	Position responsible for implementation
1						
2						
3						
4						

Step 10: Write Recommendations 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.

Recommendations report checklist	
Recommendations	☐ Appropriate numbering to correspond to causation statements ☐ Is this the strongest possible recommendation which can be made to address the issue identified? ☐ Does the wording of the recommendations clearly convey to those who will be responsible for implementing them what it is the RCA team wants to happen? ☐ Recommendation focuses on the intent of the change, rather than become overly specific about the detailed process. ☐ Does the recommendation directly address the issue identified in the causation statement to which it relates (or is it part of another agenda) and is it realistic? ☐ Do the recommendations specify who is responsible for their implementation by title and role? ☐ Do the recommendations include an oversight committee? ☐ Do the recommendations describe how the effectiveness of actions will be monitored over time? Are the proposed outcome measures realistic? Measurable? ☐ Has a realistic time frame been allocated? ☐ If all recommendations were implemented, would patient safety be improved or are there more effective recommendations that could be made?

References

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

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