

# Serious Adverse Event Review

## Concise Incident Analysis –workbook for teams

*Immediacy, Accountability, Kindness*



CLINICAL  
EXCELLENCE  
COMMISSION

# Background

The Incident analysis workbook has been developed to support IA teams to complete all of 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 **concise incident analysis** can address these questions over two 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 – Concise incident analysis

The following flow is 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

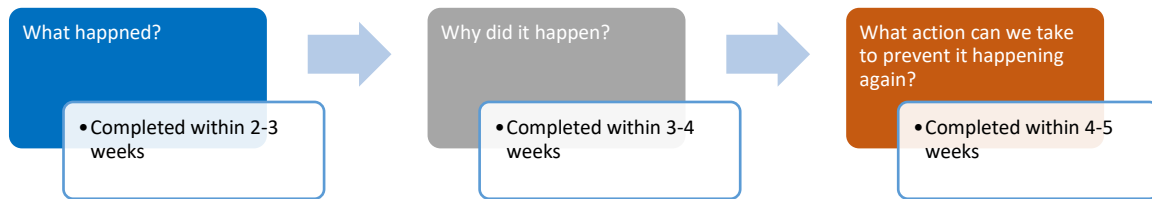
### Meeting 2

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



# 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										
	Appoint team										
	Team leader sends medical records & other documentation to team for review prior to first meeting										
	Team leader phones team member and agrees on who will be interviewed and develops a plan for same										
	Family and staff interviews										
	Incident chronology developed										
	First team meeting held										

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending										
	Additional meeting dates scheduled including date for CE sign off meeting (as appropriate).										
	Incident chronology reviewed, updated and confirmed										
	Guiding questions applied: <ul style="list-style-type: none"> <li>• Domains reviewed for relevance</li> <li>• Questions of relevant domains addressed</li> </ul>										
	Constellation diagram developed										
	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										
	CE appoints additional team members to team, if required, to prepare recommendations										
	Brief new team members on findings of RCA										
	Develop recommendations										

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending										
	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?

Usually, the concise IA team works out 'what happened' prior to coming together for the first meeting

### Tasks for completion before meeting one

- Team leader contacts team member and explains process (references made to just in time training materials)
- Next steps explained
- Team leader sends incident report, PRA report and medical record to team member
- Site visit considered and completed if considered appropriate
- Tea, leader phones team member and they jointly determine who needs to be interviewed
- Interviews completed
- Team leader constructs the incident chronology

### 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. 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
<b>What happened?</b>	
<b>Factors that may have contributed to the incident</b>	
<b>Factors that may have mitigated the severity of the incident</b>	
<b>How might an incident like this be prevented in the future?</b>	

### Step 3: Construct incident chronology

#### Instructions

The team review information gathered and document in a chronological narrative

Date / time	Information item	Comment / source

### Meeting one tasks

- Overview of tasks to be achieved this meeting
- Recap of information gathered including incident report, PRA report, medical record and feedback from interviews
- Incident chronology is finalised and confirmed
- The team review the domains of the guiding questions to identify relevant ones for further analysis
- The team review the guiding questions in identified domains.
- 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

## Section two: Why did it happen?

### Step 3: Identify contributing factors

#### 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
Organization – Policies and priorities
Organization – Culture
Organization – Capacity (resources)

## Guiding questions

Domain / category of contributing factors	Relevant?
<b>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)</b>	
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?	
<b>Task (care/work process)</b>	
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?	
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?	
<b>Care team – Caregiver(s)</b>	
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?	
<b>Care team – Supporting team (all involved in care process)</b>	
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?	
<b>Equipment (including materials, fixtures, information and communication systems)</b>	
Were the displays and controls understandable?	
Did the equipment automatically detect and display problems?	
Was the display functional?	

Domain / category of contributing factors	Relevant?
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?	
<b>Organisation - Policies and priorities</b>	
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?	
<b>Organisation – Culture</b>	
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?	
<b>Organisation – Capacity (resources)</b>	
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?	
<b>Other – consider</b>	
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

### 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.

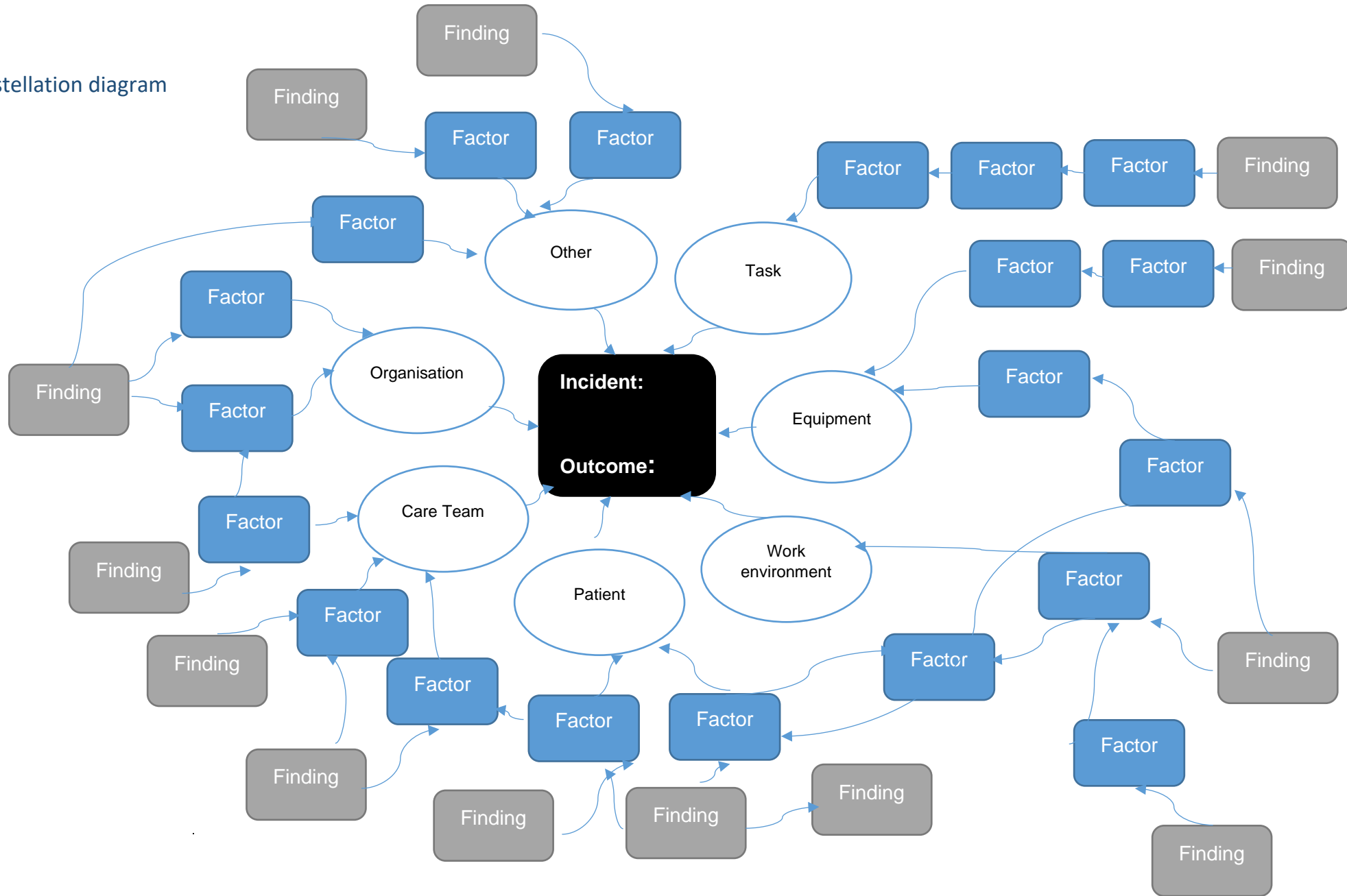
c. Mitigating factors – factors that didn't allow the incident to have more serious consequences and represent solid safeguards that should be kept in place. An example of a completed constellation diagram is illustrated in the figure below.

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 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		Yes / No		
2		Yes / No		
3		Yes / No		
4		Yes / No		

## Findings report checklist

Element of the final report	Needs to include	Avoid
<b>Description of Reportable incident</b>	<input type="checkbox"/> less than one page in length Includes: <ul style="list-style-type: none"> <li><input type="checkbox"/> Patient's age, sex,</li> <li><input type="checkbox"/> diagnosis, reason for admission, co-morbidities,</li> <li><input type="checkbox"/> relevant dates, planned or actual procedure,</li> <li><input type="checkbox"/> key points related to the patient's course of care.</li> </ul>	<input type="checkbox"/> Dot points <input type="checkbox"/> Non-factual information – not assumptions <input type="checkbox"/> Identifying information such as hospital name, service, initials or locations titles to be referred to by function e.g. JMO <input type="checkbox"/> Irrelevant information
<b>Report Summary</b>	<input type="checkbox"/> Demonstrate the team's comprehensive analysis <input type="checkbox"/> Clear statements in regard to the appropriateness of deficiencies of policy or guidelines <input type="checkbox"/> System vulnerabilities and the associated risks identified	<input type="checkbox"/> 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 <input type="checkbox"/> - 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
<b>Causation Statements / Factors Linked to Outcome</b>	<input type="checkbox"/> Clearly convey the contributing system vulnerabilities identified by the team and clearly demonstrate how each of these factors contributed to the incident. <input type="checkbox"/> Must demonstrate the cause and effect relationship <input type="checkbox"/> Must meet the five rules of causation <input type="checkbox"/> Have you got to the contributing factors?	<p>“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”.</p> <p>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.</p>

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

### Meeting two 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
<p><b>Stronger actions</b></p> <p>(these tasks require less reliance on humans to remember to perform the task correctly)</p>	<ul style="list-style-type: none"> <li>• Architectural / physical plant changes</li> <li>• New devices with usability testing</li> <li>• Engineering control (forcing function)</li> <li>• Simplify the process</li> <li>• Standardise on equipment or process or care maps</li> <li>• Tangible involvement and action by leadership</li> </ul>	
<p><b>Intermediate Actions</b></p>	<ul style="list-style-type: none"> <li>• Redundancy</li> <li>• Increase in staffing/decrease in workload</li> <li>• Software enhancements,</li> <li>• Modifications</li> <li>• Eliminate/reduce</li> <li>• Distractions</li> <li>• Education using simulation based training, with periodic refresher sessions and observations</li> <li>• Checklist/cognitive aids</li> <li>• Eliminate look- and sound-alikes</li> <li>• Standardised communication tools</li> </ul>	

	Action Category	Recommended action/s
	<ul style="list-style-type: none"> <li>Enhanced documentation,</li> <li>communication</li> </ul>	
<b>Weaker Actions</b> (these tasks require more reliance on humans to remember to perform the task correctly)	<ul style="list-style-type: none"> <li>Double checks</li> <li>Warnings</li> <li>New procedure/ memorandum/policy</li> <li>Training</li> </ul>	

Action hierarchy levels and examples adapted from National Patient Safety Foundation<sup>4</sup>.

## 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.



#	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	
<b>Recommendations</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Appropriate numbering to correspond to causation statements</li><li><input type="checkbox"/> Is this the strongest possible recommendation which can be made to address the issue identified?</li><li><input type="checkbox"/> 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?</li><li><input type="checkbox"/> Recommendation focuses on the intent of the change, rather than become overly specific about the detailed process.</li><li><input type="checkbox"/> 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?</li><li><input type="checkbox"/> Do the recommendations specify who is responsible for their implementation by title and role?</li><li><input type="checkbox"/> Do the recommendations include an oversight committee?</li><li><input type="checkbox"/> Do the recommendations describe how the effectiveness of actions will be monitored over time? Are the proposed outcome measures realistic? Measurable?</li><li><input type="checkbox"/> Has a realistic time frame been allocated?</li><li><input type="checkbox"/> If all recommendations were implemented, would patient safety be improved or are there more effective recommendations that could be made?</li></ul>

## 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](http://www.patientsafetyinstitute.ca)