Serious Adverse Event Review

Root cause analysis workbook for teams

Immediacy, Accountability, Kindness

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

Background

The Root cause analysis (RCA) workbook has been developed to support RCA 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 RCA 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, RCA teams can address these questions over three meetings. This workbook provides guidance on the tasks for completion at each of the three meeting.

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

Table of contents

RCA Flow

The following flow is recommended for RCA review. The flow and process may vary depending on the complexity of the incident under review.

Before the first meeting

The medical record and any other relevant documentation are reviewed by the team

Meeting 1

1. A simple flow diagram is constructed.
2. Checklist questions are applied to identify questions that need to be answered.
3. How, what and why questions are used to 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. The information gathered is reviewed and used to construct the final flow diagram
2. At each point in the flow diagram, the team ask ‘so what’ or ‘what is the relevance’ of each box in the incident chain.
3. The team identify whether barriers at each step might stop the problem from occurring again.
4. The team agree on the most significant issues outlined in the final flow diagram and use these for the cause and effect diagram.
5. They continue to ask ‘why’ or ‘caused by’ at each box on the tree until there are no more answers. These are the contributing factors.
6. The team define any practices, processes or systems that could be reviewed

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. Factors that caused or contributed to the incident are linked to outcomes”.
2. 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 report is submitted to the Ministry of Health and shared with the family.

Planning Calendar and 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 dates the findings report and recommendations report are 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										
☐	Schedule first team meeting										
☐	Schedule additional meeting dates including date for CE sign off meeting (as appropriate).										

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending										
	Book rooms for meeting venue										
	Develop simple flow diagram										
	Identify information to be gathered / questions to be asked										
	Gather information including: - Patient, carer and family interviews - Staff interviews - Relevant policies and local procedures - Relevant paperwork (e.g. rosters) - Relevant journal articles										
	Develop detailed flow diagram										
	Develop cause and effect diagram/s										
	Identify factors which caused or contributed to the incident.										
	Link these to the outcome or develop causation statements										
	Identify areas for review (practices, processes and systems)										
	Team leader finalises draft findings report										
	Circulate draft findings report to team for approval										

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending										
	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										
	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 RCA team learn ‘what happened’ over two meetings.

Meeting one tasks

- ☐ Introductions
- ☐ Team leader provides overview of RCA process (references made to just in time training materials)
- ☐ Meeting rules established
- ☐ Brief overview of incident by team leader who ensures incident report, medical record and PRA report are available
- ☐ Simple flow diagram constructed – 4-6 boxes
- ☐ Team brainstorm additional information they would like to know
- ☐ Trigger questions from flip chart are reference
- ☐ Each box is flow diagram is worked through and questions developed using ‘how’, ‘what’ and ‘why’
- ☐ The team identify who they need to talk to and which team member will meet with them
- ☐ Action plan developed with responsibilities and timelines for gathering information
- ☐ Future meeting dates agreed

Step 1: Draw a simple flow diagram

Instructions

I. Using post-it notes construct an initial flow diagram of 5 to 6 boxes outlining the chronology of events that led to the incident.
II. Hint: Sometimes it is easier to start at the end and work backwards.

Step 2: Identify what information needs to be gathered

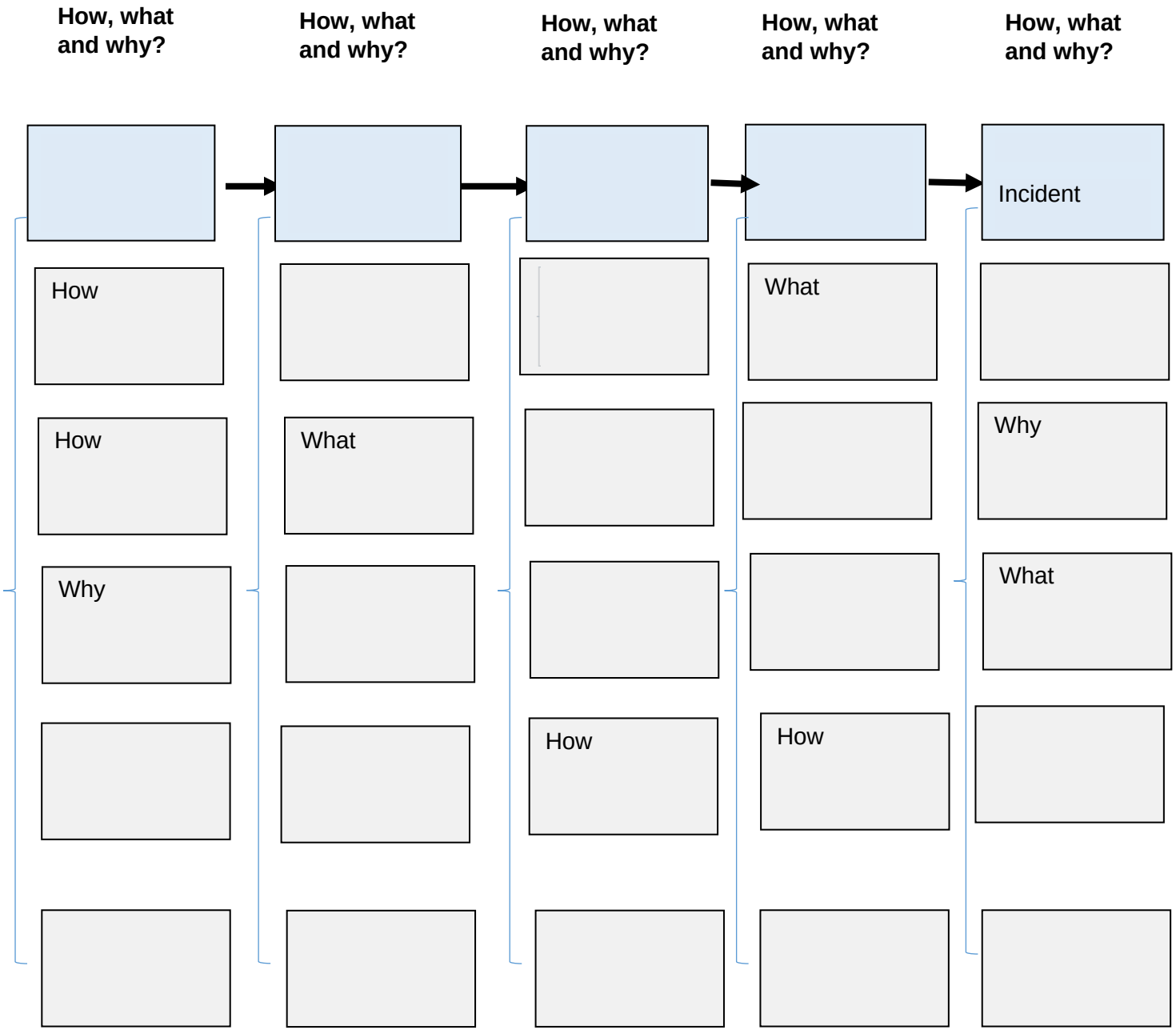
Instructions

I. Brainstorm as a group the key questions or things you would like to know about the sequence of events. The RCA Triggering Questions (below) will lead teams to appropriate questions for consideration.

II. Work through each box to identify questions outlining what isn't known. Write out questions and phrase in terms of how, what and why under each box of the initial flow diagram.

III. Identify who you need to interview and who on the is going to do the interviews.

IV. Identify what additional information you need and who is going to collect it e.g. literature, standards, policies, rosters.



Triggering Questions

Triggering questions help teams consider areas for further reviews. For any questions answered 'no', a plan is formed for further exploration through staff interviews and / or reviewing documentation e.g. policies, literature and or standards).

Category	Yes	No	N/A
Communication			
1. Was the patient correctly identified?	☐	☐	☐
2. Was information from various patient assessments shared and used by members of the treatment team on a timely basis?	☐	☐	☐
3. Did existing documentation provide a clear picture of the work-up, the treatment plan and the patient's response to treatment? (These could include: assessments, consultations, orders, treatment team notes, progress notes, medication charts, x-ray reports, laboratory reports etc.)	☐	☐	☐
4. Was communication between management /supervisors and front-line staff adequate? (Was it: accurate, complete, using standard vocabulary and not jargon, and unambiguous?)	☐	☐	☐
5. Was communication between team members adequate?	☐	☐	☐
6. Were policies and procedures communicated adequately?	☐	☐	☐
7. Was the correct technical information adequately communicated to the people who needed it 24 hours a day?	☐	☐	☐
8. Were there methods for monitoring adequacy of staff communication? (Were there methods for: 'read back', confirmation messages, debriefs etc?)	☐	☐	☐
9. Was the communication of potential risk factors provided to the people who needed to know?	☐	☐	☐
10. Was there manufacturer's recall/alert/ bulletin on file for equipment, medication, or transfusion related elements at the time of the event or close call? Were relevant staff members aware of the recall/alert/bulletin?	☐	☐	☐
11. If relevant, were the patient and their family/significant others actively included in the assessment and treatment planning?	☐	☐	☐
12. Did management establish adequate methods to provide information to employees who needed it in a manner that was easy to access/use, and timely?	☐	☐	☐
13. Did the overall culture of the facility encourage or welcome observations, suggestions, or 'early warnings' from staff about risky	☐	☐	☐

Category	Yes	No	N/A
situations and risk reduction? (Also, has this happened before and was anything done to prevent it from happening again?) 14. Did adequate communication across organisational boundaries occur?	☐	☐	☐
Training 1. Was there a program to identify what is actually needed for training of staff? 2. Was training provided prior to the start of the work process? 3. Were the results of training monitored over time? 4. Was the training adequate? (Consider the following factors: supervisory responsibility, procedure omission, flawed training, flawed guidelines, policy, or procedure) 5. Were all staff trained in the use of relevant barriers and controls?	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐
Fatigue / scheduling 1. Were the levels of vibration, noise of other environmental conditions appropriate? 2. Were environmental stressors properly anticipated? 3. Did personnel have adequate sleep? 4. Was fatigue properly anticipated? 5. Was the environment free of distractions? 6. Were there sufficient staff on hand for the workload at the time (ie workload is too high, too low, or wrong mix of staff)? 7. Was the level of automation appropriate (i.e. neither too much nor not enough)?	☐ ☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐ ☐
Environment / equipment 1. Was the work area / environment designed to support the function it was being used for? 2. Had there been an environmental risk assessment (i.e. safety audit) of the area 3. Were the work environment stress level (either physical or psychological) appropriate (e.g. temperature, space, noise, intra-facility transfers, construction projects) 4. Had appropriate safety evaluations and disaster drills been conducted?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐

Category	Yes	No	N/A
5. Did the work area meet current codes, specifications and regulations?	☐	☐	☐
6. Was equipment designed to properly accomplish its intended purpose?	☐	☐	☐
7. Did the equipment work smoothly in the context of: staff needs and experience, existing procedures, requirement, and workload; physical space and location?	☐	☐	☐
8. Did the equipment involved meet current codes, specifications and regulations?	☐	☐	☐
9. Was there a documented safety review performed on the equipment involved? If relevant, were recommendations for service/recall/maintenance, etc completed in a timely manner?	☐	☐	☐
10. Was there a maintenance program in place to maintain the equipment involved?	☐	☐	☐
11. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?	☐	☐	☐
12. If previous inspections pointed to equipment problems, what corrective actions were implemented and were they effective?	☐	☐	☐
13. Had equipment and procedures been reviewed to ensure that there was a good match between people and the equipment they used or people and the tasks they did?	☐	☐	☐
14. Were adequate time and resources allowed for physical plant and equipment upgrades, if problems were identified?	☐	☐	☐
15. Was there adequate equipment to perform the work processes?	☐	☐	☐
16. Were emergency provisions and back-up systems available in case of equipment failure?	☐	☐	☐
17. Had this type of equipment worked correctly and been used appropriately in the past?	☐	☐	☐
18. Was the equipment designed such that usage mistakes would be unlikely to happen?	☐	☐	☐
19. Was the design specification adhered to?	☐	☐	☐
20. Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy?	☐	☐	☐
21. Were personnel trained appropriately to operate the equipment involved in the adverse event/ close call?	☐	☐	☐

Category	Yes	No	N/A
22. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?	☐	☐	☐
23. Was the equipment designed so that corrective actions could be accomplished in a manner that minimised/eliminated any undesirable outcome?	☐	☐	☐
24. Were equipment displays and controls working properly and interpreted correctly?	☐	☐	☐
25. Was the medical equipment or device intended to be reused (eg not a Single Use Device)?	☐	☐	☐
26. Was the medical equipment or device used in accordance with its design and manufacturer's instructions?	☐	☐	☐
Rules / policies / procedures			
1. Was there an overall management plan for addressing risk and assigning responsibility for risk?	☐	☐	☐
2. Did management have an audit or quality control system to inform them how key processes related to the adverse event are functioning?	☐	☐	☐
3. Had a previous investigation been done for a similar event, were the causes identified and were effective interventions developed and implemented on a timely basis?	☐	☐	☐
4. Would this problem have gone unidentified or uncorrected after an audit/review of the work / process / equipment / area?	☐	☐	☐
5. Was required care for the patient within the scope of the facility's mission, staff expertise and availability, technical and support service resources?	☐	☐	☐
6. Were the staff involved in the adverse event or close call properly qualified and trained to perform their functions?	☐	☐	☐
7. Had all staff involved been oriented to the job, facility and unit policies regarding: safety, security, hazardous material management, emergency preparedness, life-safety-management, medical equipment, and utilities management?	☐	☐	☐
8. Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?	☐	☐	☐
9. Were these policies/procedures consistent with relevant state policies, standards, and regulations?	☐	☐	☐

Category	Yes	No	N/A
10. Were relevant policies/procedures clear, understandable and readily available to all staff? . 11. Were the relevant policies and procedures actually used on a day-to-day basis? 12. If the policies and procedures were not used, what prevented their use by the staff? 13. If policies and procedures were not used, what positive and negative incentives were absent?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐

Barriers

Barriers protect people and property from adverse events and can be physical and procedural. Negative / positive pressure rooms are an example of a physical barrier that controls the spread of bacteria / viruses. The surgical time out is an example of a procedural barrier that protects patients from wrong site, wrong patient, wrong procedure surgeries.

Before completing this section consider: What barriers and controls were involved in this event. Were these barriers designed to protect patients, staff, equipment or the environment?

1. Was patient risk considered when designing these barriers and controls? 2. Were these barriers and controls in place before the serious incident happened? 3. . Had these barriers and controls been evaluated for reliability? 4. Were there other barriers and controls for work processes? 5. Was the concept of 'fault tolerance' applied in system design (A fault tolerant system can withstand the failure of one or more barriers without the patient being harmed)? 6. Were relevant barriers and controls maintained and checked on a routine basis by designated staff?	☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐

Questions to which the answer is 'no'	Answer to 'why not?'

Step 3: Gather information

Interviewing staff, patients, carers and families

Question / information to be sourced	Who can help with response?	RCA team member /s allocated

Meeting two tasks

- ☐ Recap of process to date
- ☐ Overview of tasks to be achieved this meeting
- ☐ Team leader invites each member to share information gathered
- ☐ Detailed flow diagram constructed using post it notes
- ☐ Team review each step and ask ‘so what’
- ☐ Barrier points are identified
- ☐ Cause and effect diagram/s constructed
- ☐ Causation statements developed
- ☐ Areas for review identified
- ☐ 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 detailed flow diagram

Instructions

I. Each piece of information gathered is written on a post-it note.

II. Post-it notes are moved around until all the information forms a detailed final flow diagram of everything that happened. This provides a detailed chronology of events

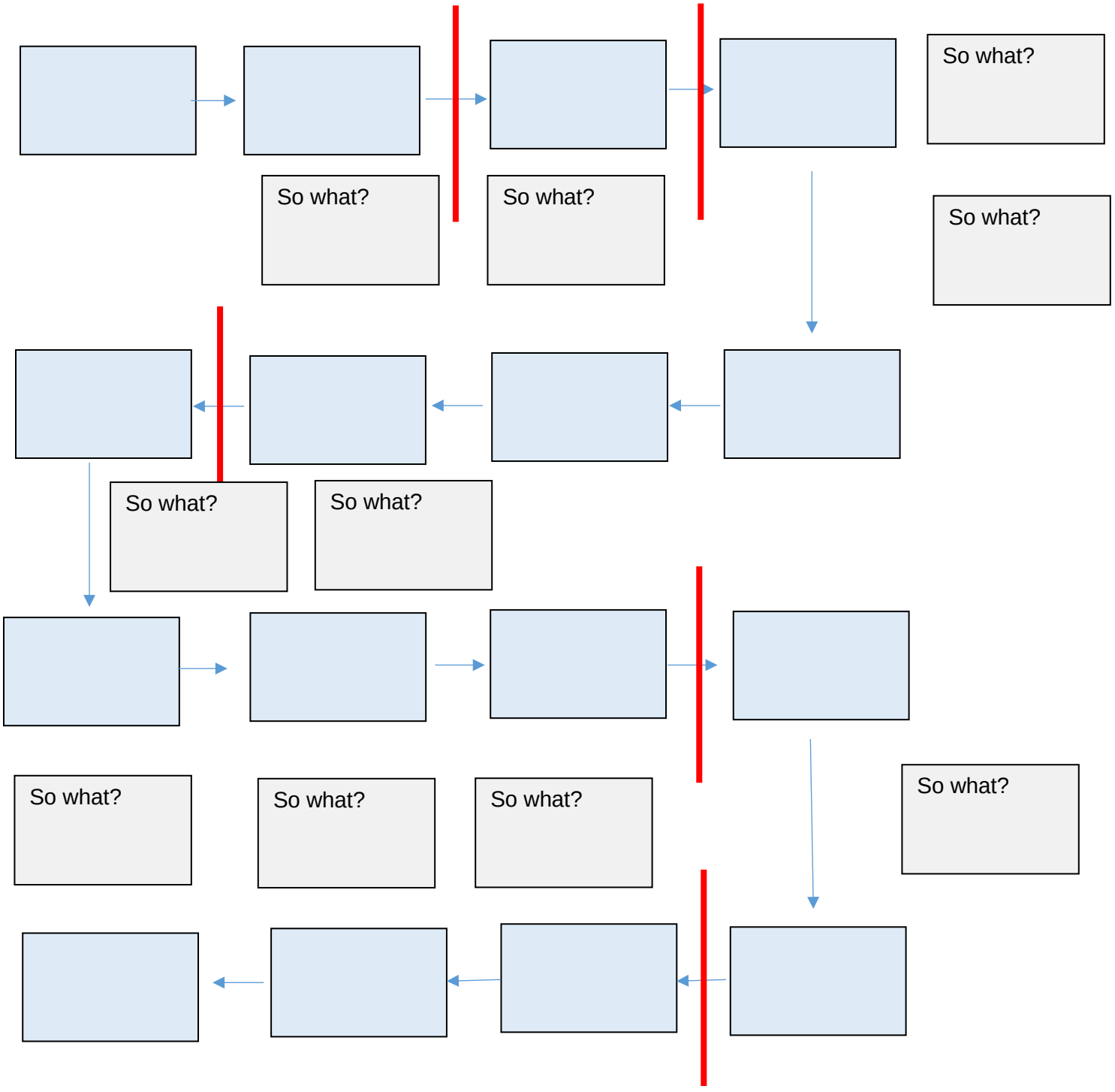
III. At each box of the final flow diagram ask where, if things were changed, would the incident have been prevented from occurring – i.e. where could things be improved - this could be done by asking 'so what?' or 'what is the relevance of each piece of information?'.

IV. These barrier points in the final flow diagram are where there are holes in the "Swiss cheese" and if an intervention were made at these points, the problem may not have occurred – place a red bar at each of these points; these will translate into your primary causes.

Instructions for using template

1. Blue boxes are used to document steps / flow in the detailed chronology
2. Grey boxes are for asking 'so what' questions and highlighting where processes could potentially be improved (Grey boxes can be moved around page under relevant blue box as required).
3. Red bars indicate barrier points i.e. if an intervention were made at this point, the problem could be prevented / mitigated. (Red bars can be moved around template).

Detailed flow diagram



Section two: Why did it happen?

Step 5: Identify any factors that caused or contributed to the incident using a cause and effect diagram

Instructions

I. Define the problem that you are trying to eliminate in one sentence.

II. Document the barrier points which have were identified in the final flow diagram as either an action, inaction or condition in the cause and effect diagram.

III. For each primary cause, a series of why questions or caused by questions are asked until no further information is available – this will become the contributing factor. Repeatedly asking the question "why?" allows for the layers of an issue to be examined.

IV. Continue the above for each primary cause – remember these are not linear trees.

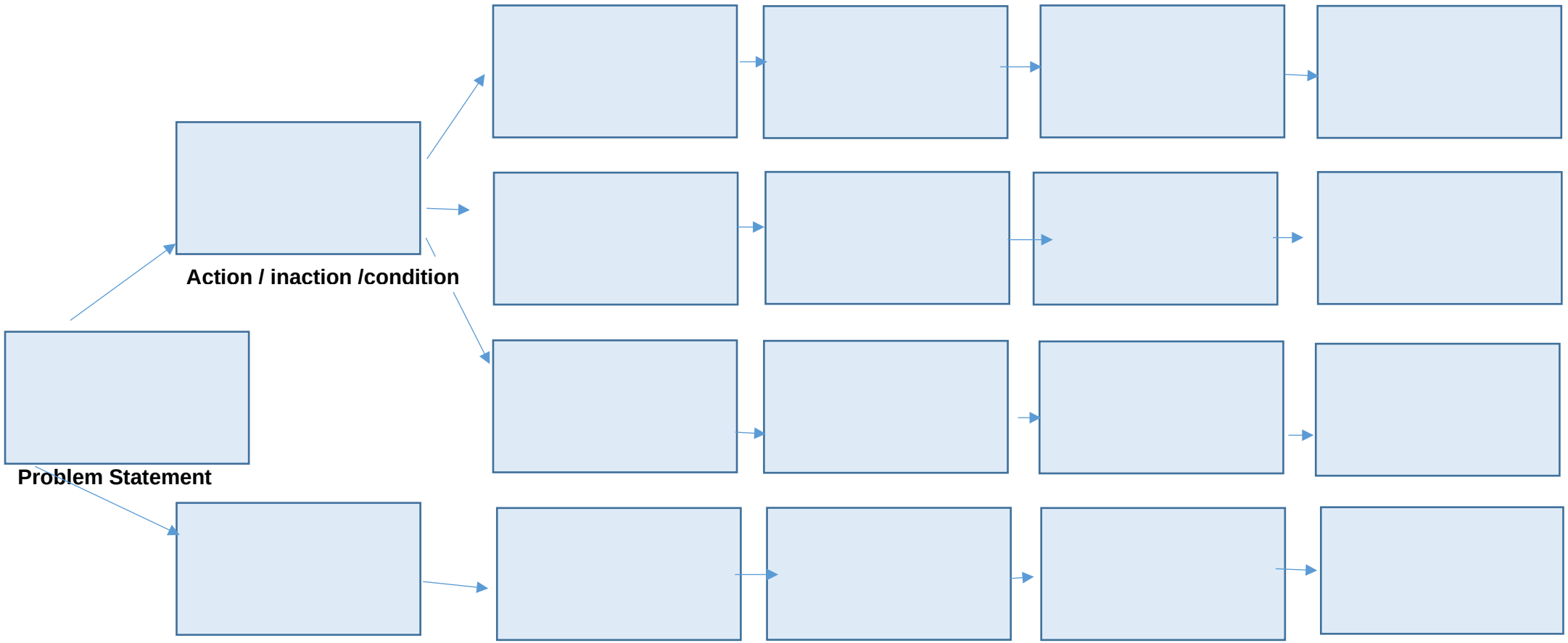
V. Check each causal chain by:

- Moving from the problem statement to the contributing factor and asking at each step – was this directly caused by….?
- Moving from the contributing factor up to the problem statement and asking at each step – did this result in or lead to…?

Instructions for using template

1. The problem statement is written in the left box
2. The action / inaction / condition is written in the adjacent boxes
3. Causes are determined by asking why. The number of causes will vary in how many levels of why are asked before the contributing factor is identified. Delete or add boxes to template as necessary.

Cause and effect diagram



Step 6: Write up factors linking them to outcome

Instructions

I. Identify the contributing factors from the cause and effect diagram

II. Prioritise the order of potential impact i.e. begin with the factor with the greatest potential to prevent this event from occurring in the future.

III. Write up factors linking them to outcome. Some teams may wish to do this by developing causation statements for each contributing factor

IV. Check each factor / causation statement against the five rules of causation[3].

#	**Linking factors to outcome**
1	
2	
3	
4	

Causation statement worksheet

A causation statement has three parts:
The cause: “This happened…”
The effect: “…which led to something else happening…”
The event: “…which caused this undesirable outcome.”

Causation statements should be checked against the 5 rules of causation

#	Causation statement	5 rules of causation
1		☐ Clearly shows cause and effect relationship ☐ Uses specific & accurate descriptors for what occurred ☐ Human errors have a preceding cause ☐ Violations of procedure are not contributing factors / root causes ☐ Failure to act is only causal if there is a pre-existing duty to act
2		☐ Clearly shows cause and effect relationship ☐ Uses specific & accurate descriptors for what occurred ☐ Human errors have a preceding cause ☐ Violations of procedure are not contributing factors / root causes ☐ Failure to act is only causal if there is a pre-existing duty to act
3		☐ Clearly shows cause and effect relationship ☐ Uses specific & accurate descriptors for what occurred ☐ Human errors have a preceding cause ☐ Violations of procedure are not contributing factors / root causes ☐ Failure to act is only causal if there is a pre-existing duty to act
4		☐ Clearly shows cause and effect relationship ☐ Uses specific & accurate descriptors for what occurred ☐ Human errors have a preceding cause ☐ Violations of procedure are not contributing factors / root causes ☐ Failure to act is only causal if there is a pre-existing duty to act

Step 7: 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	
4	

Step 8: 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

#	Area for review	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**
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

- ☐ Recap of achievement to date
- ☐ Feedback from findings report e.g. CE or delegate, family
- ☐ Overview of tasks to be achieved this meeting
- ☐ Review causation statements
- ☐ Recommendations developed
- ☐ Action plans developed
- ☐ Action plan developed with responsibilities and timelines for gathering information
- ☐ Summary of next steps including process for writing, approval and submission of Recommendations Report

Step 9: 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.

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 10: 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

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#	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 11: 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