Serious Adverse Event Review

Root cause analysis toolkit

Immediacy, Accountability, Kindness

NSW GOVERNMENT | CLINICAL EXCELLENCE COMMISSION

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 or reduce 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 a root cause analysis (RCA) review. It includes the tools and processes that will assist a team in answering the three questions. The tools and templates have been adapted from the root cause analysis and action (RCA[2]) methodology[1].The RCA Workbook [link] acts as a compendium to this toolkit and should be used by teams to ensure that all necessary steps have been completed.

Table of contents

Acronyms

ASE	Australian Sentinel Event
CE	Chief Executive
DFC	Dedicated family contact
PRA	Preliminary risk assessment
RCA	Root cause analysis
RCA^2	Root cause analysis and action
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

- Incident Analysis – Canadian Framework

- Clinical Review

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 PD2020_047 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 family

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

3) A reportable incident brief (RIB) is submitted to the Ministry of Health

4) The CE appoints assessors to undertake a preliminary risk assessment (PRA) to guide next steps

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

6) The Open Disclosure team meet with the family to share the PRA advice

Team composition

The Chief Executive (CE) appoints an RCA team composed of 3-5 members:

- Some have essential knowledge of the care processes where the incident occurred

- Preferably one member is external to the facility/service

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

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

Team members should not:

- 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.

A CE can put a standing appointment in place for certain experienced staff to be core members of all SAERs (e.g. DCG, Patient Safety Manager). Once the remaining team members are identified, a CE appoints them with reference to the standing appointment.

Training team members

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

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

http://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: https://www.cec.health.nsw.gov.au/Review-incidents/incident-management-policy-resources

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).

Root cause analysis

Root cause analysis (RCA) is a structured method used to review an incident in order to identify the healthcare systems issues that contributed to patient harm. By understanding the factors that caused or contributed to an incident, teams can improve patient safety and take action to prevent future harm[2].

An effective RCA allows for the design and implementation of a solution that addresses the failure at its source. It has the following characteristics:

- Completed by an inter-disciplinary team with involvement of those close to the work

- Analysis focuses on systems and processes; not individual performance

- Ensures human factors have been considered

- Seeks to engage patients, carers and families

- Drills down to the contributing factors of an incident

- Identifies actions to make changes to systems and processes that reduce the recurrence of clinical incidents[2].

RCA is one of the approved methods for a SAER. The CE determines the appropriate review method for each incident, however in general RCAs are the preferred approach for:

- Australian Sentinel Events (ASEs)[3]

Overview RCA process and tools

| What happened? | Why did it happen? | What action can we take to prevent it happening again? |
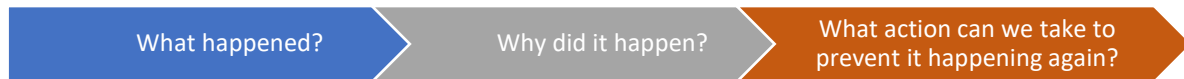
Phase	Process / tools used
Gather information	Trigger questions Family and staff interviews Literature review Review of documents e.g. standards, policies
Construct a timeline	Flowchart diagrams Barrier point identification
Identify factors that caused or contributed to the incident	Brainstorming The five why's Cause and effect diagrams
Link factors to the outcome	Causation statement worksheet 5 rules of causation
Make recommendations	Action hierarchy worksheet RCA Action Planning worksheet

Timeline for completion of review: 60 days

What happned?	Why did it happen?	What action can we take to prevent it happening again?
•Within 5-6 weeks	•Within 6-7 weeks	•Complete within 7-8 weeks
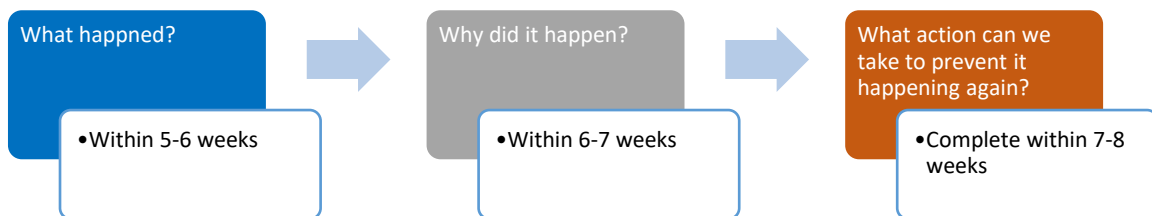
RCA Flow

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.

Section one: What happened?

For an: RCA team to understand what happened they:

Step 1:   Construct a simple flow diagram

Step 2:   Identify information that needs to be gathered

Step 3:   Gather information

Step 4:   Develop a detailed flow diagram

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: Draw a simple flow diagram

At the first meeting, the team develop a shared understanding of the event by constructing a simple flow chart. This outlines the chronology of the incident from the first known fact through to the final event (incident under review).

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.

Presented to ED with atypical chest pain	→	Patient reviewed by Registrar	→	The Registrar ordered tests	→	Discharged by different medical officer	→	Patient arrested in car park	→	Patient readmitted in cardiac arrest
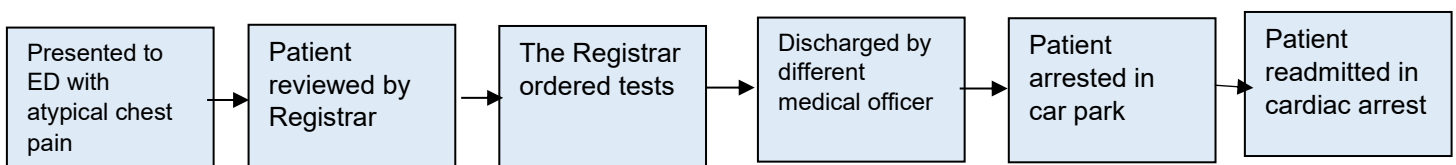
Step 2: Identify information that needs to be gathered

The team review each flow chart box and ask what is and isn't known about what happened before, during and after each point. What additional information would the team like to find out? The team determine who can help them and distribute tasks for completion before the next meeting

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 (see RCA workbook for teams) 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.

How, what and why?   **How, what and why?**   **How, what and why?**   **How, what and why?**   **How, what and why?**   **How, what and why?**

Presented to ED with atypical chest pain	Patient reviewed by Registrar	The Registrar ordered tests	Discharged by different medical office	Patient arrested in car park	Patient readmitted in cardiac arrest

Presented to ED with atypical chest pain
- Why did the patient sit in the waiting room
- What risk factors were present?
- Was the patient put on the chest pain pathway?
- How was the patient triaged?

Patient reviewed by Registrar
- What assessment was performed?
- What did he think of the patient risk factors?
- How experienced is the registrar?
- What information was communicated between him and other clinicians?

The Registrar ordered tests
- What tests were ordered?
- What are the processes for ordering and following up tests?
- Was the patient and/or wife told what the investigation plan was?

Discharged by different medical office
- What follow up arrangements were made for the patient?
- What handover occurred?
- What is the usual discharge practice?
- Were normal processes for assessment and review of chest pain followed?

Patient arrested in car park
- What was the patient's condition on departure?
- Did the patient develop more pain on exit?
- What did the patient's wife think of his condition on discharge? Were they happy to leave?

Patient readmitted in cardiac arrest
- What was the patient's condition on readmission?
- What conversation did the team have with the patient's wife?

Step 3: Gather information

The RCA team collects information using a number of methods which may include:

- Walking through or observing areas involved in the incident

- Reviewing medical records

- Examining equipment

- Researching recommended practices

- Interviewing patients, carers and families

- Interviewing staff
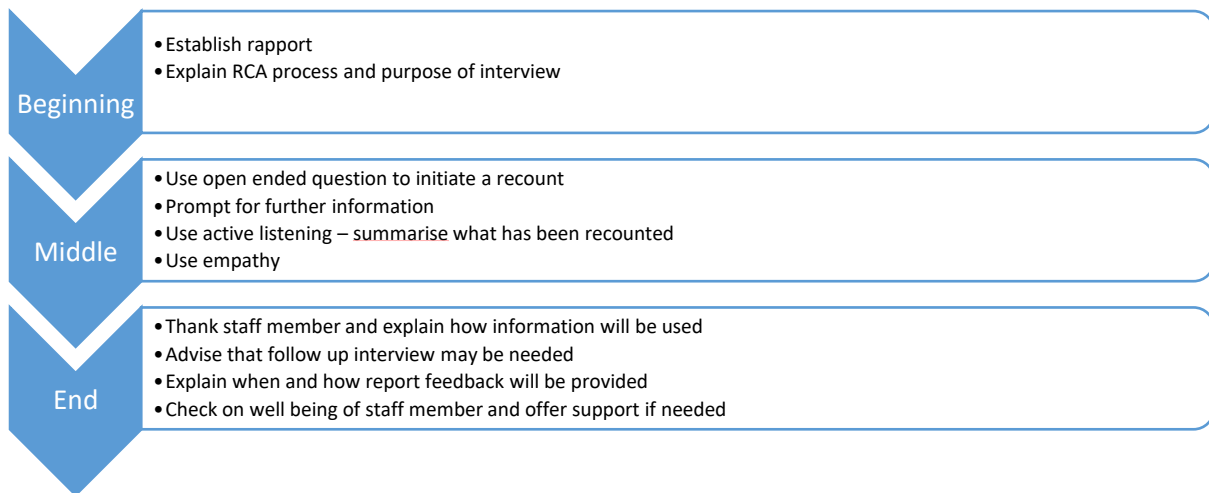
Interviewing patients, carers and families

Patients, carers and family members should always be invited to meet with the RCA team. The dedicated family contact will initiate the offer and advise the team leader if the family are willing to meet with the review team.

If the family are not comfortable with a formal interview, they should be supported to provide input in other ways e.g. written statements.

Interviewing staff

RCA team members meet with a variety of staff members to compile a system level view. Staff who are interviewed should be provided with a letter explaining their legal rights and responsibilities.

Being interviewed about a serious incident can be anxiety provoking for staff. To actively participate in discussions, they need to feel safe. By displaying empathy and focusing on learning to improve systems of care, the RCA team member /s establish psychological safety.

Beginning	• Establish rapport • Explain RCA process and purpose of interview
Middle	• Use open ended question to initiate a recount • Prompt for further information • Use active listening – summarise what has been recounted • Use empathy
End	• Thank staff member and explain how information will be used • Advise that follow up interview may be needed • Explain when and how report feedback will be provided • Check on well being of staff member and offer support if needed

Setting up meetings

- Meetings should be conducted as soon as practical. A person's memory of the event will fade with each passing day.

- Staff being interviewed are sent a letter explaining that the conversation is privileged. This means that the interviewer must maintain confidentiality and any of the notes taken are not admissible in any court proceedings.

- If possible, peers should be used to interview staff e.g. a nurses interview nurses, allied health interview allied health staff

- Meetings are ideally conducted in person. Telephone interviews may be appropriate when the individuals know and trust each other.

- Where possible, two RCA team members attend each meeting. This enables one person to facilitate the discussion while the other records the conversation.

- Meetings should take place at a mutually convenient time in a venue free from distraction.

- The RCA team member/s prepare for the session by bringing RCA team queries and preparing some open-ended questions.

- The staff member may bring a support person if they wish.

Conducting meetings

The RCA team member opens the session by explaining the RCA process and the purpose of the meeting. The focus on systems issues to prevent recurrence is stressed. Concerns and issues are discussed to allay anxieties.

The interviewer seeks permission from the individual to take notes throughout the discussion.

Effective questioning makes fact finding easier and the individual more comfortable with the process. Open-ended questions are used to elicit a factual recount of the event. The discussion begins with broad questions and then moves to specific clarifying questions. The staff member is encouraged to limit their comments to what they observed and avoid conjecture.

The RCA team member asks the staff member what they believe were the contributing factors to the incident. The staff member should be also asked to make suggestions about what could be put in place to prevent a similar incident happening in the future.

The RCA team member conveys empathy and uses reflective listening to check that that the story is being understood.

The RCA team member should not disclose who else will be interviewed or what others have already said.

The interview is closed with an expression of thanks, ensuring the interviewee has had an opportunity to ask any questions about the SAER process. The individual is advised of when the final report is due and how they will receive feedback.

The staff member is provided with the details of the designated RCA team member to contact if they think of any additional information. They are also advised that a follow up discussion may be required if new information is discovered in other interviews from the investigation.

This can be a highly emotive process for staff. A welfare check is completed to determine if the individual requires any follow up support.

Gaining insights and ideas from patients, carers and families

Patients, carers and families provide a unique perspective to the review process. They should be invited to meet with the RCA team.

In general the same principles are followed for setting up and conducting interviews with staff. Some additional considerations include:

- Always have at least two RCA team members meet with the family. This will support accurate information gathering.

- Coming back to the health service where the incident took place may be challenging. The family should specify their preferred location.

- An expression of apology should be provided and an acknowledgement of distress.

- The family may have questions for RCA team members. These should be noted and followed up at another time as appropriate.

- The patient, carer and family should be advised that they will be provided with feedback at an open disclosure event after the final report is completed. An approximate date should be provided.

- Accessibility requirements need to be factored in when planning for meetings.

- Communication approach may need to be adapted to accommodate health literacy levels.

- The cultural needs of the family should be assessed and support services arranged if appropriate e.g. Aboriginal Liaison Officer, healthcare interpreter

If the family are not comfortable with a formal meeting, they should be supported to provide input in other ways e.g. written feedback.
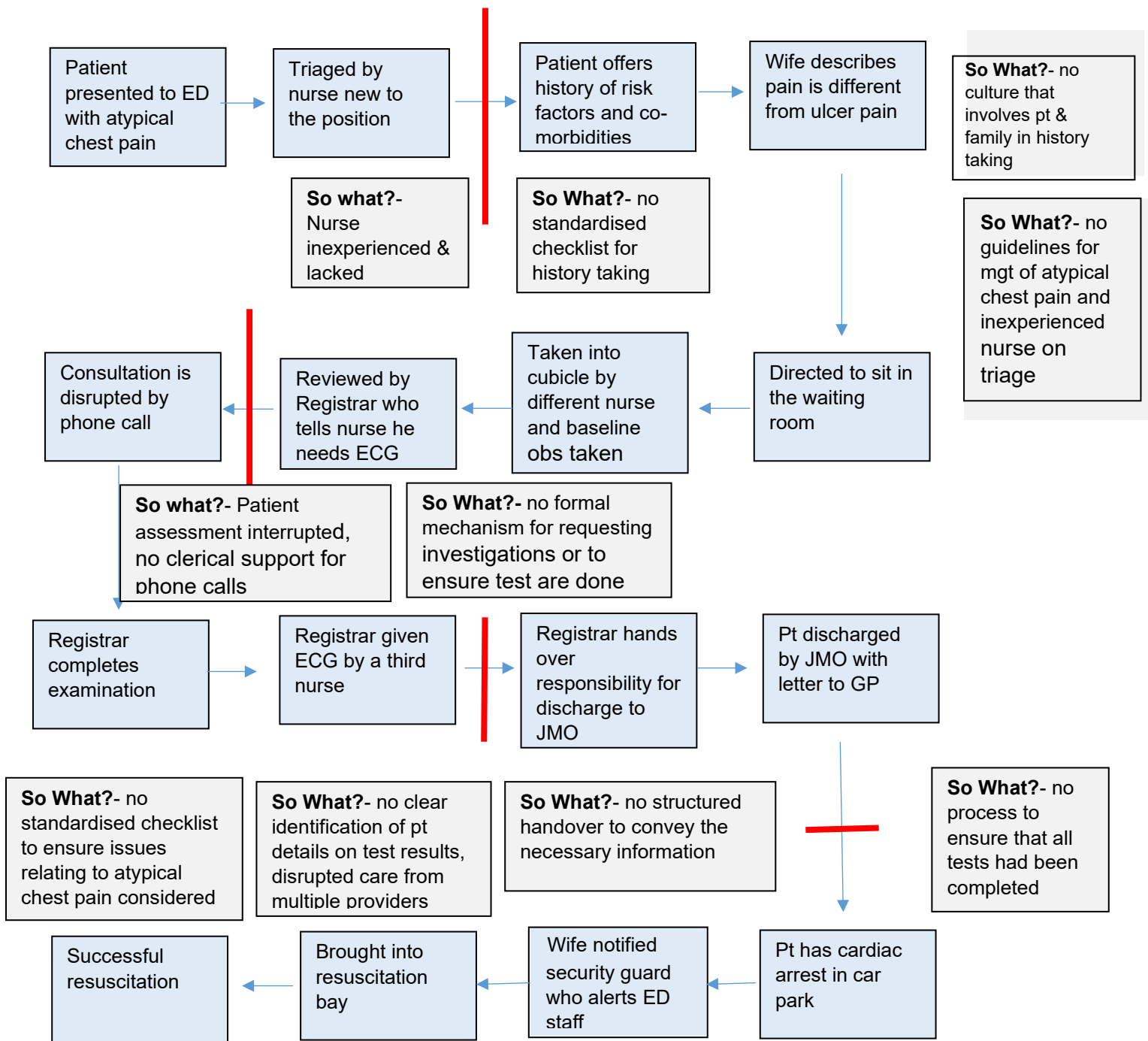
Step 4: Develop a detailed flow diagram

Once all the information has been gathered, the team can construct a final flow diagram. The provides a detailed chronology of factors leading to the event. At each point the team should ask 'what is the relevance?' of each piece of information. Could what happened /did not happen have contributed to that part of the sequence of events. The team should then identify where barriers may be put in place to prevent the problem occurring again.

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.

Detailed flow diagram

```
Patient presented to ED with atypical chest pain
  →
Triaged by nurse new to the position
  →
Patient offers history of risk factors and co-morbidities
  →
Wife describes pain is different from ulcer pain
```

So what?- Nurse inexperienced & lacked

So What?- no standardised checklist for history taking

So What?- no culture that involves pt & family in history taking

So What?- no guidelines for mgt of atypical chest pain and inexperienced nurse on triage

```
Consultation is disrupted by phone call
  ←
Reviewed by Registrar who tells nurse he needs ECG
  ←
Taken into cubicle by different nurse and baseline obs taken
  ←
Directed to sit in the waiting room
```

So what?- Patient assessment interrupted, no clerical support for phone calls

So What?- no formal mechanism for requesting investigations or to ensure test are done

```
Registrar completes examination
  →
Registrar given ECG by a third nurse
  →
Registrar hands over responsibility for discharge to JMO
  →
Pt discharged by JMO with letter to GP
```

So What?- no standardised checklist to ensure issues relating to atypical chest pain considered

So What?- no clear identification of pt details on test results, disrupted care from multiple providers

So What?- no structured handover to convey the necessary information

So What?- no process to ensure that all tests had been completed

```
Successful resuscitation
  ←
Brought into resuscitation bay
  ←
Wife notified security guard who alerts ED staff
  ←
Pt has cardiac arrest in car park
```

Section two: Why did it happen?

For an RCA team to understand why an incident happened they:

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

Step 6:   Write up factors linking them to the outcome ("causation statements")

Step 7:   Identify any practices, processes or systems that could be reviewed

Step 8:   Write findings report

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

The cause and effect diagram assists in analysing the relationships between a problem and its causes. It is a systematic way of combining the previous brainstorming, information gathering and flowcharting tasks.
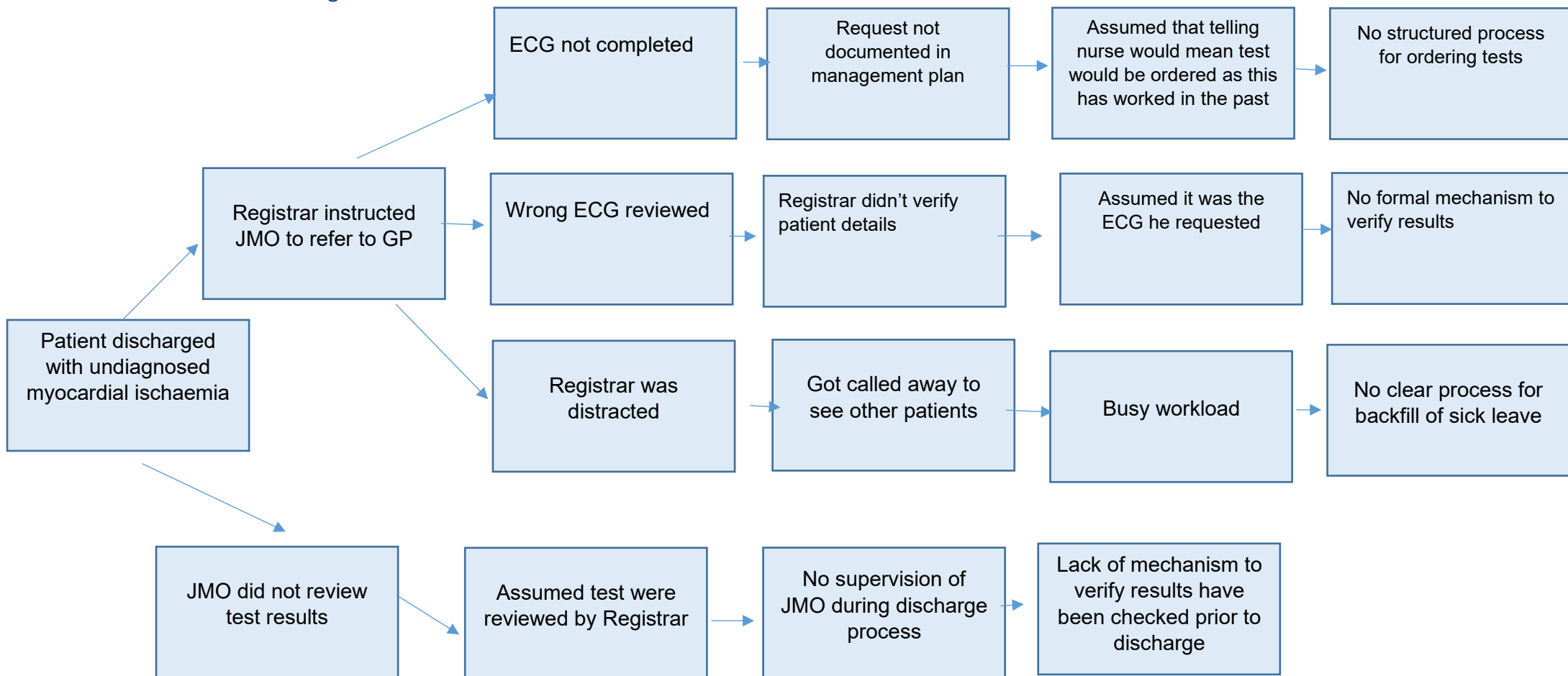
The cause and effect diagram:

- Describes the problem for which causes need to be identified
- Identifies the primary causes that directly preceded the problem. Primary causes can be described as either:
    - Action – event or action that happened at a point in time
    - Inaction -something that didn't happen
    - Condition – exists over time, may relate to systems, processes or culture
- Ensures the team questions each cause to the form of error chains and identify the contributing factors

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 leading to the root cause of a problem.

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 factors 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…?

Cause and effect diagram

```
Patient discharged          Registrar instructed          ECG not completed    →    Request not            →    Assumed that telling        →    No structured process
with undiagnosed      →     JMO to refer to GP                                       documented in               nurse would mean test            for ordering tests
myocardial ischaemia                                                                 management plan             would be ordered as this
                                                                                                                 has worked in the past

                                                         Wrong ECG reviewed    →    Registrar didn't verify →    Assumed it was the          →    No formal mechanism to
                                                                                     patient details             ECG he requested                 verify results

                                                         Registrar was         →    Got called away to      →    Busy workload               →    No clear process for
                                                         distracted                  see other patients                                           backfill of sick leave

JMO did not review    →     Assumed test were            No supervision of     →    Lack of mechanism to
test results                reviewed by Registrar    →   JMO during discharge        verify results have
                                                         process                     been checked prior to
                                                                                     discharge
```

Step 6: Write up factors linking them to outcome

The team link the identified factors to the outcome to clearly define why something occurred. Factors focus on processes and systems, not individuals.

Examples of factors linked to outcome

#	Linking factors to outcome
1	Informal handover practices led to the wrong patient being discharged
2	Processes for test ordering led to an ECG not being completed resulting in undiagnosed myocardial ischaemia
3	Inconsistent review processes for reviewing test results led to clinical decisions based on the ECG results of another patient
4	Rostering practices of senior medical staff did not take into account college examination periods

Alternately, causation statements can be used to link factors to outcomes. A Director Clinical Governance may state a preference for this approach.

A causation statement links the causes identified to the effects and then back to the event that prompted the RCA . It is written in unambiguous terms, easily understood by stakeholders who are not part of the RCA team.

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."

Examples of causation statements

#	Causation statements
1	There were no procedures established or expectations regarding formal handover of identification of patient, thereby increasing the chance that patient's would be misidentified. This resulted in the patient being discharged and without full review with undiagnosed myocardial ischaemia
2	The level of activity in the emergency department, combined with the absence of appropriate requisition forms for ordering of ECGs resulted in the registrar not completing the request form and verbally asking for the tests to be completed. This resulted in the request not being recognised as uncompleted and contributed to the patient's discharge with undiagnosed myocardial ischaemia
3	The informal manner for handling ECG's and the practice of not clearly stating the patients name, led to the ECG of a different patient being handed over to the doctor. This contributed to the wrong ECG being reviewed and subsequent instruction for discharge of a patient with undiagnosed myocardial ischaemia
4	The absence of an effective rostering process that provides for appropriate leave for senior staff undertaking college exams, resulted in the registrar being fatigued and stressed. This contributed to the registrar not performing a comprehensive assessment and the discharge of a patient with undiagnosed myocardial ischaemia.

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 develop causation statements for each contributing factor

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

The Five Rules of Causation

Rule 1 - Show the "cause and effect" relationship.

Show the link between your root cause and the harmful outcome.

e.g. The surgical unit rostering practices, which required residents to work overnight for two consecutive days, led to the resident's fatigue which increased the likelihood that he submitted a test request for the incorrect patient via the electronic system.

Rule 2 – Use clear and accurate words, not negative or vague ones

Broad and/or negative statements do not help us understanding underlying issues.

e.g. Practical training and written instructions were not provided in the use of the new infusion pumps increasingly the likelihood that the nurse misunderstood the IV pump controls [conditions] which led to missing steps in the programming of the dose and rate This resulted in the patient receiving a rapid infusion of the drug [key event] and his cardiac arrest [outcome].

Rule 3 – Identify the underlying cause/s, not the human error

The cause of the error, not the error itself, leads us to effective prevention strategies.

e.g. The absence of replacement medical staff to cover registrars on sick leave [condition] led to the registrar being rushed and taking short cuts resulting in the patient being discharged with an incorrect discharge summary [key event]. This resulted in the GP continuing the wrong dose of anticoagulant therapy and the patient's gastrointestinal bleed [outcome].

Rule 4 - Identify the underlying cause/s to procedural deviations

We must understand the reasons for procedural violations to take action based on them. If a clinician is violating a procedure because it is the local norm, we will have to address the reasons that created the norm.

e.g. The pharmacy had its own informal dispensing procedure which was inconsistent with the NSW Health dispensing procedure [condition]. This led to the new pharmacy technician being unaware of the practice of routine checking by two persons which resulted in the incorrect dispensing of the medication [key event]. This led to the provision of the wrong strength of solution resulting in the respiratory arrest of the child [outcome].

Rule 5 - Failure to act is only causal when there was a pre-existing duty to act.

The duty to act arises from standards, guidelines for practice and other documents around patient care. For example, a doctor's failure to prescribe a cardiac medication after an infarct can only be causal if established guidelines required her/him to do so.

e.g. The revised surgical guidelines about when a VMO is required to review a patient after surgery were not communicated to all surgical teams. This led to the patient not being attended by a VMO for 2 days which contributed to the delay in recognition of the patient's deterioration and her subsequent death.

Step 7: 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 factors / 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 practices in the Emergency Department
2	Standardisation of processes for test ordering in the Emergency Department
3	Processes for review of results prior to discharge across the organisation
4	Rostering practices during college examinations across the organisation

Step 8: Write Findings Report

The RCA 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 RCA can be shared verbally 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 family are invited to suggest recommendations to prevent future incidents from recurring. Any proposals are relayed to the RCA team for consideration.

The CE 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: RCA team to develop actions they:

Step 9:   Recommend actions

Step 10:   Develop action plan

Step 11:   Write recommendations report

Step 9: 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 implementedSAER teams can identify system improvements unrelated to the incident. [recommendations or referrals].

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.
	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.

	Action Category	Example
	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[1].

Step 10: 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 imagers 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 experience a fall after hours are reassessed for falls related injuries by the admitting team	B	Audit of patients who fell after hours shows 95% compliance with review by admitting team	October 2020	Patient Safety and Clinical Quality	Director Clinical Services

Step 11: 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 https://www.safetyandquality.gov.au/our-work/indicators/australian-sentinel-events-list
Causation statement	Causation statement or causal statements link the causes identified by an RCA team to the effects and then back to the serious incident It has three parts: 1. The cause: "This happened…" 2. The effect: " …which led to something else happening…" 3. The event: "…which caused this undesirable outcome."
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.
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.

References

1. National Patient Safety Foundation (2015). *RCA[2]: Improving root cause analyses and actions to prevent harm.* https://www.ashp.org/-/media/assets/policy-guidelines/docs/endorsed-documents/endorsed-documents-improving-root-cause-analyses-actions-prevent-harm.ashx

2. UNC Institute for Healthcare Quality Improvement (2020). *Root cause analysis.* https://www.med.unc.edu/ihqi/resources/root-cause-analysis/

3. Australian Commission on Safety and Quality in Health Care (2019). *Australian Sentinel Events List* https://www.safetyandquality.gov.au/our-work/indicators/australian-sentinel-events-list

4. 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