Serious Adverse Event Review

Systems analysis of clinical Incidents - London Protocol (2nd edition) toolkit

Immediacy, Accountability, Kindness

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

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Background

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

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

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

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

Serious adverse event reviews in NSW are underpinned by:

- Just culture – when an incident occurs, individuals are treated fairly and not held accountable for system failings over which they have no control
- Focus on systems and not people – review processes consider the conditions under which individuals work, taking into account the complexity and interdependencies
- Human factors – action is taken to improve the interaction of staff with one another and the environment in which they work
- Learning – outcomes are shared to generate insights for action

This toolkit provides guidance for teams undertaking a Systems analysis of clinical incidents – London Protocol (LP) review. It includes the tools and processes that will assist a team in answering the three questions. The Systems analysis of clinical incidents – London Protocol Workbook acts as a compendium to this toolkit and should be used by teams to ensure that all necessary steps have been completed.

Acronyms

ASE	Australian Sentinel Event
CDP	Care delivery problem
CE	Chief Executive
DFC	Dedicated family contact
LP	London Protocol
PRA	Preliminary risk assessment
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
- NSW Health Concise incident analysis
- NSW Health Comprehensive incident analysis

Privilege

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

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

The Incident Management Policy provides further guidance on privilege.

Before the team is appointed

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

These include:

1) Clinician disclosure – staff share what they know about the incident with the family
2) The incident is notified in ims^{+} and relevant staff are informed
3) The CE appoints a team of staff to undertake a preliminary risk assessment (PRA) to ensure that people and the environment are sate and supported
4) A Reportable Incident Brief (RIB) is submitted to the Ministry of Health
5) A dedicated family contact is appointed. This staff member is the main contact for the family during the SAER process
6) The Open Disclosure team meet with the family and share the findings of the PRA

Team composition

The Chief Executive (CE) appoints an LP team composed of 3-5 members including representation from:

- Staff with essential knowledge of the care processes where the incident occurred
- Senior management expertise (e.g. Divisional Manager, Director Nursing and Midwifery, Director Medical Services)
- Preferably one member is external to the facility/service
- One team member (usually team leader) has SAER expertise

Team members should not:

- Have been directly involved in the incident
- Have a conflict of interest
- Be the manager of the department or unit where the incident occurred

Team appointment

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

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

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

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

Issues with individual clinicians

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

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

Systems analysis of clinical Incidents – London Protocol

The Systems analysis of clinical Incidents - London Protocol[1] (LP) takes a systems approach to incident review and was developed for the healthcare context by patient safety expert, Charles Vincent.

LP identifies problems that may have occurred during the **care delivery process,** and any **contributory factors** present at the time of the incident. An incident may involve several CDPs.

Care Delivery Problems

Care delivery problems (CDPs) are problems that arise in the process of care, usually actions or omissions by staff. The two essential features are:

1. Care deviated beyond safe limits of practice
2. The deviation had at least a potential direct or indirect effect on the adverse outcome for the patient, member of staff or general public.

Some examples include:

- Failure to monitor patient adequately, observe or act upon some test results
- Incorrect decision such as the wrong drug prescribed for a particular situation
- Not seeking help when a patient's condition is deteriorating.

Contributory Factors

Many factors may contribute to a single CDP. The factors are listed below with examples. The table on page 20 provides a framework for contributory factor types that should be considered by the LP team.

- Patient factors e.g. the patient was very distressed or unable to understand instructions.
- Task and technology factors e.g. poor equipment design or the absence of protocols

- Individual factors e.g. lack of knowledge or experience of particular staff
- Team factors e.g. poor communication between staff
- Work environment factors e.g.an unusually high workload or inadequate staffing.

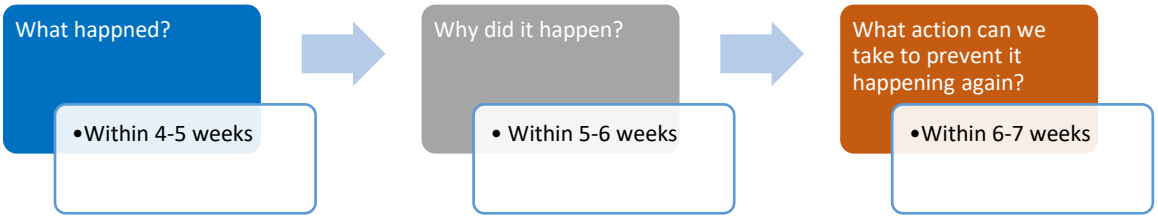
LP is one of the approved methods for a SAER. The CE determines the appropriate review method for each incident, however in general LP is the preferred approach for:

- Inpatient falls
- Maternity and obstetrics

High level overview of process and tools

Phase	Process / tools used
Organise and gather data	Review incident including medical record, incident report, relevant policies, physical evidence and information about conditions at the time of the incident (e.g. rosters)
Determine incident chronology	Flow diagram
Define care delivery problems	Flow diagram Chronological mapping of care delivery problems and associated contributory factors
Identify factors that caused or contributed to the incident	Feedback from interviews Brainstorming (+/- fishbone diagram) Chronological mapping summary table
Link factors to the outcome	Causation statement worksheet 5 rules of causation
Make recommendations	Action hierarchy worksheet Action Planning worksheet

Timeline for completion of review: 60 days



London Protocol flow

The following flow is recommended flow for conducting a London Protocol (LP) review. The flow and process may vary depending on the complexity of the case.

Before the first meeting

The team leader gathers information from all available sources and constructs a timeline for review by the LP team at the first meeting

Meeting 1

1. The LP team review the incident chronology and at each identify if there were any care delivery problems (CDPs) that arise in the process of care.
2. CDPs are documented on the “Chronological Mapping of CDPs and Associated Contributory Factors” table
3. If CDPs are identified, staff interviews are required. Questions are developed and interviews allocated to team members.

After the first meeting

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

Meeting 2

1. Team member provide feedback on outcomes of interviews
2. The team review and update the initial flow diagram with consideration given to information gathered.
3. The team review each CDP separately and identify / brainstorm contributory factors outlined in the table above. Information from staff interviews is used to inform this process
4. The identified contributory factors are documented in the Chronological Mapping of CDPs and Associated Contributory Factors table
5. Causation statements / factors linked to outcome are developed

After the second meeting

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

Meeting 3

1. Any new team members are briefed
2. Causation statements / factors linked to outcome are reviewed
3. Actions, 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 LP team to understand what happened they:

Step 1: Organise and gather data

Step 2: Identify care delivery problems

Step 3: Interview staff and family

Step 4: Confirm incident chronology

Preparation

The LP 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: Organise and gather data

The team leader constructs a timeline from available sources for review by the LP team at the first meeting.

Instructions

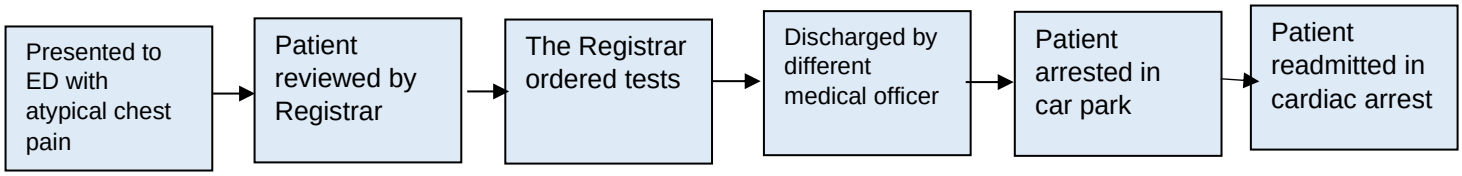
I. The team leader gathers and reviews all facts, knowledge and physical items related to the incident including medical records, incident reports, relevant policies, physical evidence and information about conditions affecting the event (e.g. rosters)

II. If the incident was an inpatient fall, the team leader completes the Falls Factor Analysis

III. The team leader develops a simple flow diagram of key events prior to the first meeting.

IV. At the first meeting, the LP team review and agree on simple flow diagram the and Falls Factor Analysis (if indicated)

V. The team leader documents a draft sequence of events based on the LP team discussion at the first meeting.



Falls Factor Analysis – completed for inpatient falls

Post fall management	Yes	No	NA	Comment
Did the incident cause an injury? Head Injury If yes, was it open? ☐ or closed? ☐				
Did the patient have a fracture as a result of the fall?				
What was the fracture? Please note: #NoF, #Pelvis, Other#:				
Other injury e.g. soft tissue? Please note:				
Were investigations- (*e.g. X-ray, CT scan)* attended What did investigations reveal?				
Post fall vital signs observations (as per CEC Adult or Paediatric post-fall chart) documented?				
Following the fall was that patient showing signs of altered mental status /confusion? *(eg wandering/restless/aggressive* *Poor attention/memory/anxious/* *behaviour change)* Was a medical review conducted? What diagnosis was made? What was investigated? What plan was implemented?				
Medical Officer reviewed the patient Time taken within 60 mins Time taken > 60 mins				
Was family/carer contacted and informed of the fall? *When was the family contacted*				
When was the admitting doctor notified?				

Risk identification	Yes	No	N/A	Comment
Prior to the fall had risk factors been identified and was a plan of care in place? *(history of falls, poor vision, unsteady when walking/mobilising, continence/incontinence issues)*				Describe
Was the patient identified as being malnourished/dehydrated? *(was as a plan in place ie needing assistance with meals & fluids?***)**				
Was anyone surprised that this patient fell?				
History of previous falls?				
Mental status				
Prior to the fall was that patient showing signs of altered mental status /confusion? *(eg wandering/restless/aggressive Poor attention/memory/anxious/ behaviour change)*				
Recorded Diagnosis of Dementia?				
Cognition screen completed?				
Recorded Diagnosis of Delirium?				
Delirium screen completed?				
If delirium was identified were underlying causes addressed? *e.g. infection, pain, constipation, dehydration, inadequate nutrition, physical restraint)*				
Was a clinical review completed?				
Was the patient impulsive and not able to reliably follow instructions, were the following in place?				
Located to allow adequate surveillance by staff (*e.g. located close to Nurses station or cohort in 2 -4 bed room)*				
Intentional rounding in place				
Regular toileting provided				
Strategy for close supervision in the bathroom: *(e.g. never being left on their own for planned toileting and self-care).*				
Use of hi-lo/lo-lo/floor bed?				
Audible alerts (*e.g. bed/chair alarms, sensor mats, other)*				
Increased supervision (*e.g. IPS, family/carer or volunteer companion observer/sitter.*				
Were **bed rails** involved with the fall? (eg. bed rails up and patient tried to climb over or around them)				

Risk identification	Yes	No	N/A	Comment
Mobility				
Did the patient mobilise without assistance if required?				
Did the bed height contribute to the fall? *(e.g. too high too low)*				
Patient attachments – e.g. IV pole, O2 etc				
Toileting needs				
Did the patient attempt toileting without assistance if required?				
Was a toileting plan in place? *(continence/frequency/urgency/nocturia)*				
Medications				
Was the patient on fall –related medications? (antipsychotics, antidepressants, Sedatives/hypnotics or opioids) *(e.g was night sedation administered?)*				
Was the patient on medications (*anticoagulants, antiplatelets or coagulopathy)* identified at the time or medical review? (*may increase severity/ consequences of injury)*				
Was a medication review completed?				

Ward Factors – environmental and cultural				
Team Safety Fundamentals				
Safety risks identified at: • Clinical bedside handover • Safety Huddles				
Intentional/Proactive Rounding in place				
Ward and staffing factors				
Environment *(e.g. layout of ward, access to bathroom, isolation, adequate lighting, able to be seen by staff, patient able to contact staff, hazards such as wet floor/clutter*)				
Ward Equipment *(e.g. availability and maintenance of mobility aids, height adjustable beds)*				
Staffing (e.g. staff shortages, staff member aware of falls prevention plan, skill mix, rostering, meal breaks, regular team, PS)				
Unusual activity in the ward at the time of the fall *(e.g. outbreak of illness: COVID – 19, Flu/Gastro, acuity of other patients, fire alarm etc)*				

Step 2: Identify the care delivery problems

Having identified the sequence of key events, the LP team focus on identifying the CDPs. Several CDPs may be involved in one incident. They have two essential features:

- Care deviated beyond safe limits of practice
- The deviation had at least a potential direct or indirect effect on the eventual adverse outcome for the patient, member of staff or general public.

Instructions

I. CDPs are documented on the "Chronological Mapping of CDPs and Associated Contributory Factors" table

Step 3: Staff and family interviews

Staff interviews are undertaken to obtain information from staff and other persons involved regarding the incident. The LP team determine who needs to be interviewed and arrange for these interviews to take place as early as possible. The staff member is encouraged to identify both the CDPs and the contributory factors which greatly enriches both the interview and investigation

Patients, carers and family members should always be invited to meet with the LP team. The dedicated family contact will initiate the offer and advise the team leader if the family agree. If the family are not comfortable with meeting with review team member/s, they should be supported to provide input in other ways e.g. written statements

Instructions

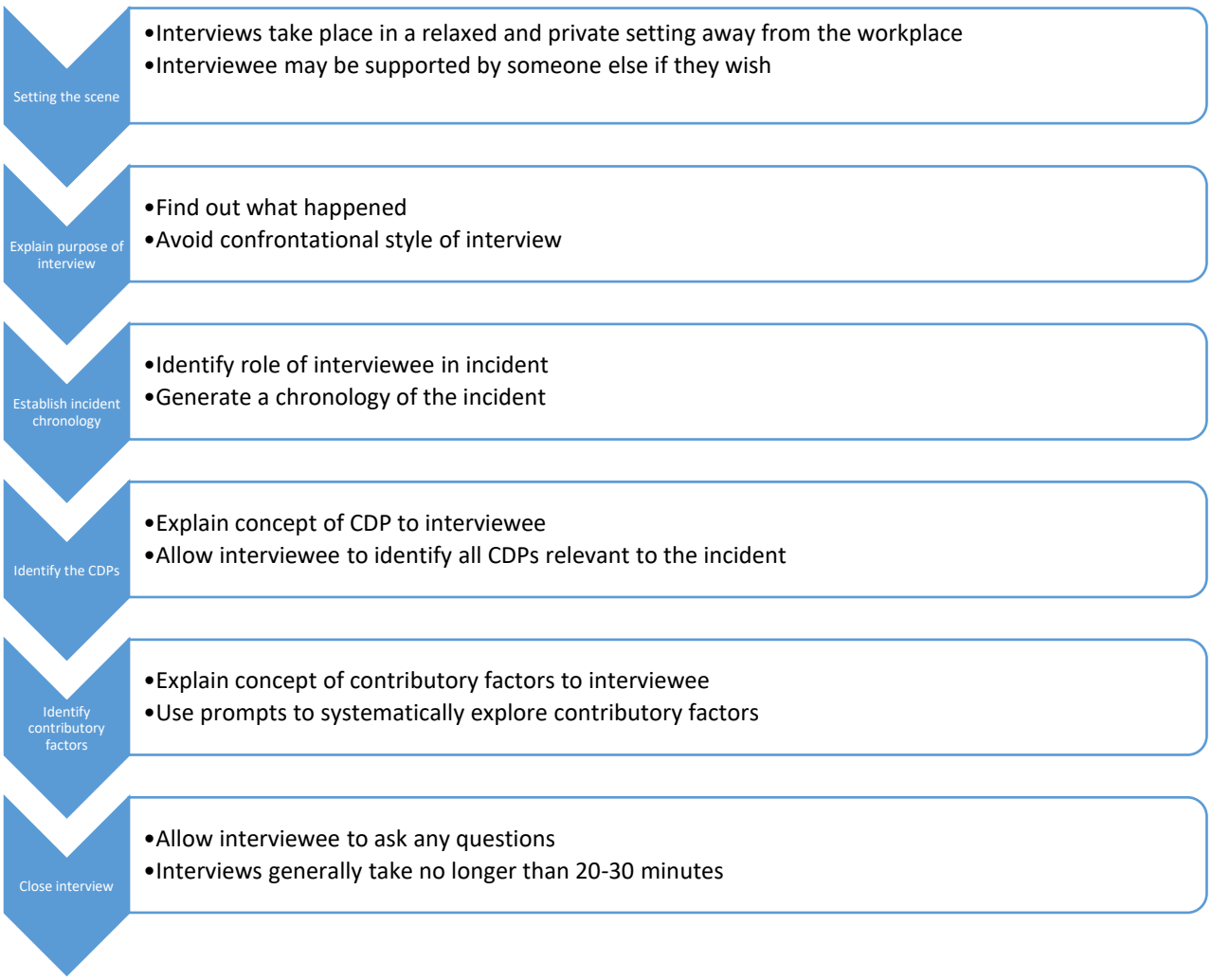
I. The staff member is asked to describe their observation and understanding of the events leading to the incident

II. The LP team member /s explain what CDPs are and ask the interviewee their opinion on the CDPs involved in the incident.

III. The LP team member /s explain what contributory factors are and ask the interviewee their opinion on the contributory factors involved in the incident.

IV. Interview is closed, ensuring interviewee has had an opportunity to ask any questions about the SAER process

Summary of LP Interview Process



Setting the scene

- Interviews should be undertaken as soon as practical. A person's memory of the incident will fade with each passing day.
- Staff being interviewed are sent a letter by the CE 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.
- 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.
- If possible, peers should be used to interview staff e.g. a nurse interviews nurses,
- Meetings are ideally undertaken in person or via online platforms e.g. Skype for Business. Telephone interviews may be appropriate when the individuals know and trust each other and when online platforms are not available.

- Where possible, two LP team members are present at each meeting. This enables one person to facilitate the discussion while the other takes notes.
- Meetings should take place at a mutually convenient time in a quiet setting.
- The staff member may bring a support person if they wish

Explain purpose of the interview

- The LP team members explain that the purpose of the interview is to find out what happened and to identify the factors that contributed to the incident.
- The purpose of review is to take action to prevent recurrence and not to apportion blame on individuals

Establish incident chronology

- The role of the staff member in the incident is established including the limits of their involvement
- The staff member relays the chronology of events as they saw them.

Identify care delivery problems

- The LP team member explains the concept of CDPs and provides examples.
- Staff member is asked to identify the main CDPs as they see them, identifying all acts or omissions made by staff, or other breakdowns in the clinical process. This includes any major departures from guidelines or policies.

Identify the contributory factors

- LP team member explains the concept of contributory factors to interviewee
- Prompts are used to systematically explore contributory factors for each CDP identified. For example, if the person identifies a failure in the routine observation of a disturbed patient. The interview can prompt the staff member by asking in turn about the relevance of patient factors, the clarity of the task, individual staff factors, team factors and so on. If necessary the LP team member posse specific questions, again following the general framework. Was the ward particularly busy or short staffed? Were the staff involved sufficiently trained and experienced?
- Where a member of staff identifies a clearly important contributory factor the LP team member asks a follow-up question. For example, was this factor specific to this occasion or would you regard this as a more general problem on the unit?

Close interview

- The interview is closed with an expression of thanks. 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 LP 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 LP team.

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

- Always have at least two LP 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 LP 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: Confirm incident chronology

The team review and confirm the sequence of with any additional information obtained from interviews. They map the simple flow diagram on a table, to which CDPs and contributory factors can be added in the next steps of the LP review process

Instructions

I. Team provide feedback on outcomes of interviews
II. The team review the initial flow diagram with consideration given to information gathered.
III. Amendments are made if required and incident chronology is finalised

Section two: Why did it happen?

For an LP team to understand why and incident happened they:

Step 5: Identify any factors that caused or contributed to the incident

Step 6: Write up factors linking them to outcomes

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

Step 8: Write Findings Report

Step 5: Identify any factors that caused or contributed to the incident

The team identify the contributory factors associated with each of the CDP's using the table below as a guide and as a way of reflecting on the many factors that may affect the clinical process. If there are a large number of CDPs, the team prioritises a smaller number of the ones that have the greatest bearing on the outcome.

Factor types	Contributory factor
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors
Task and technology factors	Task design and clarify of structure Availability and use of protocols Availability and accuracy of test results Decision-making aids
Individual (staff) factors	Knowledge and skills Competence Physical and mental health
Team Factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership, etc)
Work Environmental Factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support Environment Physical
Organisational & Management Factors	Financial resources & constraints Organisational structure Policy, standards and goals Safety culture and priorities
Institutional Context Factors	Economic and regulatory context National health service executive Links with external organisations

Each CDP may be associated with several factors at different levels of the framework (e.g. poor motivation *Individual*, lack of supervision *Team,* inadequate training policy *Organisation and Management).*

Instructions

I. The team review each CDP separately and identify / brainstorm contributory factors outlined in the table above. Information from staff interviews is used to inform this process

II. The identified contributory factors are documented in the Chronological Mapping of CDPs and Associated Contributory Factors table

Some teams may choose to use a fishbone diagram to explore the contributory factors. One fishbone diagram is needed for each CPD. This step is not mandatory however LP teams have reported that this is a useful tool. Instructions are listed separately

Chronological Mapping of CDPs and Associated Contributory Factors

Chronology						
	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
Care delivery problems	Incomplete assessment	Interrupted assessment as Registrar called away to another patient	Registrar assumed by telling RN that ECG was required it would be ordered	-Registrar reviewed another patients ECG & advised JMO to discharge with GP follow up -JMO did not check patients results	-Patient was discharged with undiagnosed myocardial ischemia	
Contributory Factors	-Short staffing in ED led to junior nurse triaging patient -Absence of chest pain pathway/protocol	-Staff shortages in ED -High level of activity	-Lack of standardised process for test ordering	- Lack of standardised process for results management - Absence of supervision of JMOs	-Lack of staff training in management of atypical chest pain.	
Recommendations	-Review rostering process to ensure adequate skill mix at all times -Introduce chest pain pathway	-Review rostering practices to allow for high fluctuations in activity	- Develop process for test ordering	- Develop process for test ordering -Introduce clinical supervision for junior staff	-Staff education in management of atypical chest pain -Introduce chest pain pathway	

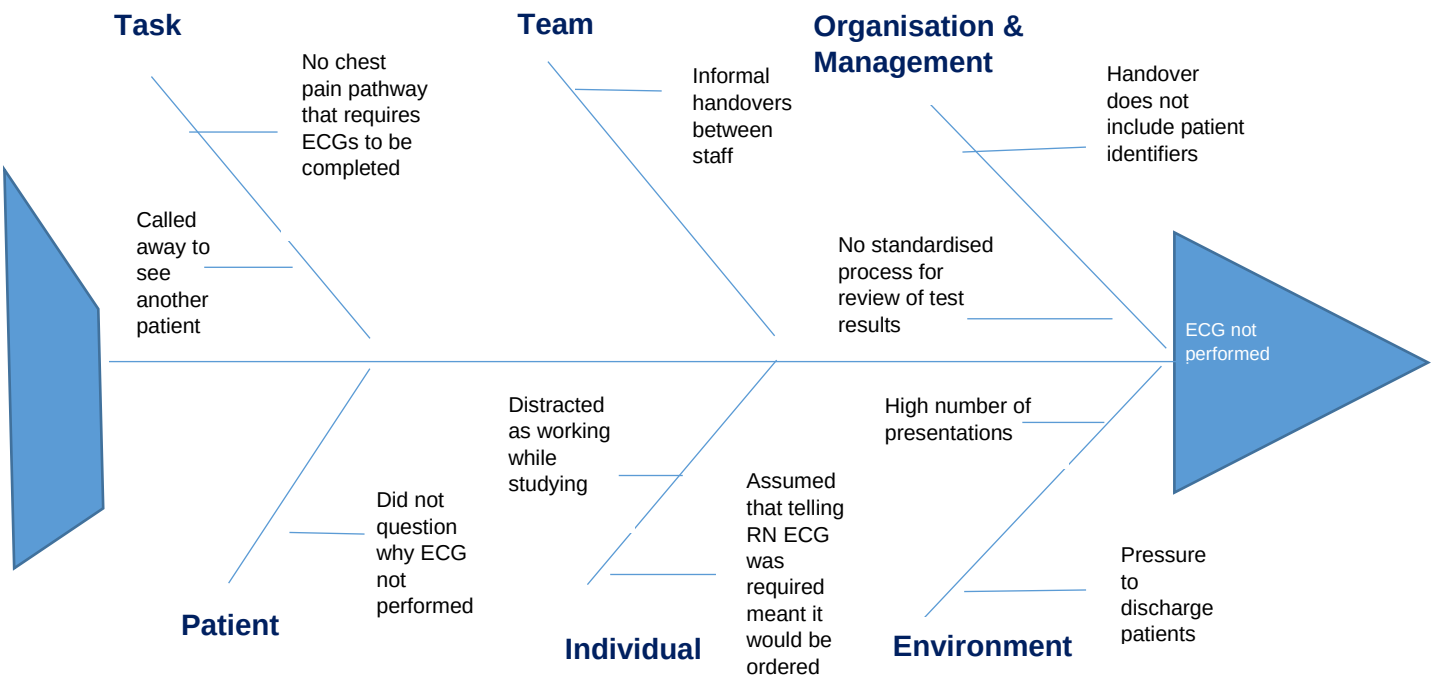
Using fishbone diagrams to explore contributory factors – optional step

A fishbone diagram provides a visual representation of all of the contributing factors to a CDP. It is constructed by a team using a collaborative approach.

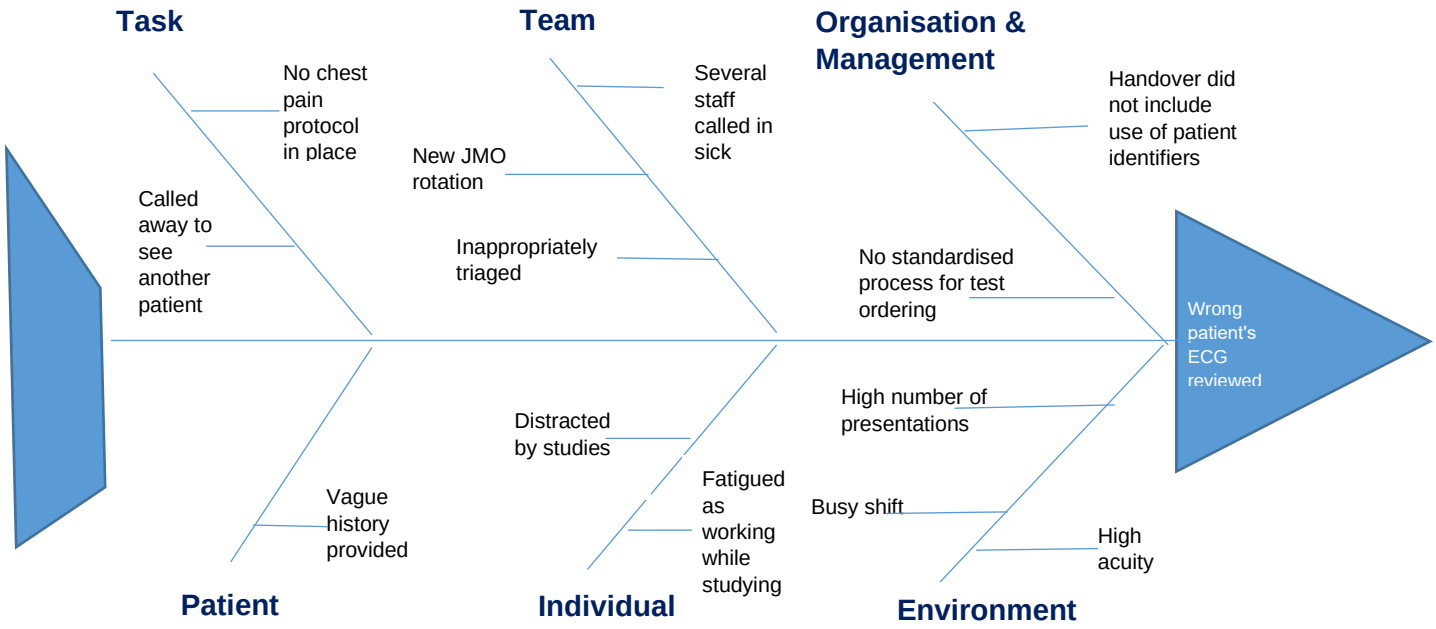
Instructions

I. As individuals, the team brainstorm all of the factors they believe contributed to the CPD in silence. One idea per post it note.
II. On completion of brainstorming the team group the post it notes under the headings of the contributing factor types. The ideas listed on the post it notes become the sub-categories
III. The team repeat the process described to review each CPD separately

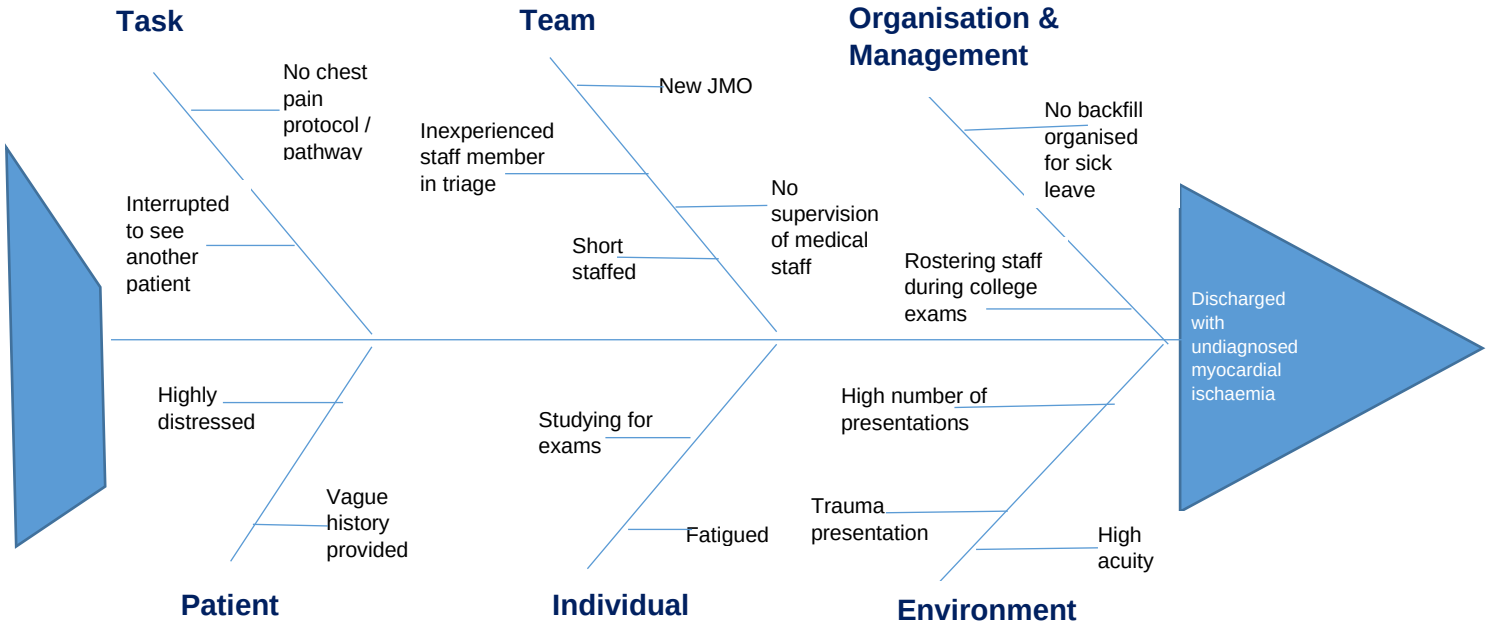
Example Fishbone diagram of CDP "ECG not performed" and contributory factors



Example Fishbone diagram of CDP “Wrong patient’s ECG reviewed” and contributory factors



Example Fishbone diagram of CDP Discharged with undiagnosed myocardial ischaema and contributory factors



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 LP. 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

#	Causation statements
	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 contributory factors

II. Prioritise the order of potential impact i.e. be.g.in 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

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 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 LP 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 Report to the CE or nominated officer for approval

The findings of the LP 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 website.

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 LP 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 implemented. SAER 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

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.

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

Action hierarchy levels and examples adapted from National Patient Safety Foundation[2].

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 images are review after hours and at weekends.	A	Audit of medical handover checklists show 95% use-compliance Audit conducted 3 monthly for 1 week.	November 2020	Patient Safety and Clinical Quality	Cardiology Head of Department
2	Develop a process to ensure that all patients who 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 www.safetyandquality.gov.au/our-work/indicators/australian-sentinel-events-list
Care delivery problems (CDPs)	Problems that arise in the process of care, usually actions or omissions by staff. The two essential features are: 1. Care deviated beyond safe limits of practice 2. The deviation had at least a potential direct or indirect effect on the adverse outcome for the patient, member of staff or general public
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."
Fishbone diagram	A representation of a CDP and the factors that caused or contributed to the outcome. It assists in analysing the relationships between an CDP and its causes.
Contributory factor	The influencing and causal factors that contributed to a CDP
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. Taylor-Adams S & Vincent C 2004. *Systems analysis of clinical incidents: The London Protocol.* https://www.imperial.ac.uk/patient-safety-translational-research-centre/education/training-materials-for-use-in-research-and-clinical-practice/the-london-protocol/

2. 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