



Clinical Incident Management Toolkit

Department of Health 2011

Acknowledgements

The Patient Safety Directorate (PSD) acknowledges and appreciates the input of all individuals and groups who have contributed to the development of this policy toolkit.

In particular, the PSD would like to recognise the valuable contribution made by members of the **South Metropolitan Area Health Service Safety, Quality and Performance Unit** who developed section four of this document: Major Clinical Incident Investigation Processes/Tools.

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1.0 Introduction and background

The purpose of the Clinical Incident Management (CIM) Toolkit is to assist WA Health staff in undertaking the management of clinical incidents as defined by the CIM Policy. Specifically, this toolkit aims to provide practical advice and resources for clinicians and managers to understand, undertake and utilise health data to improve the safety and quality of health care delivery. This toolkit is available electronically to enable access to templates at:

<http://www.safetyandquality.health.wa.gov.au>

To provide some background, the CIM Policy was developed to ensure appropriate management of clinical incidents to prevent or reduce future harm to patients/consumers by:

- identifying and treating hazards before they cause harm
- identifying when patients are harmed and promptly intervening to minimise the harm
- taking preventative actions and sharing lessons learned.

A **clinical incident** is an event or circumstance resulting from health care which could have, or did, lead to unintended and/or unnecessary harm to a patient/ consumer.

Clinical incidents include:

- **Near miss** – an incident that may have, but did not cause harm, either by chance or through timely intervention.¹
- **Adverse event** – an injury caused by medical management or complication thereof, instead of the underlying disease. It results in an increase in the level of care and/or prolonged hospitalisation and/or disability at the time of discharge. ¹ Medical management refers to management under health care services.
- **Sentinel event** – refers to unexpected occurrences involving death or serious physical or psychological injury or risk thereof.¹

There are eight nationally endorsed sentinel event categories. Preventable deaths identified via mortality review processes are to be notified as a sentinel event as per the WA Review of Mortality Policy available via: <http://www.safetyandquality.health.wa.gov.au>.

The above mentioned incidents are further categorised using the following Severity Assessment Code (SAC) ratings, to determine the appropriate level of analysis, action and escalation:

- **SAC 1** includes all clinical incidents/near misses where serious harm or death is/could be specifically caused by health care rather than the patient's underlying condition or illness.
- **SAC 2** includes all clinical incidents/near misses where moderate harm is/could be specifically caused by health care rather than the patient's underlying condition or illness.
- **SAC 3** includes all clinical incidents/near misses where minimal or no harm is/could be specifically caused by health care rather than the patient's underlying condition or illness.²

The key steps to effective clinical incident management are:

- identification of a clinical incident and immediate action to reduce risk to the patient/ consumer
- notification
- prioritisation of investigation
- analysis and investigation
- development of recommendations
- reporting of investigation outcomes
- feedback
- implementation of recommendations
- monitoring of recommendations
- evaluation of recommendations.

2. Managing a clinical incident

All clinical incidents involving patients receiving health care from a WA hospital/health service should be reported and managed in keeping with the CIM Policy (2011) regardless of the setting where the incident occurred.

The CIM Toolkit provides detailed guidelines and tools to assist in the analysis and investigation of clinical incidents and should be used in conjunction with the CIM Policy (2011) available via: <http://www.safetyandquality.health.wa.gov.au>

2.1 Figure 1 – Overview of key steps to managing a clinical incident

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Initial Response	Notification	Investigation	Recommendation	Reporting	System Change
Identification of a clinical incident.	Commence AIMS notification.	All clinical incidents notified via AIMS require a review by the Line Manager to determine the level of investigation required.	Develop recommendations that address the causative factors and lead to system improvement.	SAC 1 incident investigation outcomes: Following endorsement of the final investigation report (including recommendations) forward the report to: PSD Office of the Chief Psychiatrist for mental health events AHS Safety and Quality Performance team within 45 days of the events notification. Refer to the CIM policy for other reporting requirements.	Approved recommendations arising from clinical investigations are to be implemented within 12 months.
Immediate action to reduce the risk to the patient/ consumer.			Recommendations are to be assigned to a particular position for implementation.		PSD request information from hospitals/health services on a 12 monthly basis on the status of the implementation of recommendations for SAC 1 events.
Make the surroundings safe to prevent immediate recurrence of the incident.	Notify relevant health service executive and AHS Safety and Quality Performance team of SAC 1 (sentinel events), and incidents that may have legal, media or political implications, as per local hospital/health service guidelines.	Request hospital/ health service executive approval for the investigation to occur and for the appointment of the investigation team, in accordance with local hospital/health service guidelines. Decide if the clinical investigation is going to be undertaken with or without qualified privilege.	Recommendations must have a specified time frame for implementation.		
Remove malfunctioning equipment or supplies.			Final recommendations require endorsement by the hospital/health service Chief Executive or delegate.	SAC 2 incident investigation outcomes: All SAC level 2 clinical incidents require completion of a report to their hospital/health service within 60 days of the clinical incident notification.	For SAC 2 and SAC 3 events the responsibility for monitoring the implementation of recommendations is managed at a hospital/health service level.
Gather basic information about a chain of events and record facts in the patient health record.	Notify the Office of the Chief Psychiatrist of unexpected deaths or serious incidents involving mental health patients.	Conduct investigation using tools and techniques appropriate to the nature and severity of the incident.		SAC 3 level clinical incidents require the completion of a report to their hospital/health service within 60 days of the clinical incident notification.	When recommendations have been imbedded within the system, hospital/health services are to evaluate the effectiveness of these system improvements and share lessons learned.
Notify a medical officer if the patient/ visitor has suffered harm or injury as a result of the clinical incident.	Notify the Director Patient Safety Directorate (PSD) of SAC 1 (sentinel events) within 7 working days of the events by completing a SAC 1 Form.	Where one or more health services are associated with the care of the patient/ clinical incident, all organisations are to be consulted and represented regarding investigation plans.			
Commence the Open Disclosure Process.					

2.2 Detailed steps in managing a clinical incident

A clinical incident may be identified/reported by a patient/consumer, visitor or any WA Health employee. It is important for all staff to recognise when a clinical incident has occurred.

2.2.1 Immediate action

When a clinical incident is identified **immediate action** is necessary to reduce risk to the patient/consumer. This action may include:

- providing immediate care to the patient/consumer involved in the incident
- making the surroundings safe to prevent immediate recurrence of the incident
- removing malfunctioning equipment or supplies
- gathering essential information about a chain of events.

A medical officer must be notified if a person suffers any harm or injury as a result of a clinical incident.

2.2.2 Notification and initial review of a clinical incident

Notification of a clinical incident is made via a hard copy clinical incident form (refer to your line manager for this form). However, WA Health is currently working toward implementing an electronic notification system. An additional notification step occurs if the clinical incident is a SAC 1 clinical incident (see Table 1).

Notification of a clinical incident involves:

1. Completing the notification form and submitting it, preferably by the end of the work day. However, if adverse publicity is likely notify management immediately.
2. Providing detailed information that will assist with further review and management of the incident.
3. Documenting in the patient/consumer health record only clinically relevant information.
4. The line manager/delegated authority will review all clinical incidents to determine the level of investigation required.

2.2.3 Prioritisation of investigation using the severity assessment codes

Before an investigation of the clinical incident can take place a severity assessment rating must be decided which will determine the prioritisation of the clinical incident investigation (see Table 1 for further details).

Table 1: WA Health Severity Assessment Codes (SAC) to be used by Public Hospitals and Health Services

	SAC 1	SAC 2	SAC 3
Actual/potential consequence to patient/consumer	Serious harm or death that is/could be specifically caused by health care rather than the patient's underlying condition or illness.	Moderate harm that is/could be specifically caused by health care rather than the patient's underlying condition or illness.	Minor or no harm that is/ could be specifically caused by health care rather than the patient's underlying condition or illness.
Type of event/incident	<p>A SAC 1 clinical incident includes:</p> <ul style="list-style-type: none"> National Sentinel Event Categories (see categories 1-8 below) Any other clinical incident which results in serious harm or death of a patient/consumer Increased length of stay greater than 7 days Near miss that could have resulted in serious harm or death. <ol style="list-style-type: none"> Procedure involving the wrong patient or body part resulting in death or major permanent loss of function. Suicide of a patient in an inpatient unit. Retained instruments or other material after surgery requiring re-operation or further surgical procedure. Intravascular gas embolism resulting in death or neurological damage. 	<p>A SAC 2 clinical incidents includes, but is not limited to, the following:</p> <ul style="list-style-type: none"> Increased length of stay (More than 72 hours to 7 days) Additional investigations performed Referral to another clinician Surgical intervention Medical intervention Near miss that could have resulted in moderate harm. 	<p>A SAC 3 clinical incidents includes, but is not limited to, the following:</p> <ul style="list-style-type: none"> No harm Only first aid treatment required Minor harm resulting in increased length of stay of up to 72 hours Near miss that could have resulted in minor harm.
Action required	<ul style="list-style-type: none"> Complete and submit a notification via AIMS or equivalent. Complete and submit a SAC 1 notification form to PSD (and the Office of the Chief Psychiatrist (OCP) for mental health patients/consumer) within seven working days and other reporting as required (see section 11 of the CIM Policy). Notify executives as per hospital/health service guidelines and Area Health Service Safety, Quality and Performance team. Initiate a formal Open Disclosure Process. Undertake SAC 1 investigation by Root Cause Analysis or equivalent. 	<ul style="list-style-type: none"> Complete and submit a notification via AIMS. Notify Unit Manager/Director within 24 hours. Investigate at a local level an incident using clinical review as a minimum requirement. 	<ul style="list-style-type: none"> Complete and submit a notification via AIMS. Notify Unit Manager within 24 hours. Investigate at a local level an incident using aggregated analysis or similar tools.
Reporting requirements	<ul style="list-style-type: none"> Completed investigation report is to be sent to the PSD Director, OCP (for mental health patients/consumers) and Area Health Service Safety, Quality and Performance team within 45 working days of notification. Refer to section 11 of the CIM Policy for other reporting requirements. 	<ul style="list-style-type: none"> Completed report to be sent to the hospital/health care service within 60 working days of incident notification. 	<ul style="list-style-type: none"> Completed report to be sent to the hospital/health care service within 60 working days of incident notification.
Recommendations Implemented:	Within 12 months of the reporting date.		

2.2.4 Understanding SAC 1 clinical incidents – sentinel events

Sentinel events refers to unexpected occurrences involving death or serious physical or psychological injury or risk thereof.¹ Sentinel events are events involving serious patient harm or death that are specifically caused by healthcare rather than the patient's underlying condition/illness.

In April 2004, Australian Health Ministers endorsed a set of eight core sentinel event categories that are reportable nationally (see Table 2). Hospitals/health services and privately licensed healthcare facilities in Western Australia are required to report the sentinel events outlined in Table 2. Notification of sentinel events is mandatory and requires the completion of a SAC 1 clinical incident notification form (see Appendix A).

Sentinel events often signal serious breakdowns in health care systems and require thorough investigation and response. The investigation of a sentinel event should involve a comprehensive and systematic analysis of the facts to identify contributing factors. Hospitals/health services are required to investigate sentinel events via Root Cause Analysis or via an appropriate standard for the investigation of high and extreme risk clinical incidents and submit the final report using the SAC 1 clinical incident investigation report template (see Appendix B).

WA Health publishes aggregated sentinel event data annually via the WA Sentinel Event Report and at a national level via the Australian Government Productivity Commission's Report on Government Services (ROGS) and the Australian Commission on Safety and Quality in Healthcare's annual Windows into Safety and Quality in Healthcare report.

2.2.5 Investigation of all SAC 1 clinical incidents for both public and private hospitals and non-government organisations

1. All SAC 1 clinical incidents (including sentinel events) require mandatory Root Cause Analysis investigation (or similar investigative methodology).

The notification of SAC 1 clinical incidents (including sentinel events) is mandatory for all public hospital/health service staff and contracted private licensed healthcare facilities and non government organisations. SAC 1 clinical incident must be notified using the SAC 1 clinical incident notification form (see Appendix A) or on the PSD website:

<http://www.safetyandquality.health.wa.gov.au>

2. All SAC 1 clinical incidents require the initiation of the Open Disclosure Process (in accordance with the WA Open Disclosure Policy), ideally within 24 hours of the clinical incident occurring. <http://www.health.wa.gov.au/circularsnew/attachments/395.pdf>
3. All SAC 1 clinical incidents (including sentinel events) must be reported in accordance with the hospital/health service guidelines and to the PSD, AHS Safety, Quality and Performance team and Office of the Chief Psychiatrist (OCP) (where appropriate) within **seven working days** of the clinical incident occurring (see Table 1 **and** the CIM Policy for other Statutory reporting requirements).
4. On receipt of a SAC 1 clinical incident notification the PSD will provide the notifier with a unique event number and a due date for the final report. Notifiers will be contacted if final reports are outstanding.

5. Following endorsement of the final investigation report (including recommendations) hospitals/health services must submit the report to the Director, PSD and the AHS Safety, Quality and Performance team and the Office of the OCP (where appropriate) within 45 working days of the events notification via SAC1.events@health.wa.gov (see Appendix B for SAC 1 clinical incident and Sentinel Event Investigation Report forms).

For public hospitals and health services, RiskCover is to be notified of all clinical incidents that are, or have the potential to become, actual legal claims against a hospital/health service and/or health practitioner (refer to Legal and Legislative Services/State Solicitor's Office).

Public Hospitals/Health Services and Private Licensed Health Care Facilities/Non Government Organisations are to report on all SAC 1 clinical incidents with **Categories 1-8** referring to **sentinel events** now included as SAC 1 clinical incidents.

Table 2: SAC 1 Clinical Incident Notification List

Category	Clinical incidents (category 1-8) that must be reported as sentinel events
1	Procedures involving the wrong patient or body part resulting in death or major permanent loss of function.
2	Suicide of a patient in an inpatient unit. Mental Health Services are required to report to the Chief Psychiatrist episodes of unexpected death.
3	Retained instruments or other material after surgery requiring re-operation or further surgical procedure. Retention of a foreign object in a patient after surgery or other procedure including surgical instruments or other material such as gauze packs inadvertently left inside the patient when the surgical incision is closed - excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
4	Intravascular gas embolism resulting in death or neurological damage. Death or serious disability associated with intravascular gas embolism that occurs while the patient is being cared for in a facility - excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular gas embolism.
5	Haemolytic blood transfusion reaction resulting from ABO incompatibility.
6	Medication error resulting in death of a patient. Death or serious injury associated with a medication error, including, but not limited to errors involving: <ul style="list-style-type: none"> • the wrong drug • a contaminated drug • the wrong dose • the wrong patient • the wrong time • the wrong rate • the wrong preparation • the wrong route of administration • insufficient surveillance (e.g. blood tests, clinical observation). This category excludes reasonable differences in clinical judgment on drug selection and dose.
7	Maternal death or serious morbidity associated with labour or delivery. Maternal death or serious disability associated with labour or delivery while the patient is being cared for in a facility or by maternity care providers, including events that occur within 42 days post delivery.
8	Infant discharged to wrong family or infant abduction.

Category	Examples of clinical incidents that must be reported as SAC 1
	Other adverse event resulting in serious patient harm or death, includes: * **
	Medication error (not resulting in death)
	Fetal complications: <ul style="list-style-type: none"> • Unrelated to congenital abnormality in an infant having a birth weight greater than 2500 grams causing peri natal death, or serious and/or ongoing peri natal morbidity. • Complications not anticipated yet arose and were not managed in an appropriate or timely manner resulting in death, or serious and/or ongoing morbidity. • Delivery at a site other than where labour commences and which requires transfer to another facility for a higher level of care resulting in death, or serious and/or ongoing morbidity.
	Misdiagnosis and subsequent management
	Delay in recognising / responding to clinical deterioration
	Patient absconding with adverse outcome
	Complications of resuscitation: <ul style="list-style-type: none"> • Events in which staff experienced problems in managing an emergency situation or resuscitation resulting in death, or serious and/or ongoing morbidity. • Failed resuscitation where resuscitation protocols or guidelines could not be followed due to a deficiency of equipment, communication, or staffing resulting in death, or serious and/or ongoing morbidity.
	Complications of anaesthetic management: <ul style="list-style-type: none"> • Unintended intra-operative awareness. • Anaesthetic events resulting in death, or serious and/or ongoing morbidity.
	Complications of surgery
	Complications of an inpatient fall
	Hospital process issues: <ul style="list-style-type: none"> • Events in which hospital processes such as triaging, assessment, planning or delivery of care e.g. miscommunication of test results, response to abnormal test results contributed to death, or serious and/or ongoing morbidity. • Transport or transfer – Events in which delays in transport or transfer contributed to death, or serious and/or ongoing morbidity.
	Infection control breach
	The unexpected death of a mental health patient/consumer
	Absconding of any mental health patient/consumer.

* Note this SAC 1 clinical incident notification list is not exhaustive and if unsure of whether to notify an incident, please contact your line manager or local risk manager or AHS Safety, Quality and Performance team or the PSD for advice.

** To ensure that a comprehensive understanding of SAC 1 clinical incident notification is obtained please read this toolkit in conjunction with the Clinical Incident Management Policy.

2.2.6 Analysis and investigation

All notified clinical incidents require review by the line manager/ delegated authority to determine the level of investigation required and if the investigation is to be undertaken utilising qualified privilege or without qualified privilege (see CIM policy and speak with the Risk Manager/Safety, Quality and Performance team).

The analysis and investigation phase is used to establish the course of events and to identify the contributing factors. SAC 1 clinical incidents require RCA (or similar methodology) to be undertaken. SAC 2 clinical incidents require clinical review or investigation using an appropriate methodology. While SAC 3 clinical incidents require investigation using aggregated analysis or a similar tool.

Consideration should be given to providing patients and their families with the opportunity to contribute information about the clinical incident to assist with the investigation process and the development of patient-centred recommendations.

If during the course of the investigation it is suspected that the clinical incident may contain elements of misconduct, the investigation team should refer the matter to the hospital/ health service Risk Manager, Director of Safety, Quality and Performance, or other relevant senior manager so it can be addressed using the appropriate management and governance processes.

The clinical investigation should continue separately to the misconduct processes unless advised by the hospital/health service Risk Manager/Director of Safety, Quality and Performance, or other relevant senior manager to cease the investigation.

2.2.7 Clinical incidents across health service/provider boundaries

Where one or more health services are involved in the care of a patient associated with a clinical incident, all organisations are to be consulted and are expected to participate in a collaborative investigation plan but please take into consideration the issue of patient confidentiality.

The last hospital/health service providing care (e.g. rural or metropolitan hospital, Mental Health Service, transport providers, Hospital in the Home or Rehabilitation in the Home Programs) will be responsible for initiating the clinical incident review and engaging other organisations involved in the care of the patient in establishing the investigation.

There are a number of investigation options to be considered by multiple hospitals/health services involved in the care of the transferred patient including:

- a) Joint investigation involving all hospitals/health services.
- b) Investigation by the hospital/health service where the clinical incident occurred.
 - Note: The notifying hospital/health service is also required to:
 - clinically review the care of the patient to identify any factors that may have contributed to the patient's outcome
 - provide the transferring hospital with any issues recommended to be taken into consideration as part of their investigation.
- c) External review to obtain expert opinion.

For further advice on the matter of patient confidentiality and the release of patient information for the purposes of clinical incident investigations public hospitals/health services should consult with Legal and Legislative Services/State Solicitor's Office as appropriate.

2.2.8 Reporting

SAC 1 clinical incident investigation outcomes

- Following endorsement of the final investigation report (including recommendations), the signed report is to be forwarded to the Area Health Service (AHS) Safety, Quality and Performance team and the PSD within 45 working days of the incident notification date.

SAC 2 and SAC 3 clinical incident investigation outcomes

- All SAC level 2 & 3 clinical incidents require the completion of a report to be sent to their hospital/health care service within 60 working days of incident notification.

2.2.9 Feedback

Feedback to the patient/consumer and nominated relative/carer is to occur as part of the Open Disclosure Process. Appropriate feedback on notified clinical incidents is to be given by the line manager/delegated authority involved with the incident follow-up. The success of clinical incident management is also dependent on feedback to all staff on the recommendations/outcome of investigations in a timely manner. Lack of feedback from incident reporting has been highlighted as inhibiting the willingness of staff to report incidents.³ See section 5 for models of feedback.

2.2.10 Recommendations

The development of recommendations is a fundamental component in clinical incident management. Recommendations provide the framework for action in improving or preventing adverse events from occurring.

SAC 1 clinical incidents recommendations need to:

- be based on contributing factors aimed at preventing or minimising the occurrence of similar events.
- clearly identify a recommended action.
- include a planned date for completion.
- include an outcome measure to enable improvements to be made.
- identify an individual(s) who will be responsible for the implementation and monitoring of the recommendations.
- have been signed off by the Area Chief Executive or delegate ensuring that the recommendations are actioned and submitted to the PSD and the AHS Safety, Quality and Performance team.

SAC 2 and SAC 3 clinical incidents recommendations need to be developed:

- that follow the same steps as for SAC 1 clinical incidents except for the final report.
- and the final report for SAC 2 & 3 clinical incidents are to be sent to the hospital/healthcare service AHS Safety, Quality and Performance team.

2.2.11 Implementation of recommendations

Recommendations arising from clinical incident investigations are to be implemented within 12 months of the finalised investigation. For all SAC 1 clinical incidents hospitals/health services are required to notify the AHS Safety, Quality and Performance team and the PSD when recommendations have been completed.

2.2.12 Monitoring of recommendations

The PSD will request information from hospitals/health services and private licensed health care facilities and non-government organisations regarding implementation of SAC 1 clinical incident recommendations on a six monthly basis.

For SAC 2 and SAC 3 clinical incidents the responsibility for monitoring the implementation of recommendations is managed at a hospital/health service level.

2.2.13 Evaluation of recommendations

When all recommendations have been implemented and given time to establish (e.g. six months post implementation) the hospital/health service needs to evaluate the effectiveness of the strategies in order to validate that improvements have been made.⁴ This is to ensure that:

- the systemic problems identified have been addressed
- recurrences have been reduced or eliminated
- lessons have been learned and communicated
- identified barriers to change have been removed
- the loop is closed to ensure organisational learning.⁴

Once all recommendations are implemented and evaluated the clinical incident is considered closed.

2.2.14 Transfer of clinical incident forms (AIMS)

If a patient is transferred and a clinical incident is identified by the receiving hospital/health service, then the clinical incident form should be returned to the Safety, Quality and Performance team at the hospital/health service where the incident occurred. Transfer of the clinical incident needs to include an electronic update of the organisation tree and the forwarding of the hard copy clinical incident form.

2.2.15 Retention and disposal clinical incident forms

For hospitals/health services which utilise the Clinical Incident Management System (AIMS) for capturing clinical incidents, a hard copy of the clinical incident, analysis, investigative and recommendation forms must be kept for 7 years. It is permissible to retain scanned copies of the clinical incident analysis, investigative, recommendation forms and destroy the hard copy after six months, please refer to the General Disposal Authority for Source Records available at: http://www.sro.wa.gov.au/pdfs/GDA_SourceRecords.pdf

3. Overview of clinical incident investigation methods and tools

This section outlines several methods which can be used to investigate clinical incidents. The utilisation of a particular method is guided by the CIM policy and to a certain extent the discretion of hospital/health service.

For detailed steps in conducting a clinical incident investigation please go to section 4.

3.1 Root Cause Analysis

Application: Suitable for SAC 1 clinical incident investigations.

Root Cause Analysis (RCA) has been applied to the health care industry and has been found to be a highly effective tool to improve patient care and reduce health care costs resulting from adverse events. RCA is a comprehensive and systematic methodology to identify the gaps in hospital systems and the processes of health care that may not be immediately apparent and which may have contributed to the occurrence of an event.⁵

The goal of a RCA is to find out:

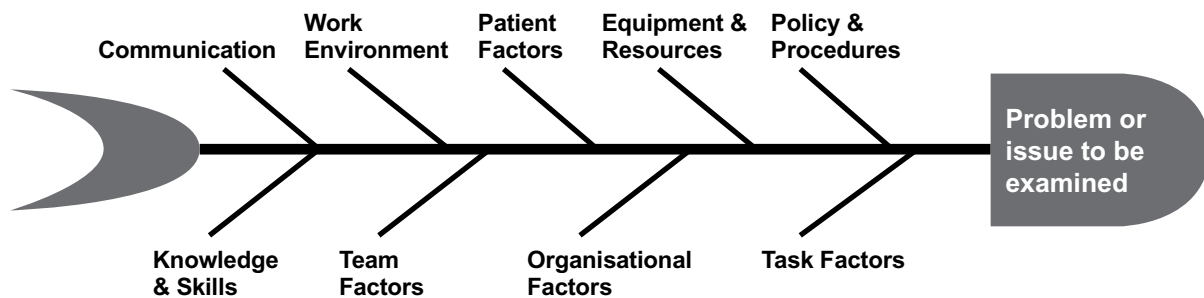
- What happened?
- Why did it happen?
- What can be done to prevent it from happening again?

Effective RCA investigations feature the following characteristics:

- Analysis that focuses on systems and processes, not individual performance or blame.
- Analysis that focuses on both clinical and organisational processes.
- Analysis that repeatedly digs deeper by asking 'why?', then when answered continues to keep asking 'why?' (see section 3.4 Using Five Whys).
- Analysis that identifies changes to be made in systems and processes (redesign or development of new systems/processes) that effectively reduce the recurrence of clinical incidents.
- An investigation team that is multidisciplinary in nature with involvement of those closest to the process. Team members should be familiar with the area in which the incident occurred but not involved in the incident.
- An investigation that is thorough and credible.⁶

The Cause and Effect diagram, sometimes called the Fishbone or Ishikawa diagram can be used as an effective first step in problem solving by generating a comprehensive list of possible causes of the clinical incident. The diagram is an effective tool for organising and categorising elements identified from the clinical incident (i.e. possible causes, solutions or contributing factors).⁴

Figure 2: Cause and Effect Diagram



Via this process, major causes can be identified and point to potential remedial actions. In addition, it may indicate the best potential areas for further exploration and analysis.

At a minimum, preparing a Cause and Effect diagram will lead to greater understanding of the problem and can be used to organise and categorise solutions to the problem.

Three steps to create a Cause and Effect diagram:

1. **Identify the problem statement:** what is the key problem you want to prevent?
2. **Brainstorm the primary causes:** the action and conditions that led to the key problem.
3. **Complete the causal chain:** ask 'why' several times to identify root causes and contributing factors.

“Contributory factors/hazards are the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident. Examples are human factors such as behaviour, performance or communication; system factors such as work environment; and external factors beyond the control of the organisation, such as the natural environment or legislative policy. More than one contributing factor and/or hazard is typically involved in a single patient safety incident.”⁴

Recommendations should directly address the root causes identified via the investigation process. Recommendations must be implementable, specific, measurable and include who will be accountable for the implementation and timelines for completion and evaluation. Implementation of recommendations should effectively prevent recurrence of the clinical incident.⁶ When developing recommendations it is useful to follow the SMART system of goal setting.

Recommendations should be SMART:

Specific: The recommendation must be specific. For example, to reduce pressure ulcer prevalence by 10% within 12 months, on all the orthopaedic wards.

Measureable: The recommendation must be measurable. The abovementioned example is an easily measurable goal as it outlines the issue, establishes a reduction measure of 10%, identifies a target group and provides a timeline.

Accountable: State who will be responsible for implementing and evaluating this recommendation.

Realistic: Recommendations needs to be realistic to ensure that the outcome goal can be achieved. For example, to reduce pressure ulcers for patients who are at high risk, we need to purchase four dynamic air flow system mattresses over the next two years.

Time related: It is imperative to state a deadline in which the goal will be achieved.

Recommendations made from a RCA are a critical component to ensuring that these types of clinical incidents are prevented or minimised. A Recommendation Hierarchy was developed by the Veterans Affairs National Center for Patient Safety to assist in the development of actions that are more likely to succeed and achieve the desired outcomes (see Table 3). Recommendations fall into three categories – strong, intermediate and weak actions.⁶

Table 3: Recommendations Hierarchy

Stronger actions	Intermediate actions	Weaker actions
<ul style="list-style-type: none"> • Remove a physical barrier that is preventing access • Architectural/physical changes • New device with usability testing before purchasing • Engineering control or interlock (forcing functions) • Simplify process and remove unnecessary steps • Standardise to minimise variation in equipment, process, care pathways, supplies, drugs, and rules • Involvement and leadership in support of patient safety improvement. 	<ul style="list-style-type: none"> • Use checklists, protocols and reminders (cognitive aids) to reduce reliance on memory • Eliminate the use of sound-‘alike or look-alike’ names • Increase in staffing/ decrease in workload • Software enhancements/ modifications • Improved documentation/ communication/handover • Eliminate/reduce distractions. 	<ul style="list-style-type: none"> • A new policy or procedure or guideline • Staff training and education • Additional study and analysis • Double checks • Warnings and labels.

RCA investigation report

To report the findings arising from an RCA investigation see Appendix B: SAC 1 Clinical Incident Final Investigation Report template.

3.2 London Protocol

The London Protocol outlines a process whereby clinical incidents can be investigated and analysed. The protocol ensures that comprehensive interviews and a framework of contributory factors are used for investigation, analysis and recommendation development.

This structured process involves the utilisation of both clinical experience and expertise by enabling:

- closer analysis of the incident to reveal the events leading to the adverse outcome, with data obtained from staff interviews
- any obvious departure from good practice to be highlighted
- a consistent approach to be utilised
- a greater openness and transparency.⁷

To use this protocol please refer to an article by Taylor-Adams S., Vincent C. System analysis of clinical incidents: the London Protocol located at the safety and quality website.⁷

3.3 Human Error and Patient Safety (HEAPS) incident analysis tool

The HEAPS incident analysis tool is subject to licensing agreements with the developer ErroMed.⁸ This is a tool that **can only be** used in hospitals/health services that have a **license to utilise it** so check with your Safety, Quality and Performance team.

Essentially the HEAPS incident analysis tool utilises a proactive approach to identifying and learning from errors to improve patient safety. The tool is used to identify patient factors, task factors, practitioner factors, team factors, workplace factors and organisational factors. Utilisation of this tool requires training so please consult with your Safety, Quality and Performance team.

3.4 Five Whys

The Five Whys⁹ originated within Toyota and formed a critical component of their problem solving methodology. Repeatedly asking the question “why?” allows for the layers of an issue to be examined leading to the root cause of a problem. The Five Whys can be used independently or as part of a Root Cause Analysis when developing a cause and effect diagram.

The Five Whys assists investigation teams to drill down and explore all potential or real causes which contributed to a clinical incident, in turn identifying the root causes.

3.5 Health Record Review

Problems with communication, and in particular documentation, are widely recognised as major contributing factors in the occurrence of sub-optimal patient outcomes. It is in the best interest of every patient and provider that the health record contains complete and accurate documentation of each episode of care. Review of a health record needs to be comprehensive and systematic to ensure that all relevant information is gathered.

3.6 Failure Modes and Effects Analysis (FMEA)

This tool is based on the Institute for Healthcare Improvement Failure Modes and Effects Analysis method¹⁰ and is a systematic approach to identifying which parts of a process are most in need of improvement. It includes some elements of “process mapping” and “gap analysis”.

3.7 Clinical risk management

The *Clinical Risk Management Guidelines for Western Australian Health Services* has been broken down into five easy to follow steps.¹¹

1. Establish the context
2. Identify the risks
3. Analyse the risks
4. Evaluate the risks
5. Treat the risks.

Each of the five steps have been detailed with reference to the Australian/New Zealand Standard *AS/NZS ISO 31000:2009 Risk Management – Principles and guidelines*¹² and the *Clinical Risk Management Guidelines*.¹¹ Strategies and questions have been provided, where appropriate, to guide their application to clinical risk management.

4. Major clinical incident investigation process and tools

While the previous section explains the methodologies that can be used to investigate clinical incidents, this section of the Toolkit provides a step by step guide to undertaking the investigation of a major clinical incident e.g. SAC 1 & 2 clinical incidents. It outlines every step from gaining authorisation to undertake an investigation through to developing relevant recommendations. All templates are available at: <http://www.safetyandquality.health.wa.gov.au>

For those clinical incidents that are less serious (SAC 3), simply choose the most appropriate method/tool to assist in the investigation of the clinical incident e.g. clinical review or aggregated analysis etc.

Step 1 Gain Approval for Investigation

Approval for the proposed investigation is required from the site/service Executive to ensure senior managers:

- are aware of and endorse the investigation team and approach
- have decided if the investigation is to be undertaken utilising qualified privilege or without qualified privilege
- are committed to providing resources required for the investigation
- are committed to consideration of the investigation recommendations.

When approving the investigation, the site/service **executive should appoint the investigation team coordinator and investigation team members.**

The investigation team coordinator must have attended training in Systems Analysis, Root Cause Analysis or similar methodology. The team coordinator is responsible for:

- facilitating the investigation process
- arranging team meetings
- ensuring all documentation is completed and retained in a secure location
- ensuring the investigation is completed within the required time period (where possible)
- providing the final report to the site / service Executive by the required date.

Investigation teams may consist of:

- staff with expertise in the clinical specialties involved in the event
- staff involved in the patient's care at the time of the incident
- staff familiar with the area in which the incident occurred
- staff from a range of different professions
- a person from outside the site/service who has expertise in a relevant clinical area, health service management or in clinical investigation methodology
- staff from the transferring hospital, where patients were transferred from one hospital to another,
- staff from the relevant community setting/s, where patients were receiving ongoing care in a community setting (e.g. outpatient services, post discharge services)
- a consumer representative.

Check Point!

Before moving to the next step, as the appointed investigation coordinator, have you:

ensured the approval is documented?

confirmed if the investigation is being performed with qualified privilege or without qualified privilege?

established a team that has an appropriate balance for the circumstances?

Step 2 Gather Information

Documentation and material related to the incident should be collected as soon as possible to:

- make sure the information is available for use in the investigation
- allow development of a description of the sequence of events leading up to the incident.

Information that may be relevant includes:

- patient health records from all service providers involved
- relevant policies and procedures
- relevant physical evidence (packaging, equipment)
- observations and comments from staff involved
- comments and information from the patient and family members as appropriate
- information about the environment and conditions (e.g. staff roster).

Information collected should be organised and logged for ease of future reference. **A sample information log is provided in section 4.1.1.**

Obtaining observations and comments from staff should focus on gaining information about their recollection of:

- the sequence and timing of events
- their involvement
- any difficulties or problems they experienced or observed.

The investigation team will determine who needs to be interviewed and conduct the interviews.

Interview Guidelines (see section 4.1.2):

- At the time an interview is arranged, interviewees should be given a clear explanation of the topic and purpose of the discussion, how the information will be used and if using qualified privilege explain any constraints, including protection from discovery.
- Interviewees should be offered the opportunity to bring a colleague with them. The above information should be explained to anyone participating in the discussion.
- Interviews should be held in a private place without interruptions.

Interview Guidelines:

- It may be helpful to have two interviewers so one is able to record comments whilst the other maintains the dialogue.
- Observations and comments should be recorded legibly and accurately (objective rather than subjective note taking). Information collected in interviews may only be used to inform the clinical incident investigation and any interview notes must be kept in locked storage facilities.
- Interviews should be held in a supportive and understanding spirit.
- If it becomes clear that a professional shortcoming or error has occurred this should be discussed without judgment or adverse comment. Staff should be offered ongoing support and counselling if they become distressed about possible errors made by them.

Information sheets for interviewers and interviewees are provided in this toolkit.

Check Point!

Before moving to the next step, have you:

- gathered all relevant documentation?
- identified and interviewed relevant staff?
- provided all relevant information to team members for review?

Step 3 Determine the Sequence of Events

The investigation team develops a chronology of events based on all information gathered. The chronology may be documented using the template (see section 4.1.3) provided for:

- a flow chart; and/or
- a narrative of steps.

Check Point!

Before moving to the next step, have you:

- reviewed the information gathered and documented the sequence of events?
- gained agreement from all RCA team members regarding the sequence of events?

Step 4 Determine Contributory Factors

The investigation team identifies the actions that directly preceded the adverse event (e.g. picking up the wrong syringe, failing to observe, wrong medication given). The conditions or circumstances that allowed those actions to occur are then identified. These conditions and circumstances are referred to as contributory factors.

To assist in identifying contributory factors the investigation team may compare what actually happened with what should have happened. Reference to policies and procedures and a review of current literature may assist in this analysis. The steps that actually happened and the steps that should have happened may be documented in different colours on the flow chart or narrative of steps to highlight gaps.

Some investigations may identify gaps or issues that did not impact on the specific event under consideration but have the potential to contribute to adverse events in the future. These should be recorded at the bottom of the flow chart and be considered in the development of recommendations.

Contributory factors may include:

- human factors - communication between staff and with the patient
- human factors - knowledge skills and competence of staff
- environment - work conditions and scheduling
- patient factors
- equipment and technology
- policies, procedures and guidelines
- safety mechanisms.

A checklist of contributory factors to be considered is provided in this toolkit.

Some contributory factors are likely to be present in future situations (e.g. medication labels of similar colour and design) and some are likely to have been specific to the event under investigation (e.g. a one off communication problem between staff). Contributory Factors likely to be present in future situations are recorded on a contributory factors statement (**template provided in section 4.1.4**). Contributory factor statements need to focus on process and system vulnerability rather than the action of individuals. Contributory statements will be most helpful if they are developed using the following rules.¹³

Examples of contributory factors

1. Show the link between the contributory factor and the outcome.

Example:

✗ A doctor was fatigued.

✓ The level of fatigue experienced by the doctor increased the likelihood that he/she missed the instructions which led to incorrect insertion.

2. Use specific and accurate descriptors of what occurred. Avoid negative and vague descriptors such as “poorly, inadequately, carelessness”. These do little to describe the actual conditions or behaviors that lead to an event.

Example:

✗ Poorly trained nurse.

✓ The level of the nurse’s training increased the likelihood that he/she misunderstood the IV pump controls which contributed to missing steps in the programming of the dose and rate.

3. Identify factors that preceded the human error.

Example:

✗ The doctor did not review the discharge summary.

✓ The level of staffing meant there were extra demands on the doctor that resulted in the doctor rushing the discharge and the patient being sent home with the wrong discharge summary.

4. Identify factors that preceded a procedural error. The goal is to identify the positive and negative incentives that created the informal ‘norm’ or accepted way of doing things.

Example:

✗ The pharmacy technician did not follow the correct dispensing procedure.

✓ Due to staffing shortages, routine checking by two persons was bypassed resulting in the incorrect dispensing of medications.

5. Include failure to act as a contributory factor only if there is a pre-existing duty to act. Such a duty may arise from practice standards and guidelines or other duties to provide patient care.

Example:

✓ Failure to prescribe a cardiac medication after a myocardial infarction can only be used if the medication was required as part of an agreed guideline.

Check Point!**Before moving to the next step, have you:**

- convened the team meeting to identify contributory factors?
- reviewed relevant policies and procedures?
- reviewed relevant literature?
- identified contributory factors likely to be present in future situations?
- completed a contributory factors statement?

Step 5 Develop Recommendations

Recommendations are developed for actions to address contributory factors (see summary template in section 4.1.5). Recommendations should aim to prevent or minimise future adverse events or near miss incidents.

Recommendations may be considered **strong**⁶ if they are highly likely to reduce risk by making it very easy for staff to do the right thing. Strong recommendations include those that:

- Introduce a forcing function (e.g. a unique connector to allow only correct assembly of equipment).
- Remove the opportunity to do the wrong thing (e.g. remove all potassium chloride from wards).
- Standardise to reduce confusion (e.g. purchase only one type of IV pump for a hospital).
- Simplify processes (e.g. provide direct contact numbers for high risk patients to access expert advice from home).
- Introduce a physical barrier to prevent harm (e.g. non slip floor coverings, bed rails).
- Remove a hazard (e.g. fix or replace a piece of equipment).

Examples of **intermediate** actions used for the development of recommendations include:

- The use of checklists, protocols and reminders (cognitive aids) to reduce reliance on memory.
- The elimination the use of 'sound-alike or look-alike' names.
- Increase staffing/decrease workload.
- Enhancement/modification of software.
- Improvements in documentation/communication/handover.
- Elimination/reduction in distractions.

Recommendations may be considered **weak** if they are less likely to reduce risk. Weak recommendations include those that:

- Rely on documentation that may be difficult to access or compete with other information (e.g. policies and procedures).
- Rely on training that may take time to provide to all necessary parties and may not be retained fully.

Weak recommendations will be more helpful if they are specific and clear.

Example:

- ✗ *Provide training.*
- ✓ *Implement a training module on medical emergency procedures for all ED staff by dd/mm/yyyy.*

The investigation team should aim to develop strong recommendations wherever possible. If an investigation finds that best possible care has been provided, there may be no recommendations for action. Positions responsible for implementing recommendations should be identified by the investigation team along with proposed implementation time frames. If positions responsible for implementing recommendations are not included, the team coordinator should contact and discuss the proposed recommendation/s with the relevant staff.

Each contributory factor should be risk rated by the investigation team. For each contributory factor the risk rating is calculated by assigning a score from 1 to 5 (**Risk Rating Matrix provided see section 4.1.6**) for the likelihood of the situation/factor occurring again and the severity of the consequences that may result. These scores are then combined to determine the rating of the risk as extreme, high, moderate or low. Recommendations should be recorded in an Investigation Recommendations Summary (**template provided**).

Check Point!

Before moving to the next step, have you:

- convened the investigation team to develop recommendations (where appropriate)?
- ensured the recommendations directly address the root causes?
- identified positions responsible for each recommendation (in consultation with relevant staff)?
- identified proposed time frames for implementation of each recommendation?
- assessed each contributory factor with respect to its risk rating?
- completed an Investigation Recommendations Summary?

Step 6 Report on Investigation

The investigation team provides a report of the investigation to the site/service executive that includes:

- a cover letter (template provided)
- the Investigation Recommendation Summary (prepared in Step 5)
- the SAC 1 Clinical Incident Final Investigation report for the Director, Patient Safety Directorate (for SAC1 clinical incidents only; see Appendix B).

The site/service executive may refer recommendations back to the investigation team for clarification or further discussion before rejecting/approving them and endorsing/assigning responsibility for implementation.

After endorsement by the site/service executive:

- The endorsed report should be sent to the PSD (for SAC 1 clinical incidents) with a copy to the Area Executive Director of Safety, Quality and Performance within 45 working days of initial notification. The report can be submitted by secure fax, email post or courier. An electronic copy of the report template is available from:
<http://www.safetyandquality.health.wa.gov.au>.

Feedback on the recommendations from the investigation should be provided to the staff involved in the incident, staff involved in the investigation; other relevant providers and the patient or family, as allowed. Risks identified from the investigation should be referred to the site/service risk register. A schedule of follow up on the implementation of recommendations should be established.

Check Point!

Before moving to the next step, have you:

Prepared and submitted to the site/service executive:

- a cover letter?
- the Investigation Recommendation Summary?
- the SAC 1 Final Investigation report for the Director, Patient Safety Directorate?

Obtained a copy of endorsed recommendations signed by the site/service executive?

Provided the endorsed report to the Director, Patient Safety Directorate and copied to the Area Executive Director of Safety Quality and Performance?

Provided feedback regarding endorsed recommendations to:

- staff involved in the incident?
- staff involved in the investigation?
- other relevant providers?
- the patient or family?

Referred identified risks to the site / service risk register?

Established a schedule for follow up of implementation of recommendations?

The PSD acts as a central repository of de-identified recommendations arising from the investigations of SAC 1 clinical incidents and where appropriate will disseminate lessons learned to hospitals and health services across the State. If hospitals and health services consider there is an urgent need to alert the whole health sector in WA of a potential risk, they are invited to highlight this when submitting the completed report. A special State-wide alert may then be issued.

Step 7 Monitor Implementation of Recommendations

The implementation of approved recommendations should be monitored by the appropriate site/services clinical governance committee. Staff (positions) assigned responsibility for implementing recommendations should contact their local Safety, Quality and Performance team to verify the frequency of their local reporting requirements. Additionally, a final report should be submitted to the PSD within 12 months of the reporting date.

4.1.2 Major clinical incident investigation – Information sheet for interviewers

Before the Interview:

At the time an interview is arranged, give the interviewee a clear explanation of the topic and purpose of the discussion, how the information will be used and the constraints of qualified privilege (if applicable) including protection from discovery.

Provide the interviewee with the Clinical Incident Investigation Information Sheet for Interviewees.

Offer the interviewee the opportunity to bring a friend or colleague with them. The above information should be explained to anyone participating in the discussion.

Consider arranging for two interviewers to attend so one is able to record comments whilst the other maintains the dialogue.

Organise a private place without interruptions for the interview.

At the Interview:

Interviews should be held in a supportive and understanding spirit. If it becomes clear that a professional shortcoming or error has occurred this should be discussed without judgment or adverse comment. Staff should be offered ongoing support and counselling if they become distressed about possible errors made by them.

Observations and comments should be recorded legibly and accurately (objective rather than subjective note taking).

Explain the purpose of the interview, how the information will be used and the constraints of qualified privilege (if applicable) including protection from discovery.

Ask the interviewee to describe the sequence of events and their role in events.

Ask the interviewee to describe any issues, problems or difficulties they experienced or observed during the sequence of events.

Ask the interviewee to comment on any factors they think contributed to the issues, difficulties or problems identified. If necessary prompt about contributory factors such as:

- communication between staff and with the patient
- knowledge skills and competence of staff
- the environment, work conditions and scheduling
- patient factors
- equipment and technology
- policies, procedures and guidelines
- safety mechanisms.

Ask the interviewee if they have any other comments to make or questions to ask.

Close the interview with thanks.

If during the course of the interview it is suspected that the clinical incident may contain elements of misconduct, the investigation team should refer the matter to the hospital/health service Risk Manager/Director of Safety, Quality and Performance, or other relevant senior manager so it can be addressed using the appropriate management and governance processes.

The clinical investigation should continue separately to the misconduct processes unless advised by the hospital/health service Risk Manager/Director of Safety, Quality and Performance, or other relevant senior manager to cease the investigation.

Major clinical incident investigation: Possible interview prompts

communication between staff and with the patient.

- Was the patient correctly identified?
- Were documents written legibly?
- Did the documentation provide a contemporaneous record of the workup, treatment plan and patient response?
- Was communication between team members clear? Did it cover all the key information?
- Was responsibility for following up outstanding clinical tasks and following up diagnostic tests made explicit?
- Is the local standard of clinical handover adequate to prevent errors of omission or miscommunication of patient information?
- Were test results easy to find?
- Were patient allergies or previous adverse reactions documented and easy to find?
- Were relevant aspects of the patient's history well documented and easy to find?
- If possible and appropriate, were the patient and/or their carer/family members included in discussions?

Knowledge skills and competence of staff.

- Were staff involved in the event properly qualified and trained to perform the tasks required of them?
- Did the staff involved have sufficient experience to undertake the actions/roles they did?
- Was adequate supervision provided for inexperienced staff?
- Were staff involved familiar with the ward/clinic/area?
- If equipment was involved, were staff deemed competent in its proper use?
- Had relevant scenario training been performed regularly?

The environment, work conditions and scheduling.

- Was the environment properly lit?
- Was there an unusual amount of noise or disruption?
- Was there sufficient space (storage, bench space, room to move) to perform the tasks required?
- Were facilities designed to permit adequate access to rooms/corridors/lifts?
- Had a hazard inspection been conducted in the relevant areas in the 3 months prior to the event?
- Were alarm or duress buttons within reach and in working order?
- Were any staff working in excess of their normal rostered hours?
- Were any staff unwell or not able to work at full capacity?
- Were staff numbers less than those rostered or less than those required for the acuity of the clinical area?

Patient factors.

- Did the patient's condition (complexity or acuity) contribute to the event?
- Was the patient able to communicate clearly (e.g. language differences, disability)?
- Did the patient have a medical condition, social circumstance or emotional history that may have contributed to or exacerbated the outcome of the event?
- Were the patient and his/her visitors helpful and cooperative?

Equipment and technology

- Was equipment/technology new? Had staff been deemed competent in its use?
- Was the equipment or technology subject to confusion with similar equipment or technology?
- Was the equipment or technology in good working order?
- Had regular maintenance and recommended repairs been performed by qualified people?
- Was there sufficient access to and availability of equipment to perform the necessary tasks?
- Was there a delay in obtaining equipment or consumables to perform the required tasks?
- Where applicable, were appropriate consumable items used with the equipment?
- Were equipment displays, controls and alarms set within appropriate parameters, working properly and correctly interpreted in a timely manner?

Policies, procedures and guidelines

- Were relevant policies and procedures:
 - clear?
 - easy to understand?
 - easy to access?
 - up to date?
- If policies and procedures were not used, what prevented staff from using them?
- Are staff aware of where to locate both electronic and hard copy policy and procedure documents?

Safety mechanisms

- What handover/review processes or safety checks were in place?
- Were controls and safety mechanisms routinely maintained and checked by designated staff?
- Did controls and safety mechanisms operate as intended? If not why not?
- If existing controls and safety mechanisms had operated correctly would the event have been prevented?
- Had additional or new controls or safety mechanisms been requested prior to the event?

Major clinical incident investigation – Information sheet for interviewees

The (site/service insert name) Executive has requested a comprehensive investigation be undertaken of a recent clinical incident and you have been identified as someone who may be able to add important information and insights about the circumstances and events.

The goal of this investigation is to find out:

- What happened?
- Why it happened?
- What can we do to prevent it from happening again?

This method of investigation is an integral part of our effort to build a culture of safety, and move beyond the tradition of blame by focusing on what happened rather than who was involved. In the clinical investigations, contributory factors are discovered in a process similar to that of diagnosing disease – with the goal in mind of preventing recurrence.

The incident investigation:

- is multidisciplinary, involving experts from frontline services
- involves those who are most familiar with the situation
- continually digs deeper by asking why? why? why?
- identifies changes that need to be made to the systems and processes with which we work
- is as impartial as possible.

Your assistance in meeting with a member of the investigation team would be greatly appreciated.

Who will be involved?

One or two members of the team appointed to investigate this incident will meet with you. If you would like to have a colleague attend as a support for you just let the team member know when the meeting is arranged.

What will be discussed?

You will be asked about:

- Your understanding of the circumstances and sequence of events leading up to the incident.
- Your role in the situation.

You will be asked about:

- Issues, problems or difficulties you observed.
- Please ensure that the information provided is **FACTUAL** and **DOES NOT BLAME** staff associated with the clinical incident.
- Factors that may have contributed to the issues, problems or difficulties observed. These contributory factors may include:
 - communication between staff and with the patient
 - knowledge skills and competence of staff
 - the environment, work conditions and scheduling
 - patient factors
 - equipment and technology
 - policies, procedures and guidelines
 - safety mechanisms
- Any other comments you wish to make.

What will be recorded?

The investigation team members will take informal notes to help them remember pertinent comments for analysis with other information collected in relation to this incident. Your comments **DO NOT** represent a formal statement however may still be subject to access under the *Freedom of Information Act 1992*.

How will the information be used?

Your comments and views will be analysed along with information from other interviews, the patient health record and other relevant documents to help identify the contributory factors most relevant to the incident and actions that are likely to reduce the likelihood of incidents recurring. Your name will not be included in any reports of the investigation.

If you have questions about the incident investigation process, please do not hesitate to contact:

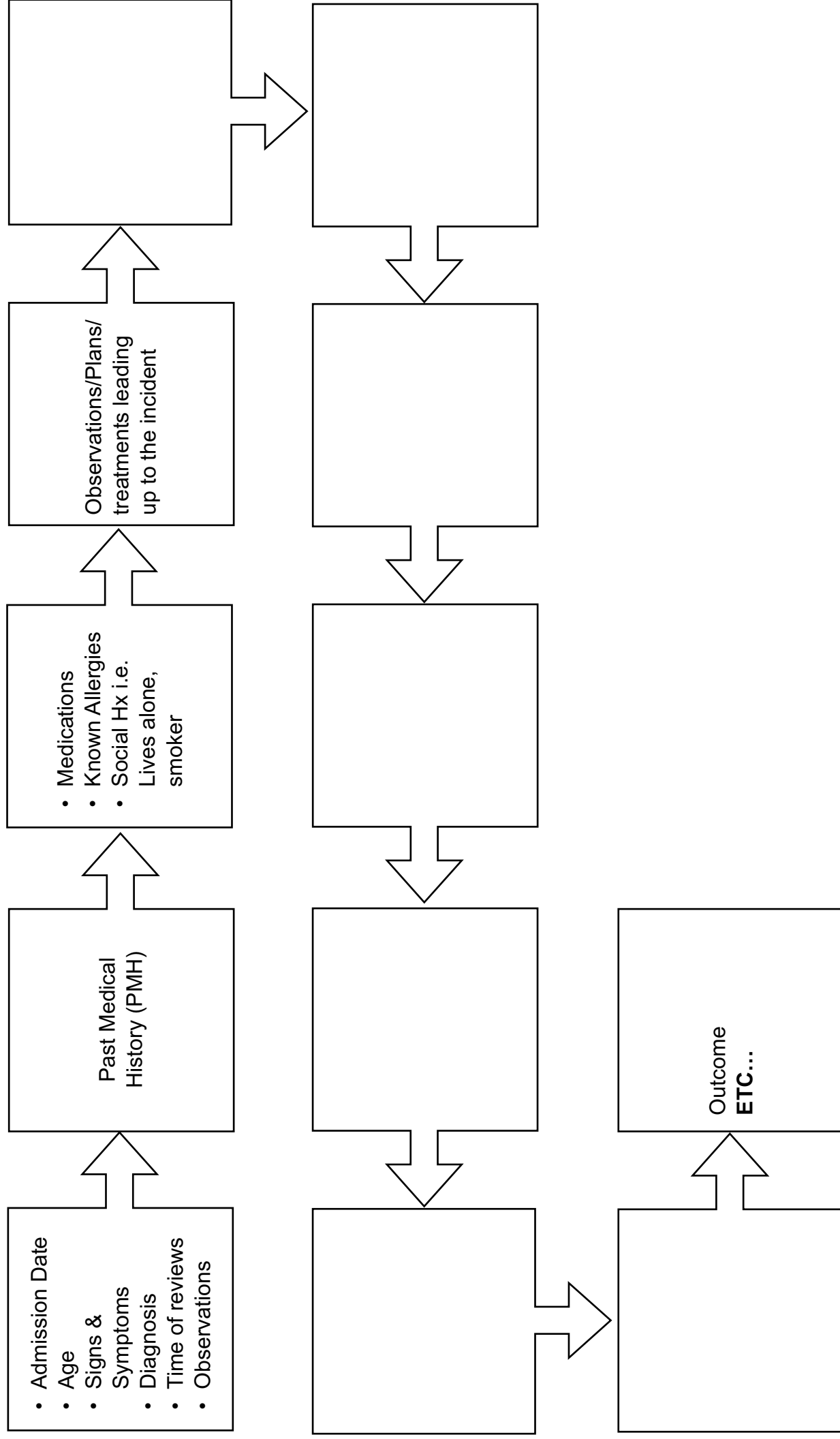
Name:

Position:

Telephone:

Email:

4.1.3 Major clinical incident investigation – Flow chart – The story



4.1.4 Major clinical incident investigation – Contributory factors statement

Use this template to identify any contributory factors that will require further consideration.

Contributory Factor	Category						
	Communication	Knowledge / skills/ competence	Work environment /scheduling	Patient Factors	Equipment	Policies / procedures / guidelines	Safety Mechanisms
1.							
2.							
3.							
4.							
5.							

Other gaps or issues identified but not considered to be contributory factors in this incident:

Contributing factors and root causes

1. Communication			Provide details:
Were issues relating to communication a factor in this event?	Yes	<input type="checkbox"/>	
<i>If yes, tick the appropriate boxes and provide details:</i>	No	<input type="checkbox"/>	
Communication issues between staff		<input type="checkbox"/>	
Communication issues between staff and patient / family / carers		<input type="checkbox"/>	
Documentation		<input type="checkbox"/>	
Patient assessment		<input type="checkbox"/>	
Information not provided		<input type="checkbox"/>	
Misinterpretation of information		<input type="checkbox"/>	
Other		<input type="checkbox"/>	

2. Knowledge / Skills / Competence			Provide details:
Were issues relating to knowledge / skills / competence a factor in this event?	Yes	<input type="checkbox"/>	
<i>If yes, tick the appropriate boxes and provide details:</i>	No	<input type="checkbox"/>	
Staff training / skills		<input type="checkbox"/>	
Staff competency		<input type="checkbox"/>	
Staff supervision		<input type="checkbox"/>	
Use / not using / misuse of equipment		<input type="checkbox"/>	
Other		<input type="checkbox"/>	

3. Work Environment / Scheduling		Provide details:
Were issues relating to work environment / scheduling a factor in this event?	Yes <input type="checkbox"/>	
<i>If yes, tick the appropriate boxes and provide details:</i>	No <input type="checkbox"/>	
Work place design	<input type="checkbox"/>	
Suitability of work environment	<input type="checkbox"/>	
Environmental stressors	<input type="checkbox"/>	
Safety assessments / evaluations / procedures	<input type="checkbox"/>	
Shortage of beds / rooms / resources	<input type="checkbox"/>	
Staff timetabling	<input type="checkbox"/>	
Other	<input type="checkbox"/>	

4. Patient Factors		Provide details:
Were there issues relating to patient factors in this event?	Yes <input type="checkbox"/>	
<i>If yes, tick the appropriate boxes and provide details:</i>	No <input type="checkbox"/>	
Communication difficulties	<input type="checkbox"/>	
Medical history / known risks	<input type="checkbox"/>	
Patient's condition	<input type="checkbox"/>	
Personal issues	<input type="checkbox"/>	
Other	<input type="checkbox"/>	

5. Equipment		Provide details:	
Were issues relating to equipment (including the use or lack of use) a factor in this event?	Yes <input type="checkbox"/>		
<i>If yes, tick the appropriate boxes and provide details:</i>	No <input type="checkbox"/>		
Suitability / availability / lack of equipment	<input type="checkbox"/>		
Safety / maintenance	<input type="checkbox"/>		
Appropriate use of equipment	<input type="checkbox"/>		
Emergency provisions / back-up systems	<input type="checkbox"/>		
Other	<input type="checkbox"/>		

6. Policies, Procedures, Guidelines		Provide details:	
Were issues relating to policies, procedures and guidelines a factor in this event?	Yes <input type="checkbox"/>		
<i>If yes, tick the appropriate boxes and provide details:</i>	No <input type="checkbox"/>		
Absence of relevant, up-to-date policies, procedures or guidelines	<input type="checkbox"/>		
Implementation issues	<input type="checkbox"/>		
Education / training	<input type="checkbox"/>		
Issues in applying policies, procedures or guidelines	<input type="checkbox"/>		
Absence of audit / quality control system	<input type="checkbox"/>		
Other	<input type="checkbox"/>		

7. Safety Mechanisms	Provide details:	
Were issues relating to safety mechanisms a factor in this event? <i>If yes, tick the appropriate boxes and provide details:</i>	Yes <input type="checkbox"/>	
Lack of appropriate safety mechanisms / systems in place	No <input type="checkbox"/>	
Breakdown of safety mechanisms	<input type="checkbox"/>	
No evaluation of safety mechanisms	<input type="checkbox"/>	
Other	<input type="checkbox"/>	

8. Other	Provide details:	
If there were other factors involved in the incident which do not fall into the above categories, please provide details.		

4.1.5 Major clinical incident investigation – Investigation recommendations summary

	Contributory Factor	Recommended Action	Action E = eliminate C = control A = accept	Position Responsible	Outcome measure	Measure Date	Executive Approval Yes/No	Executive Comment (If Not Approved)	Risk Rating
1									
2									
3									
4									
5									

4.1.6 Major clinical incident investigation – Clinical risk rating

Step 1: Having identified the risk, identify the controls in place to prevent an incident and contain its potential consequences. Evaluate their overall adequacy using the table below.

Controls adequacy table

Level	Controls Descriptors	Status Test
E	Excellent	Comprehensive, effective controls fully in place for prevention as well as mitigation of consequences. Control requirements communicated, complied with, maintained, monitored, reviewed and tested regularly. Controls assessed or tested individually and as a system where multiple controls are utilised, to obtain controls self-assurance or independent assurance. All that can be done is being done.
A	Adequate	Sufficient effective controls substantially in place for prevention as well as mitigation of consequences. Control requirements communicated, complied with, with procedures for specific circumstances. Periodic reviews. All that is reasonably practicable to be done is being done.
I	Inadequate	Controls are either non-existent, not practically in place or not effective. Not communicated and/or not complied with. No reviews. Little or nothing is being done.
U	Unknown	Controls and status are unknown.

Step 2: Given those existing controls, identify the worst REALISTIC consequences should an incident occur. Pick the best fit on the 1 to 5 scale from the table below.

Consequences assessment

Level	Consequence Descriptors	Health Impact – Patient Code - HP
1	Insignificant	Increased level of care (minimal). No increase in length of stay. Not disabling.
2	Minor	Increased level of care (minimal). Increased length of stay (up to 72 hours). Recovery without complication or permanent disability.
3	Moderate	Increased level of care (moderate). Extended length of stay (72 hours to one week). Recovery without significant complication or significant permanent disability.
4	Major	Increased level of care (significant). Extended length of stay (greater than one week). Significant complication and/or significant permanent disability. ALL SAC 1 clinical incidents.
5	Catastrophic	Death, permanent total disability. ALL SAC 1 clinical incidents.

Major clinical incident investigation – Clinical risk rating

Step 3: Using your judgement, incident data or other sources, assess the likelihood of an incident occurring and having the consequences you assessed in Step 2 above, bearing in mind the existing controls in place and their effectiveness. Pick the best fit on the 1 to 5 scale from the table below

Level	Likelihood Descriptor	Per Separations/Occasions of Service Likelihood Code C (Clinical)	Frequency
1	Rare	1 in 100,000 or more	Once in more than 10 years
2	Unlikely	1 in 10,000	At least once in 5 to 10 years
3	Possible	1 in 1,000	At least once in 3 to 5 years
4	Likely	1 in 100	At least once in 1 to 3 years
5	Very likely	1 or more in 10	More than once per year

Step 4: Multiply your assessed Consequence Level x Likelihood Level to find the Level of Risk (range 1 – 25). Refer to the table below to establish the INDICATED Risk Ranking and Risk Acceptability/Tolerance and Conditions. Other factors may need to be considered in determining risk acceptability/tolerance and action to be taken.

Indicative clinical risk ranking and criteria table

Level of Risk Score Risk Rank	1 to 4 Low	5 to 9 Moderate	10 to 16 High	20 to 25 Extreme
Risk Acceptability/Tolerance and Conditions (This indicates priorities and does not negate Continuous Improvement and other Quality Initiatives)	<ul style="list-style-type: none"> Acceptable. Controls must be adequate. Review risk annually. 	<ul style="list-style-type: none"> Tolerable. Controls must be adequate and reviewed frequently. Review risk at least annually. 	<ul style="list-style-type: none"> Intolerable. Controls must be at least adequate and improved to excellent as soon as is practicable and monitored. Review risk bi-annually. Controls self-assurance required. 	<ul style="list-style-type: none"> Intolerable. Controls must be improved to excellent immediately and closely monitored. Monitor risk continuously. Independent controls assurance required.

Major clinical incident investigation – Clinical risk rating

Step 5: Refer to the Specific Risk Criteria below

If the assessed risk is not acceptable decide the most appropriate risk treatment which broadly may be to:

- avoid the risk by ceasing the activity
- improve prevention controls to reduce likelihood
- improve other controls to reduce the potential consequences
- share or transfer the risk by contracting out or transferring the activity to another provider or location.

Specific risk criteria

Harm to Patients

The patient or their representative for this purpose determines acceptability of clinical risk from their perspective in the health care offered to them (see Informed Consent Policy and related processes).

SAC 1 clinical incidents (see Clinical Incident Management Policy). There is “zero tolerance” for the risk of sentinel events or SAC 1 clinical incidents occurring.

All that is practicable, within our power and resources to do and that any reasonable person would be expected to do in the circumstances, or is required by law or otherwise required, is to be done in controlling and treating these risks and fulfilling our duties of care.

4.1.7 Recommendation follow up memo

To:

Date:

From:

Subject: Clinical Incident Investigation

Dear <name>

The Health Service Executive requested that a clinical incident investigation be undertaken into an adverse incident, which occurred in <location> on the <date>.

<Short description of incident>

As part of our ongoing commitment to quality improvement, the implementation of recommendations from incident investigations is reviewed periodically to determine their effectiveness.

Your position was assigned responsibility for implementation of the following recommendation/s from the investigation mentioned above:

<List of recommendations>

Would you please complete the enclosed follow up feedback form with progress made to date on the above recommendation/s and return it to:

<Return address>

If you require any further information or assistance with completing the feedback form, please feel free to contact me.

Thank you

Yours sincerely

4.2 The 5 Whys process and templates

This variation of “the 5 Whys” has been adapted from the NSW Health Easy Guide to Clinical Incident Management.⁹ It applies the same systems based approach as a major clinical incident investigation in a more streamlined process and is well suited to situations where incidents have not caused major harm. Application:

- Suitable for acute sector, mental health and primary care settings.
- Best used for investigation of individual events.

The 5 Whys - Steps

Step 1 Gather Information

Documentation and material related to the incident should be collected as soon as possible to:

- make sure the information is available for use in the investigation
- allow development of a description of the sequence of events leading up to the incident.

Information that may be relevant includes:

- patient health records from all service providers involved
- relevant policies and procedures
- relevant physical evidence (packaging, equipment)
- observations and comments from staff involved
- comments and information from the patient and family members as appropriate
- information about the environment and conditions (e.g. staff roster).

Step 2 Determine the Sequence of Events

The sequence of events leading up to the incident or near miss is documented on a flow chart (**template provided**).

Step 3 Determine Points of Variation

A comparison is made between what actually happened with what should have happened. Reference to policies and procedures and a review of current literature may assist in this analysis. The steps that actually happened and the steps that did happen may be documented in different colours on the flow chart.

For each point where actual events deviated from expected events ask the question ‘Why’ five times (or more if necessary) until the basic contributory factors are identified. Some contributory factors are likely to be present in future situations (e.g. medication labels of similar colour and design) and some are likely to have been specific to the event under investigation (e.g. a one off communication problem between staff).

Contributory factors likely to be present in future situations are noted on the Investigations Recommendation Summary (see page 53).

Step 4 Develop Recommendations

Recommendations are developed for actions to address each of the contributory factors.

Recommendations may be considered strong⁶ if they are highly likely to reduce risk by making it very easy for staff to do the right thing. Strong recommendations include those that:

- Introduce a forcing function (e.g. a unique connectors to allow only correct assembly of equipment).
- Remove the opportunity to do the wrong thing (e.g. remove all potassium chloride from wards).
- Standardise to reduce confusion (e.g. purchase only one type of IV pump for a hospital).
- Simplify processes (e.g. provide direct contact numbers for high risk patients to access expert advice from home).
- Introduce a physical barrier to prevent harm (e.g. non slip floor coverings, bed rails).

Examples of **intermediate** actions used for the development of recommendations include:

- The use of checklists, protocols and reminders (cognitive aids) to reduce reliance on memor.
- The elimination the use of 'sound-alike or look-alike' names.
- Increase staffing/decrease workload.
- Enhancement/modification of software.
- Improvements in documentation/ communication/handover.
- Elimination/reduction in distractions.

Recommendations may be considered weak if they are less likely to reduce risk. Weak recommendations include those that:

- Rely on documentation that may be difficult to access or compete with other information (e.g. policies and procedures).
- Rely on training that may take time to provide to all necessary parties and may not be retained fully.

Strong recommendations should be developed wherever possible.

If an investigation finds that best possible care has been provided, there may be no useful recommendations for action.

Positions responsible for implementing recommendations should be identified/negotiated by the investigator along with proposed implementation time frames.

Each contributory factor should be risk rated and referred to the site/service risk register.

Recommendations are recorded in an Investigation Recommendations Summary.

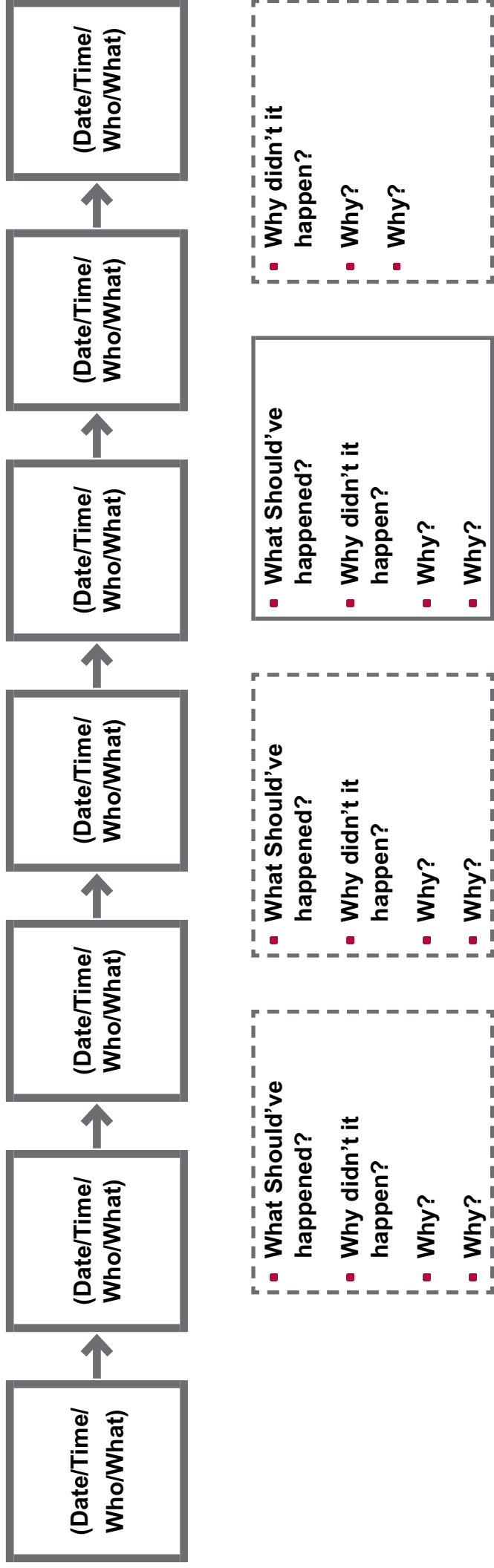
Step 5 Monitor Implementation of Recommendations

The implementation of recommendations should be monitored. Staff (positions) assigned responsibility for implementing recommendations should contact their local Safety, Quality and Performance team to verify the frequency of their reporting requirements. Additionally, a final report should be submitted to the Patient Safety Directorate within 12 months of the reporting date.

Progress toward completion can be noted on the Investigation Recommendation Summary.

The 5 Whys – Flow Chart – The Story

Investigation #:



Bold line if fact

Broken line if needs to be confirmed

The 5 Whys – Investigation Recommendations Summary

Investigation #:

	Contributory Factor	Recommended Action	Action E = eliminate C = control A = accept	Position Responsible	Planned Completion Date	Outcome measure	Risk Rating	Review Date	Progress
1									
2									
3									
4									
5									

4.3 Health Record (Chart) Review process and templates

Application:

- Suitable for acute sector, mental health and primary care settings.
- May be used for investigation of individual events or multiple similar events.
- Suitable for all incident severities.
- May be used proactively to audit quality of care.

Problems with communication, and in particular documentation, are widely recognised as major contributing factors in the occurrence of sub-optimal patient outcomes. It is in the best interest of every patient and provider that the health record contains complete and accurate documentation of each episode of care.

The health record is the document where all health care providers, contributing to the care of the patient, will record all details of that care. All entries will be timely, appropriate and legible, such that any health care provider will be able to determine the status of the patient and carry on management, by reading the record.

Health Record (Chart) Review – Steps

Step 1 Gather Information

Documentation and material related to the incident/s should be collected as soon as possible to:

- ensure all relevant health records are included in the review
- ensure timely access to health records by the reviewer
- allow development of a description of the sequence of events leading up to the incident.

Patient health records from all service providers involved need to be collated and considered in the review.

Step 2 Appoint a Reviewer

A suitably qualified and experienced person is appointed to undertake the health record review. The reviewer should not have been directly involved with the case/s but should have knowledge and experience in relevant areas of health care.

The reviewer may be appointed from another hospital or health service to ensure independence of the review.

Step 3 Determine the Scope of the Review

The scope of the health record review may be tailored to concentrate on those aspects of documentation most relevant to the incident. In a proactive audit situation, the review may target particular aspects of care that are most relevant to the case/s under review or that involve the greatest risks. The Health Record Review Tool (see page 57) may be edited to remove items deemed to be out of scope of a particular review.

Step 4 Review the Health Record

Compliance with each standard included in the scope of the review is assessed and recorded on the Health Record Review Tool along with comments about variances. Contributory factors are the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident. These factors are identified and noted on the Health Record Review Recommendations Summary (see page 62).

Step 5 Develop Recommendations

Recommendations are developed to address variances considered to have possibly contributed to the incident or which may potentially contribute to a future incident.

Recommendations may be considered strong⁶ if they are highly likely to reduce risk by making it very easy for staff to do the right thing. Strong recommendations include those that:

- Introduce a forcing function (e.g. a unique connector to allow only correct assembly of equipment).
- Remove the opportunity to do the wrong thing (e.g. remove all potassium chloride from wards).
- Standardise to reduce confusion (e.g. purchase only one type of IV pump for a hospital).
- Simplify processes (e.g. provide direct contact numbers for high risk patients to access expert advice from home).
- Introduce a physical barrier to prevent harm (e.g. non slip floor coverings, bed rails).

Examples of intermediate actions used for the development of recommendations include:

- The use of checklists, protocols and reminders (cognitive aids) to reduce reliance on memory.
- The elimination the use of 'sound-alike or look-alike' names.
- Increase staffing/decrease workload.

Examples of intermediate actions include:

- Enhancement/modification of software
- Improvements in documentation/ communication/handover
- Elimination/reduction in distractions.

Recommendations may be considered weak if they are less likely to reduce risk. Weaker recommendations include those that:

- Rely on documentation that may be difficult to access or compete with other information (e.g. policies and procedures).
- Rely on training that may take time to provide to all necessary parties and may not be retained fully.

Strong recommendations should be developed wherever possible.

If a review finds that best possible care has been provided, there may be no useful recommendations for action.

Staff (positions) responsible for implementing recommendations should be identified/negotiated by the reviewer along with proposed implementation time frames.

Each contributory factor should be risk rated and referred to the site/service risk register.

Recommendations are recorded in a Health Record Review Recommendations Summary.

Step 6 Monitor Implementation of Recommendations

The implementation of recommendations should be monitored. Staff (positions) assigned responsibility for implementing recommendations should contact their local Safety, Quality and Performance team to verify the frequency of their reporting requirements. Additionally, a final report should be submitted to the Patient Safety Directorate within 12 months of the reporting date.

Health Record (Chart) Review

Investigation #:

Health Record Review Tool

Patient Name: _____ UMRN: _____ Date of Review: _____

Name of Reviewer: _____ Position: _____ Contact No: _____

	Yes	No	N/A	Comments
1 History				
1.1 Presenting Problem The nature and duration of the symptoms that caused the patient to seek medical attention, as stated in the patient's own words.				
1.2 History of Presenting Problem A detailed chronological description of the development of the presenting problem, from the appearance of the first symptom to the present time, including relevant positive and negative descriptors and risk factors.				
1.3 Other Past History				
Summary of significant previous surgery, preferably with dates, outcomes and complications, including of anaesthesia.				
Summary of childhood illness.				
Summary of hospitalisation for other severe illness.				
Summary of current illnesses and a list of current medications (generic names where possible).				
Screening history of other systems.				
1.4 Personal History				
Drug allergies				
Other agents causing a negative reaction.				
Immunisation status, e.g. DTPa in children, Tetanus prophylaxis in trauma, Fluvax® where indicated.				
Voluntary disclosure of blood borne viruses.				
Work history, including relevant exposures.				
Social history (housing, finances, support, lifestyle, pets, hobbies, etc).				
Tobacco, alcohol, other substance use.				
1.5 Family History				
Of presenting problem.				
Other.				

	Yes	No	N/A	Comments
2 Examination				
General observations and vital signs, including mental state.				
Detailed examination of the relevant system(s).				
“Screening” examination of other systems.				
Specific risks to the patient, e.g. falls.				
3 Diagnosis				
Provisional diagnosis and/or differential diagnosis.				
4 Management				
Investigations and evidence of these requests.				
Treatment plan, including medications, mobility, AH involvement, observations required, parameters for review, discussion with patient / family.				
Management plan to address specific risks.				
Referrals for consultation.				
Limits of treatment and advanced directives with evidence of discussion with the patient or family.				
Notification to the Communicable Disease Control Directorate if the illness is of public health significance.				
5 Procedures				
Informed consent including evidence of discussion of material risks, signed by patient and doctor (preferably clinician performing the procedure).				
Every procedure documented.				
Operative notes include:				
▪ pre-operative diagnosis				
▪ evidence of the “Time Out” procedure				
▪ side and site of operation				
▪ local anaesthetic used				
▪ description of samples taken for testing and the tests requested on the same				
▪ detailed description of the procedure.				
Complications recorded as statement of fact.				
Post-procedure recovery instructions.				
Evidence of discussion of outcomes with the patient / family.				

	Yes	No	N/A	Comments
6 Anaesthetic and Recovery Room Record				
Pre-anaesthetic assessment completed.				
Evidence that risks of anaesthesia discussed with patient or a signed anaesthetic consent form.				
Drugs and dosages used.				
ASA score.				
Whether the anaesthesia was planned or emergent.				
Complications recorded as a statement of fact.				
Significant events during anaesthetic are recorded or evidence they have been communicated to the in-patient team.				
Significant events with implications for future anaesthetics (e.g. difficult airway) are documented, and evidence they have been discussed with the patient, communicated to the GP and consideration given to completing a medalert form.				
7 Progress Notes				
Contained within a Clinical Pathway (where a Clinical Pathway exists and there is no variance from that pathway).				
Progress of the treatment plan including:				
<ul style="list-style-type: none"> ▪ input from all health care providers (integrated notes), and 				
<ul style="list-style-type: none"> ▪ variations from the expected progress 				
<ul style="list-style-type: none"> ▪ changes to treatment including medications. 				
Variations from endorsed guidelines with supporting opinion.				
Comment on results of investigations and planned follow up.				
New diagnoses and revisions of treatment plan as they occur.				
Factual details of adverse events.				
Ongoing information given to patient / family.				
8 Medication Prescription				
All medications recorded on medication chart.				
Medication reconciliation.				
Drug allergies and prior adverse drug events.				
Generic drug names used.				
Dosage and administration times clear.				
Doctor signature and printed name clear.				
Dosage administration.				

	Yes	No	N/A	Comments
9 Results and Reports				
All reports signed as seen by a member of the clinical team.				
10 Patient Death in Hospital				
Date and time of death.				
Examination confirming Extinction of Life.				
Description of circumstances, as appropriate.				
Evidence of completion of a Death Certificate.				
Evidence of notification of next of kin.				
Evidence of notification of the GP.				
Evidence for cremation, or permission for autopsy, as appropriate.				
Evidence of notification of appropriate bodies (e.g. Coroner, DMS for Sentinel Events, Statutory Mortality Committees, Organ Donor Coordinator, Communicable Disease Directorate).				
Evidence of WARM reporting.				
Discharge summary.				
11 Discharge Planning				
Estimated date of discharge, planning for discharge in consultation with the patient.				
Required documents (medication scripts, discharge summary, referrals) completed prior to discharge.				
12 Discharge Summary				
Summary of events provided to patient and/or family/carer at the time of discharge.				
Summary provided to the doctor in charge of care from that point. (by e-mail, fax or mail).				
Summary generated by computer, unless extenuating circumstances.				
Summary includes:				
<ul style="list-style-type: none"> ▪ Final diagnosis/es. 				
<ul style="list-style-type: none"> ▪ Other co-morbid conditions. 				
<ul style="list-style-type: none"> ▪ Brief narrative of events. 				
<ul style="list-style-type: none"> ▪ Procedures undertaken. 				
<ul style="list-style-type: none"> ▪ Results. 				
<ul style="list-style-type: none"> ▪ Discharge medications (including new medications) with dosage and duration. 				
<ul style="list-style-type: none"> ▪ Information given to the patient, e.g. activity, diet, wound care, home help, contact if experiencing problems. 				
<ul style="list-style-type: none"> ▪ Follow-up arrangements. 				

	Yes	No	N/A	Comments
13. Format of Entries				
Entries are in black ink, legible and sequential.				
Diagrams, tables, graphs and photos have appropriate notation.				
All entries are dated and timed.				
All entries are signed. Professional designation of the writer, initial and surname are printed (by hand or via a stamp).				
There are no blank lines between entries.				
Student entries are countersigned by a registered practitioner.				
Only approved abbreviations are used.				
All entries are on approved health record forms.				
The frequency of entries is at least every 24 hours for acute care and at least twice weekly in rehabilitative care.				
Incorrect entries are ruled through with a line and marked 'written in error', by the author of the original entry. Correction fluid is not used.				
Late entries are identified as such (with the heading "Written in Retrospect"), dated, timed and signed as above.				
Every page has a patient label or a record of the patient's last name, given name, and date of birth.				
The record does not include any prejudicial, derogatory, irrelevant, speculative, emotive, judgmental or general statements.				

Health Record Review – Recommendations Summary

Investigation #:

	Contributory Factor	Recommended Action	Action E = eliminate C = control A = accept	Position Responsible	Planned Completion Date	Outcome measure	Risk Rating	Review Date	Progress
1									
2									
3									
4									
5									

4.4 Failure Modes and Effects Analysis (FMEA) – process and templates

Application:

- Suitable for acute sector, mental health and primary care settings.
- For use in assessing processes.
- Suitable for investigating groups of similar incidents that involve the same process(es).

This Tool is based on the Institute for Healthcare Improvement Failure Modes and Effects Analysis method¹⁰ and is a systematic approach to identifying which parts of a process are most in need of improvement. It includes some elements of “process mapping” and “gap analysis”.

Step 1 Select a Process

FMEA is most effective when applied to processes that do not have many sub processes. Large and complex processes may need to be considered in phases or parts to achieve the best results.

A process is selected for analysis. Processes may be targeted for FMEA because they are:

- common to a group of clinical incidents
- involved in a serious or sentinel event
- new and assurance is needed that suitable controls are in place.

Clear start and end points are identified for the process to be analysed.

Step 2 Appoint a Review Team

An FMEA team coordinator is appointed to be responsible for:

- facilitating the analysis
- arranging team meetings
- ensuring all documentation is completed and forwarded to the appropriate people
- ensuring the investigation is completed within a reasonable time frame.

An FMEA team is appointed. The team should include a representative from each area or profession involved in the process. Not all team members will necessarily be involved in the entire process but all relevant areas need to be included to ensure the flow on effects of each step are fully appreciated and captured.

Step 3 List Steps in the Process

Each step in the process is identified and documented in a list or on a flow chart (see page 66). It is important to be specific and detail every step. Gain agreement from all team members that the steps are accurate and complete then number the steps.

Step 4 Identify Possible Failure Modes and Effects

For each step in the process, all the things that could go wrong (failure modes) are identified (no matter how rare or minor). For each failure mode, all the possible causes for the failure and all the possible effects are listed using the FMEA Summary Sheet (see page 67).

Step 5 Risk Rate the Failure Modes

For each failure mode the Risk Priority Number (RPN) is calculated by assigning a score from 1 to 5 (Rating Scale see page 68) for each of three factors namely:

- likelihood of occurrence
- likelihood of being undetected
- severity of effect / consequence.

The RPN is recorded on the FMEA Summary Sheet (see page 67).

Step 6 Develop Recommendations

Recommendations are developed to address failure modes.

If the likelihood of the failure occurring is high, consider:

- whether any of the possible causes can be eliminated
- adding a forcing function such as a physical barrier that makes it impossible to do the wrong thing
- adding a verification step.

If the likelihood of the failure being undetected is high, consider:

- other events that may occur prior to the failure that could act as a 'flag'
- adding a step to the process that provides a check prior to the failure mode
- adding a technological alert or alarm that is triggered prior to the failure mode.

If the consequence/s of the failure are serious, consider:

- including the process and failure mode in drills
- provide information and resources to minimise consequences in locations where failures are likely to occur (e.g. reversal agents, antidotes, resuscitation equipment etc).

Staff (positions) responsible for implementing recommendations should be identified/negotiated by the FMEA team Coordinator along with proposed implementation time frames.

Recommendations are recorded in a FMEA Recommendations Summary (see page 70).

Step 7 Monitor Implementation of Recommendations

The implementation of recommendations should be monitored. Staff (positions) assigned responsibility for implementing recommendations should contact their local Safety, Quality and Performance team to verify the frequency of their reporting requirements. Additionally, a final report should be submitted to the Patient Safety Directorate within 12 months of the reporting date.

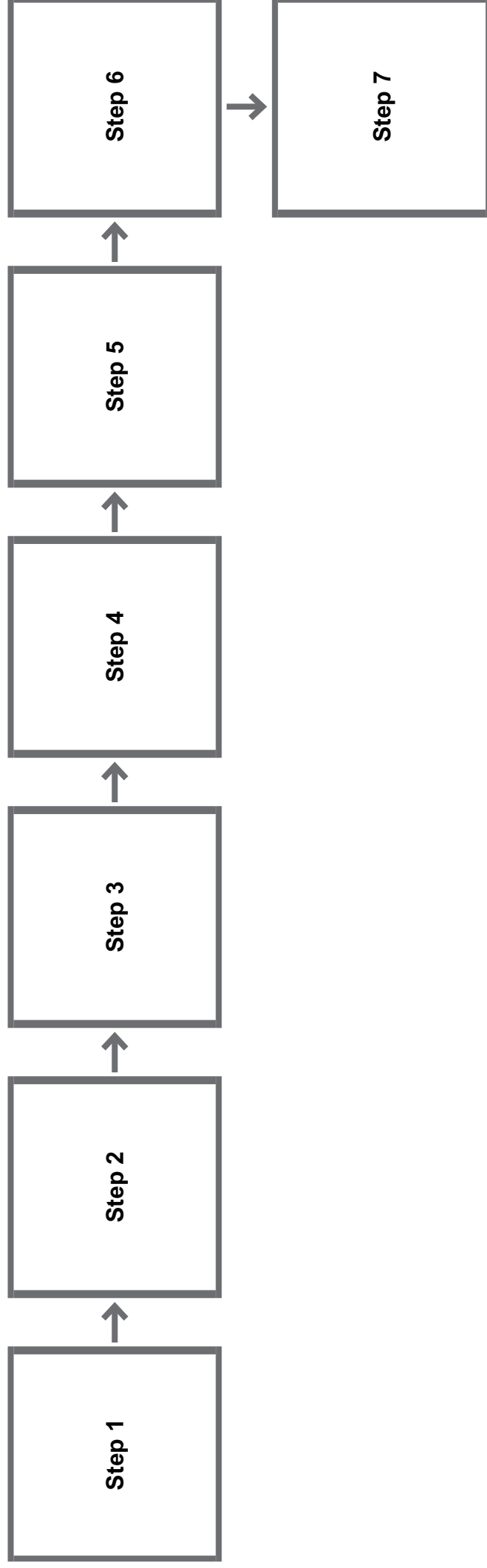
The RPN for the process is recalculated once recommendations are implemented to determine if the RPN has been reduced.

Failure Modes and Effects Analysis (FMEA) – Templates

FMEA Flow Chart

(Based on the Institute for Healthcare Improvement Failure Modes and Effects Analysis method)

Investigation #:



FMEA summary sheet
(Based on the Institute for Healthcare Improvement Failure Modes and Effects Analysis method)

Investigation #:

Steps	Failure Modes	Causes	Effects	Likelihood of Occurring (1 – 5)*	Likelihood of Detection (1 – 5)*	Severity of Effect (1 – 5)*	Risk Priority Number (1 – 125)
1							
2							
3							
4							

* Refer to rating scale over the page.

FMEA rating scale

Likelihood of Occurrence.

- 1 Rare
Once in more than 10 years
- 2 Unlikely
At least once in 5 to 10 years
- 3 Possible
At least once in 3 to 5 years
- 4 Likely
At least once in 1 to 3 years
- 5 Almost Certain
More than once per year

Likelihood of Detection.

- 1 Almost certain to be detected
- 2 Likely to be detected
- 3 Possibly be detected
- 4 Unlikely to be detected
- 5 Almost certain NOT to be detected

Severity of Effect / Consequence

	Health Impacts (Patients, staff, public, contractors)	Critical and Time Sensitive Services Interruption	Performance to Budget.	Financial Loss Liability	Organisation Objectives or Outcomes.	Reputation /Image	KPI Variation	Non-Compliance
1 Insignificant	First aid or equivalent only.	No material disruption to dependent work.	Up to 1% temporarily over budget. Recoverable within financial year.	Less than \$5,000.	Little impact.	Non-headline exposure. Not at fault. Settled quickly.	< 2%.	Innocent procedural breach. Evidence of good faith by degree of care/diligence. Little impact.
2 Minor	Routine medical attention. Temporary diminution of normal health or function. Max 2 weeks incapacity.	Short-term temporary suspension of work. Backlog cleared in day. No public impact.	More than 1% up to 2% temporarily over budget. Recoverable within financial year.	\$5,000 to less than \$100,000.	Inconvenient delays.	Non-headline exposure. Clear fault. Settled quickly. Negligible impact.	2% - <5%	Breach, objection/complaint lodged. Minor harm with investigation. Evidence of good faith arguable.
3 Moderate	Increased level of medical attention. Prolonged diminution or loss of normal health or function. 2 weeks to 3 months incapacity.	Medium-term temporary suspension of work. Backlog requires overtime or additional resources to clear. Manageable impact.	More than 2% up to 5% temporarily over budget. Recoverable within financial year.	\$100,000 to less than \$3M.	Material delays. Marginal under achievement of target performance.	Repeated non-headline exposure. Slow resolution. Ministerial enquiry / briefing.	5% - <15%	Negligent breach. Lack of good faith evident. Performance review initiated. Material harm caused.
4 Major	Severe health crisis and/ or injuries, Prolonged incapacity or absence beyond 3 months.	Prolonged suspension of work. Additional resources, budget, management assistance required. Performance compromised.	More than 5% to 10% temporarily over budget, or material over-run NOT recoverable within financial year.	\$3M to less than \$20M.	Significant delays. Performance significantly under target.	Headline profile. Repeated exposure. At fault. Impacting key groups. Ministerial involvement.	15% - <30%	Deliberate breach or gross negligence. Significant harm. Formal investigation. Disciplinary action. Ministerial involvement.
5 Catastrophic	Multiple severe health crises / injuries or death.	Indeterminate prolonged suspension of work. Impact not manageable. Non-performance. Other providers appointed.	More than 10% temporarily over budget. NOT recoverable within financial year. Unable to pay staff.	\$20M +.	Non-achievement of objective / outcome. Total performance failure.	Max multiple high-level exposure. Ministerial censure / intervention. Loss of credibility and stakeholder support.	30% +.	Serious /wilful breach. Criminal negligence or act. Litigation or prosecution with significant penalty. Ministerial censure.

FMEA recommendation summary sheet
 (Based on the Institute for Healthcare Improvement Failure Modes and Effects Analysis method)

Investigation #:

Step	Failure Mode	Recommended Action	Action E = eliminate C = control A = accept	Position Responsible	Planned Completion Date	Outcome measure	Risk Rating	Review Date	Progress
1									
2									
3									
4									
5									

4.5 Analysing clinical risk process

Step 1: Having identified the risk, identify the controls in place to prevent an incident and contain its potential consequences. Evaluate their overall adequacy using the table below.

Controls adequacy table

Level	Controls Descriptor	Status Test
E	Excellent	<ul style="list-style-type: none"> ▪ Comprehensive, effective controls fully in place for prevention as well as mitigation of consequences. ▪ Control requirements communicated, complied with, maintained, monitored, reviewed and tested regularly. ▪ Controls assessed or tested individually and as a system where multiple controls are utilised, to obtain Controls Self-Assurance or independent assurance. ▪ All that can be done is being done.
A	Adequate	<ul style="list-style-type: none"> ▪ Sufficient effective controls substantially in place for prevention as well as mitigation of consequences. ▪ Control requirements communicated, complied with, with procedures for specific circumstances. Periodic reviews. ▪ All that is reasonably practicable to be done is being done.
I	Inadequate	<ul style="list-style-type: none"> ▪ Controls are either non-existent, not practically in place or not effective. ▪ Not communicated and/or not complied with. No reviews. ▪ Little or nothing is being done.
U	Unknown	<ul style="list-style-type: none"> ▪ Controls and status are unknown.

Step 2: Given those existing controls, identify the worst REALISTIC, primary consequences should an incident occur. Pick the best fit on the 1 to 5 scale from the table below. It is not necessary to address each category.

Consequences assessment

SEVERITY LEVEL	1	2	3	4	5
CONSEQUENCES CATEGORIES	Insignificant	Minor	Moderate	Major	Catastrophic
HEALTH IMPACT ON PATIENT (S)	Increased level of care (minimal). No increase in length of stay. Not disabling.	Increased level of care (minimal). Increased length of stay (up to 72 hours). Recovery without complication or permanent disability.	Increased level of care (moderate). Extended length of stay (72 hours to one week). Recovery without significant complication or significant permanent disability.	Increased level of care (significant). Extended length of stay (greater than one week). Significant complication and/or significant permanent disability. ALL SAC 1 clinical incidents.	Death, permanent total disability. ALL SAC 1 clinical incidents.
HEALTH IMPACT ON STAFF OR OTHERS	First aid or equivalent only.	Routine medical attention required. Max 1 week's incapacity/time lost. No disability.	Increased level of medical attention required. 1 week to 1 month incapacity/time lost. No significant permanent disability.	Severe health crisis and/or injuries, Prolonged incapacity or absence 1 month +. Significant permanent disability.	Death or permanent total disability.
CRITICAL SERVICES INTERRUPTION	No material disruption to dependent work.	Short-term temporary suspension of work. Backlog cleared in day. No public impact.	Medium-term temporary suspension of work. Backlog requires extended work or overtime or additional resources to clear. Manageable impact.	Prolonged suspension of work. Additional resources, budget, Management assistance required. Performance criteria compromised.	Indeterminate prolonged suspension of work. Impact not manageable. Non-performance. Other providers appointed.
PERFORMANCE TO BUDGET (Over or underspend)	Less than 1% temporary variance.	1% to 2% temporary variance.	More than 2% up to 5% temporary variance.	More than 5% to 10% variance NOT recoverable within the financial year.	More than 10% variance NOT recoverable within the financial year, or being unable to pay staff, creditors or finance critical services.
FINANCIAL LOSS	Less than \$5,000.	\$5,000 to less than \$100,000.	\$100,000 to less than \$3M.	\$3M to less than \$20M.	\$20M +.
ORGANISATIONAL OBJECTIVES OR OUTCOMES	Little impact.	Inconvenient delays.	Material delays. Marginal under achievement of target performance.	Significant delays. Performance significantly under target.	Non-achievement of objective / outcome. Total performance failure.
REPUTATION AND IMAGE DAMAGE	Non-headline exposure. Not at fault. Settled quickly. No impact.	Non-headline exposure. Clear fault. Settled quickly by Departmental response. Negligible impact.	Repeated non-headline exposure. Slow resolution. Ministerial enquiry / briefing. Qualified Accreditation.	Headline profile. Repeated exposure. At fault or unresolved complexities impacting public or key groups. Ministerial involvement. High priority recommendation to preserve accreditation.	Maximum multiple high-level exposure. Ministerial censure. Direct intervention. Loss of credibility and public / key stakeholder support. Accreditation withdrawn.

SEVERITY LEVEL	1	2	3	4	5
CONSEQUENCES CATEGORIES	Insignificant	Minor	Moderate	Major	Catastrophic
KPI VARIATION	Less than 2% Innocent procedural breach. Evidence of good faith by degree of care/diligence. Little impact.	2% - <5% Breach, objection/complaint lodged. Minor harm with investigation. Evidence of good faith arguable.	5% - <15% Negligent breach. Lack of good faith evident. Performance review initiated. Material harm caused. Misconduct established.	15% - 30% Deliberate breach or gross negligence. Significant harm. Formal investigation. Disciplinary action. Ministerial involvement. Serious misconduct.	30% +. Serious and wilful breach. Criminal negligence or act. Litigation or prosecution with significant penalty. Dismissal. Ministerial censure. Criminal misconduct.
NON-COMPLIANCE					
ENVIRONMENTAL IMPACT					
PROJECT DELIVERABLES					
PROJECT BUDGET					
PROJECT TIME DELAY					

Step 3: Using your judgement, incident data or other sources, assess the likelihood of an incident occurring and having the consequences you assessed in Step 2 above, bearing in mind the existing controls in place and their effectiveness. Pick the best fit on the 1 to 5 scale from the table below.

Likelihood

Level	Likelihood Descriptor	Corporate	
		Clinical	Corporate
	Per Separations/Occasions of Service Likelihood Code "C" (Clinical)	% Chance during life of project or financial year for budget risk Likelihood Code "C" (% Chance)	Time Scale for ongoing non-project activities or exposures Likelihood Code "T" (Time)
1	Rare 1 in 100,000 or more	Up to 5%	Once in more than 10 years
2	Unlikely 1 in 10,000	6 - 30%	Once in 5 - 10 years
3	Possible 1 in 1,000	31% - 60%	Once in 3 - 5 years
4	Likely 1 in 100	61% - 90%	Once in 1 to 3 years
5	Very Likely 1 or more in 10	Over 90%	More than once a year

Step 4: Multiply your assessed Consequence Level x Likelihood Level to find the Level of Risk (range 1 – 25). Refer to the table below to establish the INDICATED Risk Ranking and Risk Acceptability/Tolerance and Conditions. Other factors may need to be considered in determining risk acceptability/tolerance and action to be taken.

Indicative risk ranking and criteria table

Level of Risk Score	1 to 4	5 to 9	10 to 16	20 to 25
Risk Rank	Low	Medium	High	Extreme
Risk Acceptability/Tolerance and Conditions (This indicates priorities and does not negate Continuous Improvement and other initiatives)	<ul style="list-style-type: none"> Acceptable. Controls must be Adequate. Review risk annually. 	<ul style="list-style-type: none"> Tolerable. Controls must be Adequate and reviewed frequently. Review risk at least annually. 	<ul style="list-style-type: none"> Intolerable. Controls must be at least Adequate and improved to Excellent as soon as is practicable and monitored. Review risk bi-annually. Controls self-assurance required. 	<ul style="list-style-type: none"> Intolerable Controls must be improved to Excellent immediately and closely monitored. Monitor risk continuously. Independent Controls Assurance required.
Indicated DOH Management Level for Corporate Risk Acceptance / Tolerance Decisions (see your Health Service Authorities and Delegations Schedules for equivalents and clinical authorities)	Tier 5 officers Project Managers Authorised delegates.	Tier 4 officers Project/Program Managers Authorised delegates.	Tier 3 officers Program Directors Authorised delegates.	Tier 2 officers Chief Officers or Executive Directors Authorised delegates.

Step 5: Refer to the Specific Risk Criteria below. If the assessed risk is not acceptable decide the most appropriate risk treatment which broadly may be:

- avoid the risk by ceasing the activity
- improve prevention controls to reduce likelihood
- improve other controls to reduce the potential consequences
- share or transfer the risk by contracting out or transferring the activity to another provider or location.

SPECIFIC RISK CRITERIA

Harm to Patients

The patient or their representative for this purpose determines acceptability of clinical risk from their perspective in the health care offered to them. (see Informed Consent and related processes).

SAC 1 clinical incidents (see Clinical Incident Management Policy). There is “zero tolerance” for the risk of sentinel events or SAC 1 clinical incidents occurring.

Harm to Workforce

In accordance with WorkSafe legislation any foreseeable risk of injury or disease to employees must be reduced as far as is practicable. This requirement should be applied in principle to contractors and their employees, volunteers and any work experience persons. There is “zero tolerance” for workplace violence.

Harm to the Public

Any foreseeable risk of injury to others or loss or damage to their property must be reduced to be the standard expected in law and provide proper discharge of any duty of care owed. Compliance with all relevant legislation addressing liability and duty of care requirements, such as the WA Occupier’s Liability Act 1985, is required. Judgements in relevant cases are to be considered. If in doubt discuss with Legal and Legislative Services or the State Solicitor’s Office.

Budget Management

There is no acceptable level of risk for budget over-runs.

Compliance

There is “zero tolerance” of any material risk of breach of legislative, regulatory, or other Government requirements.

All that is practicable, within our power and resources to do and that any reasonable person would be expected to do in the circumstances, or is required by law or otherwise required, is to be done in controlling and treating these risks and fulfilling our duty of care.

5. Models of feedback

The five models of feedback outlined in Table 4 are based upon descriptions of effective feedback processes studied by Benn et al.³

Table 4 Five models of feedback for incident reporting systems with examples of how each may be implemented.

Mode	Type	Content and examples
A. Bounce back	Information to reporter	<ul style="list-style-type: none"> ▪ Acknowledge report filed (e.g. automated response). ▪ Debrief reporter. ▪ Provide advice from safety experts. ▪ Outline issue process (and decision to escalate).
B. Rapid response	Action within local work systems	<ul style="list-style-type: none"> ▪ Measures taken against immediate threats to safety or serious issues that have been marked for fast-tracking. ▪ Temporary fixes/workarounds until in-depth investigation process can be completed (withdraw equipment, monitor procedure, alert staff).
C. Raise risk awareness	Information to all front-line personnel	<ul style="list-style-type: none"> ▪ Safety-awareness publications (posted/online bulletins and alerts on specific issues, periodic newsletters with example cases and summary statistics). ▪ Highlight vulnerabilities and promote correct procedures.
D. Inform staff of actions taken	Information to reporter and wider reporting community	<ul style="list-style-type: none"> ▪ Report back to reporter on issue progress and actions resulting from their report. ▪ Widely publicise corrective actions taken to resolve safety issue to encourage reporting.
E. Improve work systems safety	Action with local work systems	<ul style="list-style-type: none"> ▪ Specific actions and implementation plans for permanent improvements to work systems to address contributory factors evident within reported incidents. ▪ Changes to tools/equipment/working environment, standard working procedures, training programs, etc. ▪ Evaluate/monitor effectiveness of solutions and repeat.

6. References

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12. Australian/New Zealand Standard AS/NZS ISO 31000: 2009, Risk Management – Principles and guidelines, Standards Australia, viewed on 16 September 2010, Perth, <<http://www.safetyandquality.health.wa.gov.au>>.
13. Clinical Excellence Commission and NSW Department of Health. Checklist Flip Chart for Root Cause Analysis Terms, 2003, 3rd Edition.

7. Appendices

APPENDIX A: SAC 1 clinical incident notification form



SAC 1 Clinical Incident Notification Form

All Severity Assessment Code (SAC) 1^a clinical incidents, including sentinel events are to be notified via this form to the Director, Patient Safety Directorate within seven working days of the events occurrence.

Notified by/date:	SAC 1 / Sentinel Event Number:	Investigation Report Due:
PSD USE ONLY		
Hospital Name:	Hospital ID:	Event Date:
Event Description:		
Is this SAC 1 clinical incident a sentinel event?	Yes <input type="checkbox"/> If yes, complete sections one and three .	No <input type="checkbox"/> If no, complete section two and section three .
SECTION ONE: SENTINEL EVENT CATEGORIES		Tick one only (✓)
1. Procedures involving the wrong patient or body part resulting in death or major permanent loss of function.		
2. Suicide of an inpatient (including patients on leave).		
3. Retained instruments or other material after surgery requiring re-operation or further surgical procedure.		
4. Intravascular gas embolism resulting in death or neurological damage.		
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility.		
6. Medication error resulting in death of a patient.		
7. Maternal death or serious morbidity associated with labour or delivery.		
8. Infant discharged to wrong family or infant abduction.		
SECTION TWO: OTHER SAC 1 INCIDENTS		Tick one only (✓)
Misdiagnosis and subsequent management	Complications of an inpatient fall	
Fetal complications	Hospital process issues	
Patient absconding with adverse outcome	Infection control breach	
Complications of resuscitation	Medication error not resulting in death	
Complications of anaesthesia	Unexpected death of a mental health patient	
Complications of surgery	Absconding of any mental health patient	
Delay in recognising / responding to clinical deterioration	Any other incident resulting in serious harm or death of a patient. ^b	

^a Severity Assessment Code (SAC) 1 – serious harm or death that is specifically caused by healthcare rather than the patient’s underlying condition or illness. Sentinel event refers to unexpected occurrences involving death or serious physical or psychological injury, or risk thereof.

^b Note this SAC 1 clinical incident notification list is not exhaustive and if unsure of whether to notify an incident, please contact your line manager or local risk manager or AHS Safety Quality and Performance Unit or the PSD for advice.



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SAC 1 Clinical Incident Notification Form

SECTION THREE:

Patient outcome (tick one ✓)	Death <input type="checkbox"/>	Disability <input type="checkbox"/>	No adverse outcome/ patient harm <input type="checkbox"/>
Tick (✓) if this SAC 1 clinical incident (sentinel event) notification occurred following review of an inpatient via the WA Review of Mortality (WARM) process.			WARM <input type="checkbox"/>
Have any additional reporting requirements been completed? (tick ✓ one response for each)	YES	NO	Not applicable
• The Executive Director, Public Health for maternal deaths, perinatal and infant deaths and deaths of persons under anaesthesia.			
• The Coroner for reportable deaths.			
• Office of the Chief Psychiatrist for patient suicides and serious incidents that occur in mental health.			
If no, please provide an explanation:			
Indicate how the event will be investigated (tick ✓ one):	State qualified privilege via registered committee <input type="checkbox"/>	Without qualified privilege <input type="checkbox"/>	
Indicate whether the hospital will undertake the Open Disclosure Process with the patient, and, with their permission, their nominated relatives/caters regarding the clinical incident (tick ✓ one) :	YES <input type="checkbox"/>	NO <input type="checkbox"/>	
If no, please provide an explanation:			
Forward the completed SAC 1 Clinical Incident Notification Form via email or fax. On receipt of the initial notification the PSD will provide the hospital/health facility with a reference number, to be indicated on all future correspondence regarding the notified event.	Email: SAC1.events@health.wa.gov.au	Fax: (08) 9222 4014	

For further information regarding management and investigation of SAC 1 clinical incidents (including sentinel events) see *the Clinical Incident Management Policy (2011)* or to obtain an electronic copy of this form go to: <http://www.safetyandquality.health.wa.gov.au/home>

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SAC 1 Clinical Incident (sentinel event) Notification Form (2011)

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Appendix B: SAC 1 clinical incident and sentinel event final investigation report



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CONFIDENTIAL SAC 1 Clinical Incident Investigation Report

Hospital Name:	Hospital ID:	SAC 1 / Sentinel Event Reference Number:
Date of event:	Date of notification:	Investigation report date:
Post mortem report:	Received	Pending

The Investigation Report must have executive sign off before being sent to the Patient Safety Directorate

Executive Director/Director Medical Services	Name Signature	Date:
Director Safety & Quality/Clinical Governance	Name Signature	Date:
Chief Investigator	Name Signature	Date:

The information provided in the SAC 1 Clinical Incident Investigation Report will remain confidential. Please return this Report within 45 working days of initial notification of event by one of the following:

E-MAIL: SAC1.events@health.wa.gov.au **FAX:** (08) 9222 4014

Contact the Patient Safety Directorate on (08) 9222 4080 if you have questions regarding this process or visit the Department website at <http://www.safetyandquality.health.wa.gov.au> for information regarding clinical incident management.



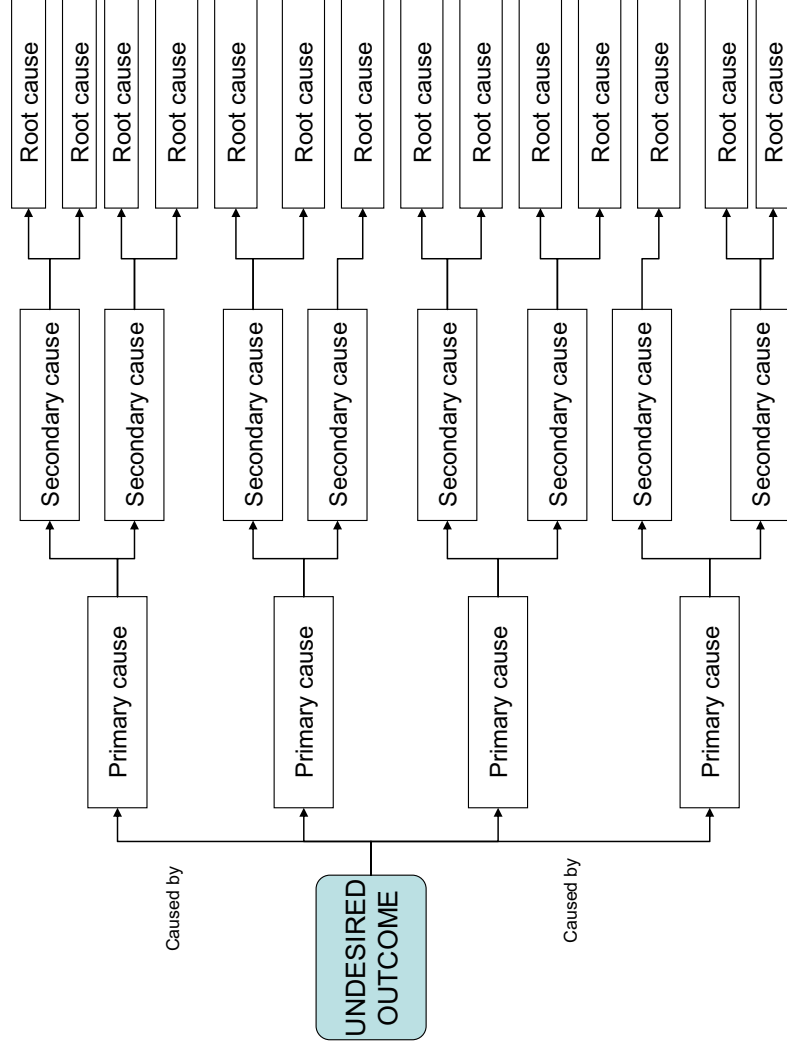
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THE EVENT

Please provide a description of the incident (it may be useful to also include a cause and effect diagram – example opposite):

CAUSE AND EFFECT DIAGRAM





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CONTRIBUTING FACTORS AND ROOT CAUSES

1. Communication	Yes <input type="checkbox"/> No <input type="checkbox"/>	Provide details:	
Were issues relating to communication a factor in this event? <i>If yes, tick the appropriate boxes and provide details:</i>			
Communication issues between staff	<input type="checkbox"/>		
Communication issues between staff and patient / family / carers	<input type="checkbox"/>		
Documentation	<input type="checkbox"/>		
Patient assessment	<input type="checkbox"/>		
Information not provided	<input type="checkbox"/>		
Misinterpretation of information	<input type="checkbox"/>		
Other	<input type="checkbox"/>		
2. Knowledge / Skills / Competence	Yes <input type="checkbox"/> No <input type="checkbox"/>	Provide details:	
Were issues relating to knowledge / skills / competence a factor in this event? <i>If yes, tick the appropriate boxes and provide details:</i>			
Staff training / skills	<input type="checkbox"/>		
Staff competency	<input type="checkbox"/>		
Staff supervision	<input type="checkbox"/>		
Use / not using / misuse of equipment	<input type="checkbox"/>		
Other	<input type="checkbox"/>		



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3. Work Environment / Scheduling		Provide details:
	Yes <input type="checkbox"/>	
Were issues relating to work environment / scheduling a factor in this event? <i>If yes, tick the appropriate boxes and provide details:</i>	No <input type="checkbox"/>	
Work place design	<input type="checkbox"/>	
Suitability of work environment	<input type="checkbox"/>	
Environmental stressors	<input type="checkbox"/>	
Safety assessments / evaluations / procedures	<input type="checkbox"/>	
Shortage of beds / rooms / resources	<input type="checkbox"/>	
Staff timetabling	<input type="checkbox"/>	
Other	<input type="checkbox"/>	

4. Patient Factors		Provide details:
	Yes <input type="checkbox"/>	
Were there issues relating to patient factors in this event? <i>If yes, tick the appropriate boxes and provide details:</i>	No <input type="checkbox"/>	
Communication difficulties	<input type="checkbox"/>	
Medical history / known risks	<input type="checkbox"/>	
Patient's condition	<input type="checkbox"/>	
Personal issues	<input type="checkbox"/>	
Other	<input type="checkbox"/>	



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5. Equipment			Provide details:
Were issues relating to equipment (including the use or lack of use) a factor in this event?	Yes	<input type="checkbox"/>	
<i>If yes, tick the appropriate boxes and provide details:</i>	No	<input type="checkbox"/>	
Suitability / availability / lack of equipment		<input type="checkbox"/>	
Safety / maintenance		<input type="checkbox"/>	
Appropriate use of equipment		<input type="checkbox"/>	
Emergency provisions / back-up systems		<input type="checkbox"/>	
Other		<input type="checkbox"/>	

6. Policies, Procedures, Guidelines			Provide details:
Were issues relating to policies, procedures and guidelines a factor in this event?	Yes	<input type="checkbox"/>	
<i>If yes, tick the appropriate boxes and provide details:</i>	No	<input type="checkbox"/>	
Absence of relevant, up-to-date policies, procedures or guidelines		<input type="checkbox"/>	
Implementation issues		<input type="checkbox"/>	
Education / training		<input type="checkbox"/>	
Issues in applying policies, procedures or guidelines		<input type="checkbox"/>	
Absence of audit / quality control system		<input type="checkbox"/>	
Other		<input type="checkbox"/>	



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7. Safety Mechanisms			Provide details:
Were issues relating to safety mechanisms a factor in this event?	Yes	<input type="checkbox"/>	
<i>If yes, tick the appropriate boxes and provide details:</i>	No	<input type="checkbox"/>	
Lack of appropriate safety mechanisms / systems in place		<input type="checkbox"/>	
Breakdown of safety mechanisms		<input type="checkbox"/>	
No evaluation of safety mechanisms		<input type="checkbox"/>	
Other		<input type="checkbox"/>	

8. Other			Provide details:
If there were other factors involved in the incident which do not fall into the above categories, please provide details.			



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SAC 1 Clinical Incident Reference Number: _____ **Hospital ID:** _____

Contributing factors/ Description of item	Description of recommendation addressing contributing factor(s)	Personnel responsible for implementing recommendation	Outcome measure	Measure date	Executive concur Yes/No	Executive notes if No

Do the RCA Panel request a declassification of this incident? Yes No
If Yes, please outline your reasons for requesting a declassification (see over page).



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SAC 1 Clinical Incident Reference Number: **Hospital ID:**

Please provide reasons for requesting a declassification of this clinical incident.

<p>9.</p>	<p>Reasons for Declassification</p>	<p>Provide details:</p>
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Appendix C: Process review by SAC 1 type

	Behavioural assessment process	Physical assessment process	Patient identification process	Patient observation procedures	Care planning procedures	Care guidelines or standards	Staffing levels	Orientation and training of staff	Competency assessment/credentialing	Supervision of staff	Communication with patient and family	Communication among staff members	Availability of information	Adequacy of technological support	Equipment and maintenance	Physical environment	Security systems and processes	Medication management
Procedures involving the wrong patient or body part resulting in death or major permanent loss of function.		X	X		X		X	X		X	X	X	X	X	X	X		
Suicide of a patient in an inpatient unit.	X	X		X	X	X	X	X	X	X	X	X	X			X	X	X
Retained instruments or other material after surgery requiring re-operation or further surgical procedure.						X	X	X	X	X		X			X			
Intravascular gas embolism resulting in death or neurological damage		X		X			X	X	X	X	X	X	X	X	X	X		
Haemolytic blood transfusion reaction resulting from ABO incompatibility			X	X			X	X	X	X	X	X	X			X		X
Medication error resulting in death of a patient			X			X	X	X	X	X	X	X	X	X	X	X		X
Maternal death or serious morbidity associated with labour or delivery		X		X	X		X	X	X	X	X	X	X					
Infant discharged to wrong family or infant abduction							X	X	X	X	X	X	X			X	X	
Fetal complications		X		X	X	X	X	X	X	X	X	X	X	X		X	X	X
Complications of resuscitation	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Complications of anaesthetic management		X		X	X	X	X	X	X	X	X	X	X			X		X
Complication of surgery		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Complications of an inpatient fall		X		X	X	X	X	X	X	X	X	X	X			X		X
Patient absconding from inpatient unit with adverse outcome (non Mental health)		X	X	X	X	X	X	X	X	X	X	X	X			X	X	X
Infection control breach						X	X	X	X	X	X	X	X			X		X
Process issue e.g. triage, assessment, response to abnormal test results etc	X			X		X	X	X	X	X	X	X	X			X		
Wrong gas or contaminated with toxic substances				X		X	X	X	X	X	X	X	X		X			
Burn incurred from any source while being cared for in a facility	X			X		X	X	X	X	X	X	X	X					X
Use of or lack of restraints or bedrails while being cared for in a facility	X			X		X	X	X	X	X	X	X	X					X
Physical assault that occurs on or within the grounds of a facility or on a home visit	X					X	X	X	X	X	X	X	X					X
Miscommunication of test results			X			X	X		X	X	X		X					



Delivering a **Healthy WA**

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