



February 2012

Root Cause Analysis For Clinical Incidents

A Practical Guide

Prepared by the National District Health
Board Quality and Risk Managers Group



This document provides advice on how to manage the Root Cause Analysis (RCA) process for Severity Assessment Code 1 and 2 incidents to assist RCA Teams.

The information provided in this document aligns with the New Zealand Health and Disability Services – National Reportable Events Policy 2012.

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1. Background

Education and training was provided nationally in 2008/2009 – “New Zealand Incident Management System: A National Approach to the Management of Health care Incidents.”

A training manual was provided which covered theory, process, templates, and articles with the aim of increasing knowledge and informing the rollout of the system.

A gap was identified by District Health Boards (DHBs) between the theory provided, the suggested tools, and how to apply the policy in practice within the resources and structures.

The National Quality and Risk Managers decided to produce this RCA Practical Guide to help DHBs across the country to standardise their approach to RCA investigations.

While the approach should be consistent and standardised, in line with the policy, it is recognised that DHBs do things in different ways so a variety of sample documents are appended to this guide which can be used and adapted as necessary.

This Guide has been prepared specifically for DHBs, but it may be of use to other health and disability service providers who are free to adapt the information to their own needs.

This Guide will be periodically updated by the Health Quality & Safety Commission (HQSC) working closely with the sector. It is current as at February 2012.

2. Overview of the RCA process

In 2005 the World Health Organization defined the characteristics of a successful reporting system:

Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organisation.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognise underlying systems causes.
Timely	Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organisations commit to implementing recommendations whenever possible.

What is an RCA?

An RCA is a formal process that involves a multidisciplinary team commissioned by the Chief Executive or delegate. It is a thorough investigation to identify root causes of a SAC 1 or SAC 2 incident and to make recommendations that can be signed off by the Chief Executive or delegate, so the incident does not reoccur within that health care setting again.

An RCA is also an approach or way of thinking. Best practice seeks to apply this type of thinking to all health care incidents. Undertaking an RCA is a way to learn as much about the incident or close call as possible so changes to systems and processes can be made internally, but just as importantly the knowledge gained and the systemic changes can be shared nationally, via the Commission.

An RCA asks what happened? Why did it happen? What are the underlying causes?

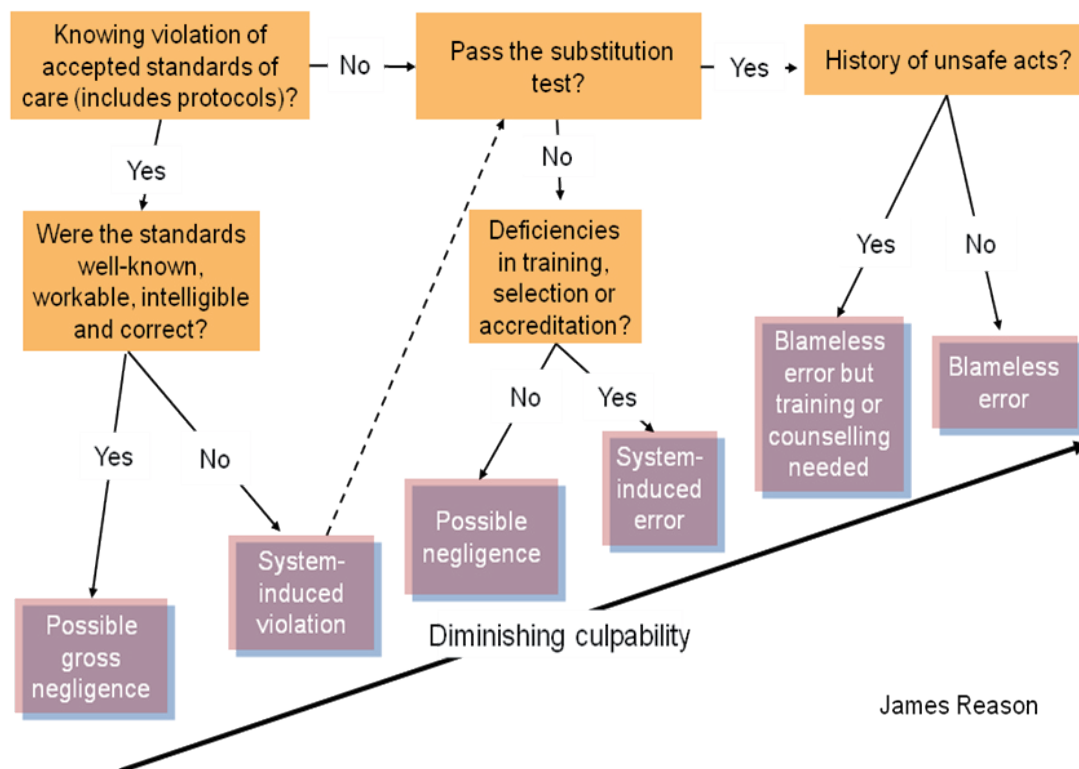
Because the process is focused on systems rather than individuals, persons involved in the incident will not be named. Documentation and communications must therefore be managed appropriately.

3. When is it not appropriate to conduct an RCA?

An RCA should not be undertaken if the incident involves a criminal act, a deliberately unsafe act, substance abuse or deliberate patient harm or abuse.

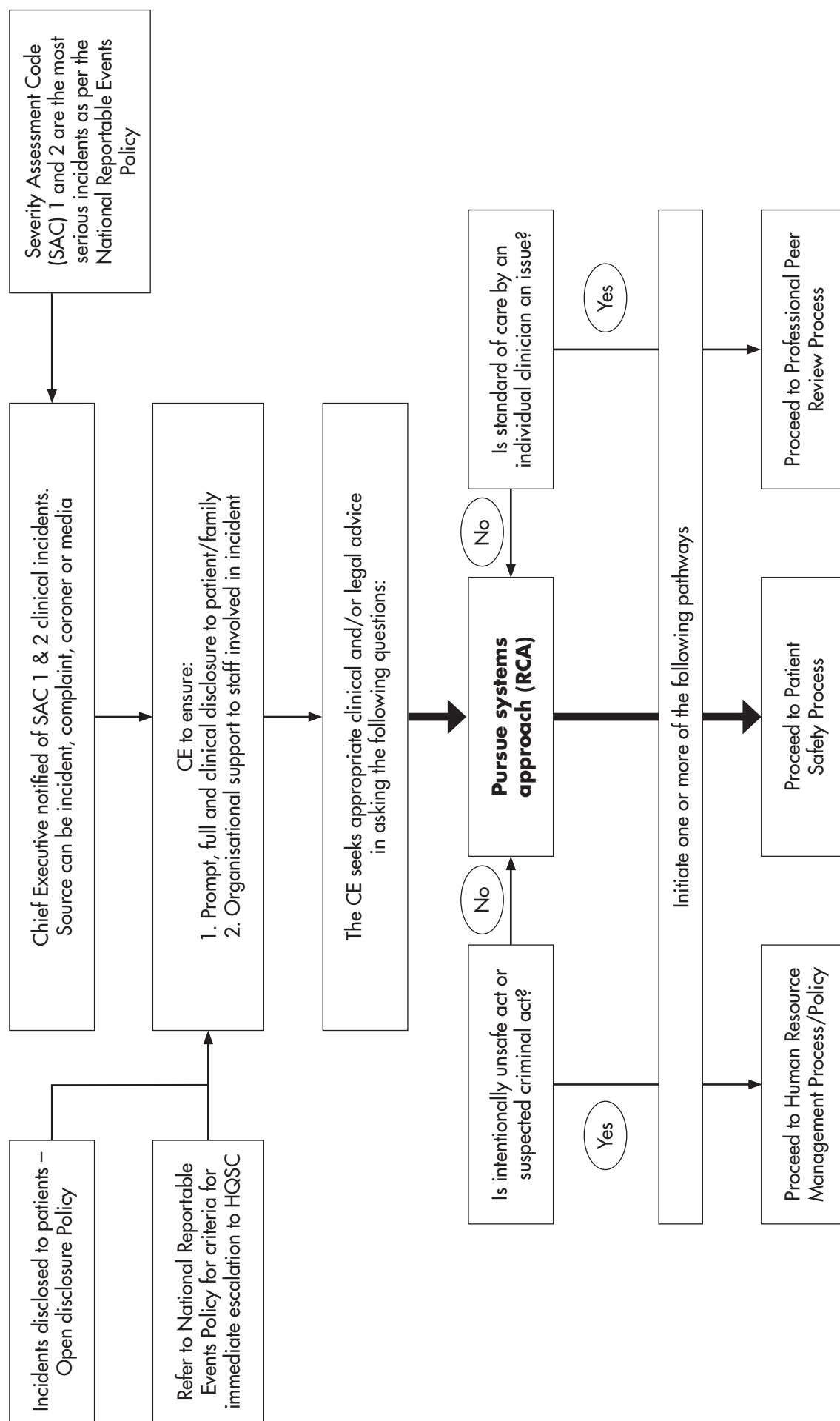
There are circumstances where individual culpability must be considered. The following tools will assist with decision making.

(a) Diminishing culpability flow chart (source: James Reason)



Substitution test: Ask the individual's peers: 'Given the circumstances at the time, can you be sure you may not have committed a similar unsafe act?'

(b) Tool to assist decision making (adapted from Whanganui DHB model)



4. Notification and escalation process

A documented local process is required that clearly articulates how to notify, by when and to whom.

The document needs to cover all level of incidents and ideally it will be accompanied by an accountability table so all staff understand their role.

This process may differ between organisations, but the essential requirements are the same.

Timeframes

Day 1	Receipt of incident notification (incident may have happened in the past and may not necessarily be the same day as notified). The clock starts ticking from the day documentation of the event is received.
Within 10 working days	A SAC rating must be assigned.
Within 15 working days	Send Part A Reportable Event Brief (REB) to HQSC for all SAC 1 and SAC 2 incidents.
Within 28 working days	Review of SAC 3 and SAC 4 incidents should be completed.
Within 70 working days	Root Cause Analysis (RCA) investigations must be completed for all actual SAC 1 incidents. Send a copy of Part B of the REB to HQSC. Investigations carried out for actual SAC 2 incidents must be completed. Send a copy of Part B of the REB to HQSC.

5. Commissioning an RCA

All RCAs must be commissioned by the Chief Executive or a delegate who has authority to sign off the final report. This may take the form of nominating a person to be responsible for overseeing the conduct of the RCA including the formation of the team or actually specifying the team.

The following are examples (a), (b), and (c) of commissioning documents:

(a) RCA commissioning document (adapted from Whanganui DHB)

ROOT CAUSE ANALYSIS COMMISSIONING DOCUMENT	
As the Commissioning Authority for the <i>(insert name)</i> District Health Board, I authorise the appointment of a Root Cause Analysis (RCA) Team to conduct an investigation into the following Reportable Event	
Incident Number:	Date event occurred:
Brief description of event:	
I authorise the following employees to undertake a RCA for this event:	
Team Role	Name
RCA Team leader	
Team Member	
The authorised RCA team will:	
• commence a Root Cause Analysis • determine the root causes and contributing factors for this Reportable Event • recommend a corrective action plan • provide a report to me within 70 working days from notification of event.	
AUTHORISATION	
Commissioning Authority Name: _____	
Signature: _____	Date: _____

(b) Memo for commissioning an RCA (adapted from Canterbury DHB)

MEMO

TO: *(Designated person responsible for convening RCA teams)*

FROM: *(CE or CE delegate)*

DATE:

SUBJECT: Commissioning an RCA Investigation for a SAC (1 or 2) Clinical Incident

Please convene an RCA team to determine the root causes and contributing factors relating to the clinical incident recorded below:

Patient name: _____ NHI: _____

Event date: _____

I have designated _____ to maintain regular contact with the patient and/family until the investigation is complete.

As part of the RCA process, the team will be responsible for developing a final report and recommendations within 70 working days from notification of event. All RCAs are quality activities and focused review processes, and the team's products will be viewed in that manner.

Note: If in the course of conducting the RCA it appears that the event under consideration was the result of:

- A criminal act
- An intentionally unsafe act
- An act related to alcohol or substance abuse of an impaired provider or staff member or the event involved alleged or suspected patient abuse,

the RCA team are to discontinue their work and contact me in order that investigation of the event can be conducted within a disciplinary pathway.

Signed: _____

(c) Terms of reference for review template (adapted from Capital & Coast DHB)

TERMS OF REFERENCE – (Patient Name)

Review of the care and treatment provided to (patient name) by Capital & Coast District Health Board on (date).

To the review team: *(List Review Leader and team members' names and roles)*

Purpose of Review:

This review is part of Capital & Coast District Health Board's (C&C DHB) ongoing commitment to improve and protect the health and safety of patients and the public, and to ensure the effective conduct of C&C DHB's affairs by:

- ascertaining as far as practicable the factual circumstances surrounding the health care incident
- recommending any further action C&C DHB should take as a result of this event.

This review is simply to find out and record what happened and to make recommendations as to any further action required. The purpose of the review is not to enquire into individual responsibility or to attribute blame. It is not a disciplinary inquiry. Wherever possible, the review and recommendations should be focused on systems rather than individuals. In the event that any issues concerning individuals' conduct are identified, a separate review may be carried out. A decision will be made on what, if any, further action or review is warranted after the review report has been received and considered.

Background to Review:

(Executive Director[s]) have asked for an internal review into the circumstances of the care provided to *(patient name and NHI)/work activity/health & safety controls (staff event)*. Please enquire, as below, and report to *(Executive Director[s])*.

Overview:

The Review Team will investigate and report on the factual circumstances surrounding the clinical care and treatment of *(patient name)* at *(specify e.g. Wellington Hospital or while a client of the X Service)* on *(date[s])*. The Review Team will make recommendations on any further action that C&C DHB should take as a result of this incident.

Terms of reference:

(These will vary and be specific to the event and should address systems, processes and human factors. These may include determining what happened in relation to normal policy/process, communication, staffing and skill mix, standard of care, equipment, environment, support systems, etc. These should NOT be worded in a way that directs the review team to consider the performance of individuals.)

1. Ascertain as far as practicable the circumstances surrounding the health care incident including:
 - (a) Providing a chronological overview of the care provided to *(name)* relevant to the health care incident;
 - (b) *Other[s] specific to event*
2. In terms of the health care incident:
 - (a) To make an assessment of the most likely causative factor(s)
 - (b) *Other[s] specific to event, e.g. to review and document subsequent progress and prognosis for recovery*
3. Recommend any further actions C&C DHB should take as a result of this review.

Steering group:

The steering group who oversee the review process and receive the final report. They are:

(Bullet list members – core membership comprises Executive Director[s], Patient Safety Officer, Legal Counsel and Quality and Risk Manager, may also include members of HHS Clinical Governance or COO as indicated)

Steering group and review team support:

The person supporting this review is *(name and role, e.g. Quality Manager/Facilitator)*.

Signed:

(Usually signed by commissioning Executive Directors).

(Name) _____ (Name) _____

(Role) _____ (Role) _____

(Directorate) _____ (Directorate) _____

Capital & Coast DHB

Capital & Coast DHB

Signature: _____ Signature: _____

Date: _____ Date: _____

INSTRUCTIONS TO REVIEW TEAM

Instructions to Review Team Members for an investigation of a health care incident that involved *(patient name)*.

Background

This review follows an incident involving *(patient name and NHI)*.

Methodology

The inquiry into what happened will use the root cause analysis methodology, be at the discretion of the review team, and may include:

- Interviews with relevant staff (whether employed by C&C DHB or otherwise) and other relevant parties. This may include the patient/family.
- Reference to all relevant documents, including medical records and reports.

Process

- For all SAC 1 and SAC 2 incidents and near misses you must complete Part A of the Reportable Event Brief and send this to the Health Quality & Safety Commission within 15 working days of being notified of the event.
- Develop a draft report. Send the draft to Legal Services and Patient Safety Officer for pre-circulation check.
- Circulate the draft report to those interviewed and other relevant people for factual correction and comment. It is important to ensure that all review participants have access to the draft report as it relates to them and are given a reasonable opportunity to comment.
- Take all feedback into consideration in development of the final report.
- Send the final report to Steering Committee.

Conduct of Review

The review will be conducted in a fair and reasonable manner which provides all affected parties with an opportunity to respond freely and frankly. Identifiers (not the names of any individuals) are used in the body of the report. The patient's name and the names of the review team members are written on the cover of the report.

The review is to be conducted strictly in accordance with the terms of reference and in line with the National Policy for the Management of Health care Incidents. Any deviation from the terms of reference must only occur with the consent of *(Executive Director[s])*.

External Release of Review Report by C&C DHB

C&C DHB will only release the review report in accordance with legal requirements (e.g. Privacy Act, Health Information Privacy Code, Official Information Act, and Health and Disability Commissioner Act).

The usual process includes release of the terms of reference and report (or Part B of the REB) to:

- Appropriate persons within C&C DHB, including those who participate in the review.
- The patient or family (as relevant).
- The Coroner, the Health and Disability Commissioner and/or Ombudsman in accordance with the law.
- The Health Quality & Safety Commission (for all SAC 1 and SAC 2 incidents and near misses).

Actions Subsequent to Review Completion

(Executive Director[s]) will make a decision on what, if any, further action or review may be warranted after considering the final report.

Timetable

Review to be completed and draft report available by: *(date in bold)*

Final report by: *(date in bold - < 70 working days from notification of event)*.

In the event that the review cannot be completed by this date, the investigators will report to the Steering Group to request an extension of time.

Review Team

To consist of the following people: *(Bullet list Review Leader and team members)*

6. Support for staff

Staff are often very traumatised when involved in a health care incident and normal DHB systems for staff support should be accessed.

7. Communication with the patient and patient's family

POLICY STATEMENTS:

Transparency and open disclosure

Consumers and their families are entitled to truthful and open disclosure. They will be told what went wrong, why it went wrong and they will be offered an apology. Feedback to consumers and staff reporting incidents is important.

All health and disability sector organisations will openly disclose health care incidents in line with the Health and Disability Commissioner's statement on open disclosure.

Definition for open disclosure (OD)

A transparent approach to responding to an incident/adverse event that places the consumer/resident central to the response. This includes the process of open discussion and ongoing communication with the consumer/resident and their support person(s). An OD approach also includes support for staff and the development of an OD culture where staff are confident that the associated investigations will have a quality improvement rather than a punitive focus.

See the National Policy on Management of Health care Incidents (2011) for more information.

Communication with the patient and/or the patient's family includes:

- immediate contact
- formal contact / open disclosure
- obtaining information / interviewing
- ongoing updates
- delivery of investigation findings.

Where serious harm or death of a patient has occurred an open disclosure process must be followed. The responsibility for this will be determined on a case by case basis. Open disclosure includes the following:

- an acknowledgement of what has happened
- an honest and genuine apology for the harm that has resulted
- listening to the patient/family concerns
- a factual and understandable explanation of what happened
- an outline of the potential consequences
- an outline of the investigation process being undertaken
- the safety and quality aspect of the review process should be emphasised so that the patient and/or their family understand that it is about making care safer, not finding someone to blame
- confirmation of a contact person and that "the door is always open" for further information and clarification
- information on their rights to make a formal complaint, to access advocacy and ACC
- information of support services provided by social workers and/or other trained support workers who can provide emotional support, help to identify issues of concern, support the patient/family at meetings with staff and information about appropriate community services.

As part of initial contact a letter may be sent to the patient/family. Please see example (a) below.

Regular ongoing contact with the patient/family should be maintained by a nominated person. This provides the opportunity to give regular updates and for the patient/family to raise any issues.

Detailed information about obtaining information (including a Sample Guide to Conducting Interviews) and the delivery of investigation findings to the patient/family is provided in Section 10 (overview of RCA investigation process).

(a) Sample letter to patient (Counties Manukau DHB)

(date)

(CE or CE delegate)

(Hospital)

(DHB)

(Address)

Dear *(patient name)*

I understand that you (are currently / were recently) receiving care at *(Hospital)*, and that during your stay *(brief description of what happened)*. I believe that *(name)* has already spoken to you about what happened *(if appropriate: and I wish to reiterate that (DHB) is very sorry for any distress that the event has caused you)*.

(DHB) is serious about the quality of care it provides and the safety of patients receiving treatment from our organisation. We routinely undertake in-depth investigations into events where the quality of care or level of safety may not have been consistent with the standards that both staff at *(DHB)* and the wider community expect, and where this may have resulted in serious harm to a patient during their stay at *(Hospital)*.

I am writing to inform you that we have initiated an investigation into the events that occurred during your stay here at *(Hospital)*. The investigation is being undertaken by a senior team who have training and experience in conducting such investigations and is overseen by our Serious and Sentinel Events Committee which meets each two weeks to review such incidents.

The purpose of the investigation is to find out what happened and why it happened so that, if possible, we can take appropriate action to reduce the likelihood of a similar event occurring in the future. The focus is on the underlying systems of care and does not set out to 'blame' any individual or groups of individuals. Understanding how the systems that are in place can contribute to poor or unsafe care helps us build safer systems of care for patients.

The DHB will keep you informed about the progress and the outcome of the investigation. We are happy to arrange a meeting with you and / or your family to discuss any concerns or questions you may have.

The person who is the primary contact person for you during this investigation is:

(Name)

(Contact details)

I would also like to inform you that each year District Health Boards are required to report serious incidents to the Health Quality & Safety Commission, and this information is then released as a public report. Depending on the outcome of our investigation, your case may be included in the next report, due for release around *(date)*. Please be assured that no names or details that could identify you will be included. If your case is going to be included, you will be sent another letter closer to the time informing you of the exact date of the release.

For your information we have enclosed a pamphlet from the Health & Disability Commission that sets out your rights.

Please don't hesitate to contact *(Name)* if there are any issues you would like to discuss.

Kind regards

8. Selecting the RCA team

A team should ideally comprise of 2 – 6 people. An RCA should not be conducted by a single person.

It is important to identify team members with multiple skills and the time to commit to the process. Typically a range of expertise is required and may be achieved by including people with:

- knowledge of the area(s), system, specialties, profession
- senior responsibility in the area
- investigation experience
- senior management experience.

It is recommended that patient advocates and/or consumers are included on the team. A team leader should be appointed who is experienced in undertaking RCAs, skilled at group dynamics and has the ability to delegate and build consensus.

A table can be used to record the team member selection process, as shown below.

Team member selection table (South Canterbury DHB)

What expertise is required?	Who fits this role?	Selected to participate

9. Guide for RCA team members

'Just in time' training will be required for members of the RCA team who have not participated in incident management training. Included are examples (a) and (b) of team information that can be adapted for local application.

(a) A guide for RCA team members (adapted from Counties Manukau DHB)

Lead investigator	
Action	Notes
Notify any relevant external organisations	Check appropriate organisations notified (Health Quality & Safety Commission, Dept of Labour, ACC, Coroner)
Manage investigation team	- Ideally 3-5 people with some training or experience in investigating incidents Can include a consumer (recommended) - Do not include people involved in the incident or the manager responsible for the unit where the incident occurred - Include appropriate senior clinicians and managers and / or staff familiar with the unit or department - Establish ground rules for conducting the investigation
Oversee investigation process	- Ensure confidentiality and integrity of the investigation - Oversee interview process – - Agree the appropriate people to do the interview - Ensure interviewers are clear about the process - Ensure interviewees are informed and clear about review principles
Complete final report	- At the conclusion of the investigation process, compile a report and circulate to all relevant people for comment - Complete final report

Investigation Facilitator	
Action	Notes
Schedule and manage meetings	- Schedule any meetings that need to take place as part of the investigation process - Keep log of meetings held
Manage timeline	Track review progress against timeline
Collect and track relevant documentation	- Establish document tracking system to keep documentation in order - Keep documents in secure location - Ensure confidentiality is maintained by the team.
Track the interview process	- Arrange interviews with staff - Collate relevant documentation
Write up investigation processes	- Write narrative of case - Complete flow diagram - Complete cause and effect diagram
Complete draft report	- Complete draft report using appropriate RCA template - Circulate to team for comment - Send completed final report for SSE review

Team responsibilities	
Action	Notes
Participate in team process	- Attend all meetings - Between meetings, complete tasks as agreed at meetings
Act with integrity	- Respect confidentiality of the process and persons involved - Take appropriate actions to maintain confidentiality and security

(b) Sample information pamphlet for RCA team members (adapted from Whanganui DHB)

ROOT CAUSE ANALYSIS (RCA) – A GUIDE FOR RCA TEAM MEMBERS

You have been asked to be on a RCA Team

This leaflet provides you with information about the Root Cause Analysis (RCA) process and outlines your responsibilities as an RCA Team Member. It is intended as a guide only. If you would like further information contact xxx

What is a 'Reportable Event'?

Any event that meets the severity assessment code 1 and severity assessment code 2 definitions under the New Zealand Health and Disability Services – National Reportable Events Policy. All reportable events require a Reportable Event Brief which is the form used for reporting.

What is a Root Cause Analysis?

A RCA is a systematic process used to determine:

- what happened
- why it happened, and
- what can be done to prevent reoccurrence.

What is a RCA Team?

A RCA Team is a group of people appointed by the Chief Executive (CE) with advice from senior clinicians and managers to analyse the events that led to the reportable event. The people appointed to the RCA Team would have the skills, knowledge and experience to participate in a RCA and would not be directly involved in the provision of the health services associated with the event. The HQSC recommends including a patient advocate and/or consumer on the team.

Why have I been asked on to the RCA Team?

Your role on the team will generally fall into one of four categories:

- content expert
- front-line worker
- technical RCA expert
- you are an unrelated area and can provide an objective or 'fresh' view.

When is a RCA not appropriate?

RCA is not the appropriate tool for investigating:

- the professional competence of individual clinicians in relation to the reportable event
- finding out who is to blame for the happening of the reportable event
- investigation of alleged 'Blameworthy Acts' or a criminal offence.

What is a blameworthy act?

A blameworthy act is:

- an intentional unsafe act
- deliberate patient abuse and/or
- conduct that constitutes a criminal offence.

What does the RCA Team do?

The role of the team is to analyse the event to determine what happened, why it happened and make recommendations to prevent similar events. The RCA Team reviews the medical record of the patient, interviews staff and any other relevant people (including the patient), and reviews relevant policy, procedure and standards. The team may also conduct site visits to the physical location where the health care incident occurred to gain a better understanding of what and why the event happened.

What obligations do I have as an RCA Team member?

- Utilise your skills, knowledge and experience to undertake a thorough analysis of the incident.
- Assist in the preparation of an RCA Report that contains a description of the event, the root causes and contributing factors that the team consider led to the event and recommendations that will prevent it happening again.
- Maintain strict confidentiality in relation to the conduct of the RCA.

What if the RCA Team members cannot agree on findings?

It is normal for differences of opinion to arise during an RCA. It is the job of the RCA Team Leader to manage any disagreement. In many cases, this can be resolved with consensus being reached. If agreement cannot be reached, a dissenting opinion can be included.

Can I discuss the RCA with colleagues?

No - strict confidentiality provisions exist in relation to RCA information. You should only talk about the event with the RCA Team members or in the context of any interviews you conduct as part of the process.

Why should I take on this role?

As a member of an RCA Team you have an opportunity to contribute to improved patient safety by assisting the xxx District Health Board to learn from health care incidents. Many RCA Team members also report a better understanding of the health care system, the work of colleagues and communication. For many, this leads to changes in their own attitudes and practice behaviours. You will be contributing to a safe, open environment where systemic problems can be identified and addressed.

10. Process – ways to conduct an RCA investigation

The investigation processes are outlined in the New Zealand Incident Management System Training Manual. On the following pages are examples (a), (b), (c), (d) and (e) of tools and guidelines that may be used to assist with the process.

(a) Sample investigation schedule (adapted from Counties Manukau DHB)

Investigation Process				
Timeline	Action	Key Tasks		Reference docs / templates
Week 1	Division assembles investigation team	Identify investigation lead with overall responsibility (senior clinician or manager) Appoint case coordinator if appropriate to manage the process/administration Schedule and conduct initial meeting as soon as possible Clarify expectations/responsibilities and timeline (final report to be completed within 70 working days)		Lead/Team responsibilities Gantt Chart
Week 1	Initial meeting	- Roles and purpose of RCA understood by all - Team ground rules understood by all - Case coordinator provides brief synopsis of the case - Brief flow chart constructed (what happened) - Identify what you do and don't know: - What additional documentation is required - Who needs to be interviewed - Other information required (expert opinion, literature etc)		Brief flowchart template
Week 1-2	Communicate with patient/family	Notify family that the incident is being investigated - Discuss with senior clinicians when it would be appropriate to make initial contact with the family - Establish primary contact person for family - Identify additional support that may be needed for the family		Guide to communicating with patients and families Communication log Letter template for patients Open disclosure policy
Week 2-4	Information gathering	Documentation - Report event including Part A REB (sent to HQSC) - Medical record/test results - Relevant policies and procedures - Photos	- Equipment - Staff rosters - Evidence of hospital/ward status at the time - Relevant literature	Documentation tracking
Week 2-4	Information gathering	People - Identify key personnel who can give you critical information - Agree who will conduct interview	- Arrange meeting times with staff members concerned and send letter/email to confirm - Ensure staff and patient fully understand the principles of the review process	EAP Information for Staff Letter template to notify staff Interview tracking document Interview guide Interview template

Week 4-5	Analysis: what happened?	- Review information from all relevant sources - Construct detailed flow diagram – identify each box with Date/Day/Time if possible - Write narrative account of incident adding additional information from interview to provide context - Identify barrier points in flow diagram	Use Visio for detailed flow diagram
Week 4-5	Analysis: why did it happen	- Construct cause and effect diagram based on barrier points as primary causes - Use five why's/fishbone diagram to identify the causal pathway - Write causation statements (refer to five rules for causation statements)	Framework for identifying contributing factors Five Why's/fishbone diagram
Week 5-6	Develop recommendations/ action plan	- Focus on 'strong' actions that address identified root causes - Note person/responsible and timelines	Table of recommendations
Week 6-7	Write draft report	- Complete draft report and circulate to those involved in the investigation - Review and edit report accordingly	Guide to writing reports Investigation Report Template
Week 8	Report presented to SSE	- Preliminary review at SSE QF meeting for preliminary review - Final report presented to SSE for endorsement of action plan - RCA signed off by CEO/SSE DR report signed off by CMO - Part B REB sent to Health Quality & Safety Commission (all SAC 1 & SAC 2 events and near misses) - Action plan referred to appropriate delegated manager/clinical leader - Action plan logged for follow up to ensure actions are completed	
Week 8-10	Complete final communication with patient/family	- Present report/summary of report to patients/families (as appropriate) - Provide an opportunity to discuss the report findings - If incident to be included in the National Release – notify family	Notification letter to patients re inclusion in National Release.
Week 10-12	Follow up action plan	Follow up with appropriate person to ensure action plan carried out and systems in place to sustain the change	

(b) Gantt Chart/planning calendar (adapted from Counties Manukau DHB)

Check	Week ending	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Initial Tasks															
	Establish team (minimum 2-3 people)															
	Schedule initial meeting															
	Notify relevant people															
	Initiate communication with family															
	Write brief synopsis															
	Information gathering															
	Develop brief flow chart															
	Identify documentation required															
	Identify interviewees															
	Send Part A REB to HQSC within 15 working days															
	Conduct interviews															
	Collect additional information															
	Analysis															
	Causation statements															
	Recommendations/actions															
	Complete and circulate draft report															
	Check feasibility of action plan															
	Complete final report															
	CEO/CMO Sign off															
	8 week Timeline															
	Action plan to appropriate personnel															
	Final meeting with patient/family															
	Send Part B REB to HQSC within 70 working days															

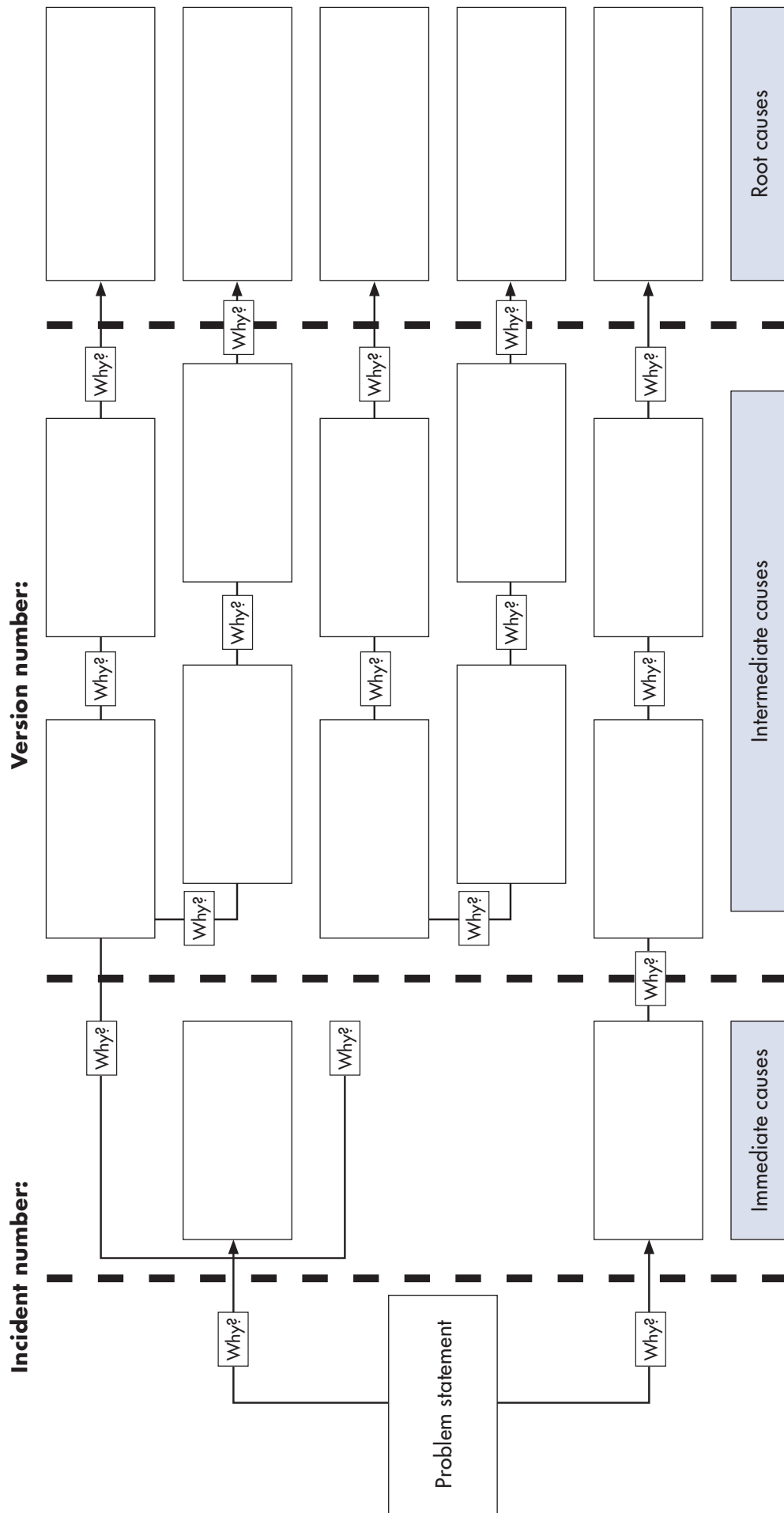
(c) Sample instructions for first RCA Team meeting (adapted from South Canterbury DHB)

FIRST MEETING PROCESS

1. Provide brief overview of RCA process
2. Introductions
3. Set meeting rules
4. Select a scribe (use post-it notes and felt tip pens - this will assist in recording steps as you proceed)
5. Give an overview of the case – have available incident report, clinical records etc.
6. Construct a simple flow diagram – 4 to 6 boxes outlining the chronology of events that lead to the incident (sometimes easier to start at the end and work backwards). Include only the major key points across the timeline (end point may be consequence of the action).
7. Brainstorm as a group key questions or things you would like to know about the sequence of events
8. Use the Initial Checklist Flip Chart
9. Work through each box of the flow diagram – identify questions outlining what you don't know before, during and after each event
10. Phrase questions in terms of 'how', 'what' and 'why' – if you ask a 'who' question, you need to rephrase it because the RCA process is not about assigning blame, but understanding the root cause of the incident
11. Build on your simple flow diagram outlining the how, what and why questions to develop an intermediate flow diagram
12. This process identifies what you know and what you don't know and what you need to find out – have you asked enough questions?
13. Utilise other tools such as Time Person Grid, Reverse Chronological Time Line etc.
14. Identify who you need to talk to and who is going to talk to each person
15. Identify what additional information you need and who is going to collect it (policies, literature reviews etc)
16. Develop an action plan with responsibility and timelines for gathering the required information

Schedule next meeting

(d) Causal chain diagram (Whanganui DHB)



(e) Sample guide to conducting interviews (Counties Manukau DHB)

Guide to conducting interviews	
Initial contact	- Initial contact to request a meeting should be by phone rather than letter - Make sure they are fully briefed about the purpose of the investigation and that they understand that the interview is about hearing their perspective of events, not about attributing blame - Reassure them about anonymity - Inform them they may bring a support person. It is important that the support person doesn't interrupt the interview as this may interfere with memory recall
Setting	Relaxed and private
Transcribing the interview	- Best to have one person to conduct the interview and another person to record the conversation - The interviewee must agree to having the conversation recorded - On completion of the interview the interviewee should be provided with an accurate transcript of their interview and given the opportunity to read and make any amendments before signing it
Conducting the interview	- Explain the purpose of the interview - Allow the interviewee to tell their account of events without interruption. - Share your understanding of the interviewee's story with them before asking questions - Ask questions in the order the story is presented – this helps information retrieval - Don't rush the interview – this allows time for the person to recall events - Avoid using judgmental comments, as this will make the interviewee defensive
Establish incident chronology	- Identify role of person in incident - Generate a chronology of the incident with times
Identify contributory factors	- Explain concept of contributing factors - Use prompts to systematically explore contributory factors
Close meeting	- Allow person to ask any questions - Meetings should only take 20-30 minutes

11. Preparing the final report

The following are examples (a) and (b) of final report templates.

(a) Sample final report (adapted from Whanganui DHB)

ROOT CAUSE ANALYSIS (RCA) REPORT CONFIDENTIAL COVER SHEET	
Title	
Date of Incident	
Incident Number	
Commissioned by	
Report Date	
Distribution	Family Date _____ Health Quality & Safety Commission (send Part B REB) Date _____ Other agencies who may enquire into this event: _____ _____ _____

(b) Sample final report (adapted from Whanganui DHB), continued

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Summary

(Insert details of the event here)

The RCA Team, after considering all these factors, identified a number of root causes, and contributing factors that the team believed directly increased the likelihood that *(insert details of event)* could occur.

The recommendations are directly connected to the root causes/contributing factors identified and were supported by all the team in the belief that if implemented the recommended changes would decrease the risk for future patients.

Introduction

This report provides an account of the Root Cause Analysis undertaken into *(insert description of incident)*. The report outlines the analysis process and methodology, the findings and the RCA's team's recommendations. This report records what happened, why it happened and what can be done to prevent the harm occurring again. The RCA focuses specifically on systems and process issues within the domain of *(DHB)*'s responsibility.

The report is, in part, intended to ensure that actions that could be taken to prevent future harm are clearly documented and able to be shared with other relevant health service providers. Future service improvements can then be measured against these recommendations.

Most importantly, this report also contributes to the process of open disclosure for the family and will be shared with the family.

Part B of the REB will be submitted to the Health Quality & Safety Commission in accordance with the National Reportable Events Policy once the recommendations are endorsed by the Chief Executive, and within 70 working days of notification of the incident.

The RCA Team

The RCA was led by *(enter team Leaders title)* of *(DHB)*. The team members were:
(only position descriptions listed do not use staff names).

Objectives of RCA Team

The RCA's Team's objectives were to:

- establish what happened
- why it happened
- identify systemic contributing factors and root causes of the incident
- formulate recommendations and a final report *(insert details of event)*
- present the final report to the Chief Executive for endorsement and distribution
- when signed off by the Chief Executive, forward Part B of the REB to Health Quality & Safety Commission to include in the national repository (for SAC 1 and SAC 2 actual incidents and near misses).

Methodology

As *(incident)* was classified as a SAC 1 event, a Root Cause Analysis Team was commissioned by The Chief Executive on *(insert date)* which is in accordance with the National Reportable Events Policy.

The RCA Team gathered information via:

- Examination of patient's health record
- Review of policies and procedural guidelines.
- Review of the literature related to best practice relating to the incident type
- Information and suggestions for improvement from nursing, medical staff and educators.
- Sourcing best practice available information.

All information gathered was discussed and documented to enable the team to identify factors and/or system barriers/root causes that may have increased the likelihood that *(insert event description)* would occur.

Findings

(Insert summary of findings)

Recommendations

Recommendations were formulated from these findings.

Number 1: Causal Statement

Recommendation	Who is accountable?	Timeframe	Evaluation

Number 2: Causal Statement

Recommendation	Who is accountable?	Timeframe	Evaluation

(Insert additional causal statement as necessary)

In addition to these recommendations based on the root causes, a number of findings were identified by the team. These can be considered lessons learnt as they most likely did not directly contribute to the harm in this case.

Additional findings (not Root Causes)

(Insert lessons learned)

Recommendation of Team regarding lessons learned

That these findings be discussed with the Professional Advisors of Nursing and Medicine by the RCA Team Leader with the expectation that the findings be considered, discussed with peers and integrated into safety improvement activities. Progress reports on these improvement activities will be provided to Clinical Governance.

In Conclusion

(Insert conclusion)

Finish with expression of sympathy to the family for their loss.

(c) Sample report template and writing guide (adapted from Canterbury DHB)

ROOT CAUSE ANALYSIS REPORT AND WRITING GUIDE

Date of Event: (or month if no specific date is appropriate)

DHB Event Reference #: (supplied by Corporate Services)

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Introduction

This section should contain the following:

- a brief summary of the clinical incident (including the date of the event)
- high level synopsis of sequence of events.

Note: Aim for no more than one page

The patients name should be referred to by name not initial

Review Team

This section contains the names and roles/titles of the review team. This is the only time staff names appear in the report. All other references to staff members should be by title only (eg. Nurse A, Doctor B).

Expertise provided	Staff involved
Clinical opinion	
Process support	
Legal opinion	

Methodology

A statement to explain the purpose of the review is included for the readers.

This Clinical Incident was investigated using the Root Cause Analysis (RCA) methodology.

The overall purpose of a RCA is to determine the underlying causes of an event and to identify ways of improving the systems of care and preventing recurrence of a similar event (or similar events).

Information reviewed

Information for the review was sourced from:

List all the high level information that was reviewed as part of the investigation eg clinical record, policy and procedure, discussions with key staff.

Background

This section is only required if it is necessary to provide context around the event that would not normally be part of the Introduction or the Sequence of Events sections.

Sequence of events

This should be brief, factual, relevant to the actual event and describe what happened. A sequence of event flowchart is included in this section.

The findings

Describe the findings of the review team including what was appropriately undertaken. The findings should validate the appropriateness of actions that occurred during the sequence of events. Not all the findings will be linked to a causal statement and appropriately may be included in Section 9.0: Other issues identified.

Causal statements

The five rules of causation are designed to improve the RCA process by creating minimum standards for structuring a causal statement. The rules are created in response to the very real biases we all bring to the investigation process.

Rule 1: Clearly show the cause and effect relationship.

When describing why an event has occurred focus on showing the link from your root cause to the undesirable patient outcome you are investigating.

Example:

Wrong: The House Physician was fatigued.

Correct: House Physicians are routinely scheduled for 80-hour work weeks; as a result, the fatigued house physicians are more likely to misread instructions, which led to the incorrect tube insertion.

Rule 2: Use specific and accurate descriptors for what occurred, rather than negative and vague words.

To force clear cause and effect statements (and avoid inflammatory statements), we recommend against the use of negative descriptors, in place of a more accurate, clear description.

Example:

Wrong: Poorly written manual.

Correct: the training manual was not indexed and used a font that was difficult to read; as a result the manual was rarely used and did not improve performance by the operators.

Rule 3: Identify the preceding cause(s), not the human error.

You must investigate to determine WHY the human error occurred. It can be a system-induced error (eg step not included in medical procedure) or an at-risk behaviour (doing task by memory, instead of a checklist). For every human error in your causal chain, you must have a corresponding cause. It is the cause of the error, not the error itself, which leads us to productive prevention strategies.

Example:

Wrong: The physician made a dosing error.

Correct: Due to no automated software to check the dosing limits and lack of cognitive aids on dosing, there was a likelihood of this dosing error which resulted in ten times the dose being administered.

Rule 4: Identify the preceding cause(s) of procedure violations.

Procedural violations are like errors in that they are not directly manageable. Instead, it is the cause of the procedural violation that we can manage. If a clinician is violating a procedure because it is the local norm, we will have to address the incentives that created the norm. If a technician is missing steps in a procedure because he is not aware of the formal checklist, work on education.

Example:

Wrong: The techs did not follow the correct procedure for CT scans.

Correct: Noise and confusion in the prep area and production pressure to quickly complete CT scans increased the probability of missing steps in the protocol resulting in an air embolism by the use of an empty syringe.

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

We need to find out why this mishap occurred in our system as it is designed at the time of the event. A doctor's failure to prescribe a medication can only be causal if he was required to prescribe the medication in the first place. The duty to perform may arise from standards and guidelines for practice; or other duties to provide patient care.

Example:

Wrong: the nurse did not check the stat orders every half hour.

Correct: The absence of an established procedure for nurses to check the stat orders on the printout created the possibility of urgent orders not being administered. This resulted in the bolus administration of the medication not being administered.

Recommendations arising from causal statements

Recommendations can be made for what is optimal practice even if not achievable right now. If they are not, state what interim measure will be put in place to minimize the risk.

Number according to section	This should be a clear recommendation stating what action is to be undertaken. Responsibility: State who is responsible. Timeframe: When the recommendation will be completed.
-----------------------------	--

Other issues identified

If other non causal issues are identified they should be recorded here.

Recommendations arising from other issues identified

Number according to section	This should be a clear recommendation stating what action is to be undertaken. Responsibility: State who is responsible. Timeframe: When the recommendation will be completed.
-----------------------------	--

12. Finishing the report

The draft report must be provided to all relevant parties involved in the incident for factual accuracy check. Those responsible for implementing the recommendations should have input into them at the draft stage.

When finalised, the report should be forwarded to the individual who commissioned the RCA for sign off and approval of the recommendations. Any decision to decline to accept a recommendation should only be made by the Chief Executive unless this authority has been formally delegated. An example (a) of a sign off template follows.

When signed off, a copy of Part B of the REB should be sent to Health Quality & Safety Commission which is the national repository for all SAC 1 and SAC 2 reportable events.

(a) Memo – completion of RCA report (Canterbury DHB)

(Logo)	(Address 1) (Address 2) (Address 3) CHRISTCHURCH
(Division)	Internal extension: Telephone: (03) Facsimile: (03) Email:
MEMO	
TO:	(GM or CE delegate)
FROM:	(RCA Team Leader)
DATE:	
SUBJECT:	Completion of RCA Report – (Organisational Identifier for Incident)

Please find attached the RCA Report¹ relating to:

Patient name	
NHI	
Organisational identifier	

The report contains the following the recommendations for your approval:

Recommendations	Approved (Initial)	Declined (referred to CE)
Recommendation: Responsibility: Timeframe:		
Recommendation: Responsibility: Timeframe:		

Issues identified	Approved (Initial)	Declined (referred to CE)
Issue: Responsibility: Timeframe:		
Issue: Responsibility: Timeframe:		

The RCA team would appreciate your confirmation or otherwise of these recommendations.
Reasons for not implementing any recommendations of the RCA must be included in Part B of the REB.

¹ Copies of the RCA Report and this memo should be filed in the RCA file for this incident.

13. Implementation and monitoring recommendations

Recommendations must be time-framed, measurable and allocated to a specific person.

Local procedures need to be in place to track the implementation of all recommendations. Examples (a) and (b) of templates for undertaking this follow.

A summary of the findings and recommendations of all SAC 1 and SAC 2 event reviews must be sent to the HQSC within 70 working days from the date the adverse event was reported. This summary must include an outline of the actions agreed by the Chief Executive Officer, Chief Medical Officer or Chief Nursing Officer (or the equivalent senior personnel), or the reasons for not implementing the recommendations of the RCA.

(a) Example of template from recommendations database (Whanganui DHB)

Instructions on how to complete this spreadsheet

Update/Status (Completed or Not Completed) Column

- 1. Please write C for (Completed) or NC for (Not Completed) in the Update/Status (Completed or Not Completed) column.
- 2. If not completed please state the reason/s and the date to be completed in the Comments column.
- 3. If complete please state the date completed and by whom in the 'Final date to be completed/by whom' column.

Action source	Recommendations	Accountable person/s	Due dates	Status (Completed or Not Completed)	Comments	Date to be completed/by whom

(b) Example of action log template (Counties Manukau DHB)

Title: (One line)		Exec sign off: / / Name: Signature:	
CASE ID:	Incident date:		
Brief summary:			
Investigation:	Services:	Lead:	SAC: Event code:
Report date:	SSE endorsement:	National release:	Patient letter date:
Root causes			
1:			
2:			
3:			
4 :			

Action log		File owner:		
Case ID:		Case closed date:		
Root cause	Actions	Responsibility	By when	Completion date
1				
2				
3				
4				
Other				
Organisational learning/alerts:				
Comments				

14. Distribution/communication of the final report

Once the final report and recommendations have been signed off by the commissioning officer a communication plan needs to be put in place. A checklist is helpful to ensure all parties are included in the communication, for example:

- patient/family
- initial reporter
- staff from area where incident occurred
- those responsible for implementing the recommendation
- management team
- Clinical Governance Chair
- any third party with a valid interest e.g Health Quality & Safety Commission, Health and Disability Commissioner and Coroner.

15. Document control

A copy of all final documents should be retained and archived. As an example at C&C DHB the following are filed in the central archive:

- reported event form
- preliminary event review form
- reportable event brief
- final signed terms of reference
- final signed report
- completed action plan
- communications with family, HQSC, HDC, etc.



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