Policy

Policy Directive: compliance is mandatory

Root Cause Analysis Policy Directive

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Summary

The Root Cause Analysis Policy Directive describes a standardised system for conducting Root Cause Analysis investigation of patient incidents to assist in identification of health system failures that may not be immediately apparent at initial review.

Keywords

Root Cause Analysis, RCA, incident, open disclosure, Safety Learning System, SLS, adverse incidents, safety, quality, policy directive, reporting, cluster incidents, harmful incidents, notification, Part 8, *Health Care Act 2008,* Report, Root Cause Analysis Policy Directive

Policy history

Is this a new policy? *Y*
Does this policy amend or update an existing policy? *N*
Does this policy replace an existing policy? *N*

Applies to

All SA Health Portfolio

Staff impacted

All Staff, Management, Admin, Students; Volunteers

EPAS compatible

Yes

Registered with Divisional Policy Contact Officer

Yes

Policy doc reference no.

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Version control and change history

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Government of South Australia
SA Health

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14/07/2016	V.1	Portfolio Executive	Original PE approved version

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Root Cause Analysis Policy Directive

1. Objective

Root Cause Analysis (RCA) is a method or methodology that is used to investigate an incident in order to assist in the identification of health system failures that may not be immediately apparent at initial review.

The purpose of this policy directive is to ensure that when an RCA is conducted under the protection of Part 8 of the *Health Care Act 2008* (SA) (the Act) all legislative requirements are met.

This policy describes what requirements need to be met during the commissioning and conducting of an RCA, to ensure that protection under Part 8 of the Act is not breached.

2. Scope

All SA Health employees who are involved in commissioning, participating in or releasing information from, an RCA conducted under Part 8 of the Act must adhere to this policy.

All persons external to SA Health who, because of their expertise, are requested to and agree to participate in an RCA conducted under Part 8 of the Act must adhere to this policy.

3. Principles

SA Health is committed to creating and maintaining a sustainable, high-quality care environment, in which:

- it actively seeks to improve the safety and quality of the health services it provides by conducting an investigation appropriate to the severity and type of incident
- information is actively sought from patients and/or families affected by the incident being investigated to help inform the RCA recommendations
- recommendations are made which will improve practices, procedures or systems used when providing a health service and these recommendations are shared with other relevant health services
- recommendations are implemented in a timely manner and the effectiveness of that implementation is monitored.

The purpose of an RCA is to identify issues within the system that contributed to or resulted in an incident occurring and to provide recommendations on actions to be taken to prevent and/or minimise a recurrence of a similar incident.

An RCA is not used to apportion blame to staff, but is designed for learning and improving the quality of the health care system.

4. Detail

An RCA without the protection of Part 8 of the Act may be undertaken to investigate any incident, however all staff participating in the process must be informed that the RCA is being conducted without protection.

If the information gained during the RCA process is to be protected under Part 8 of the Act, a number of legislated requirements must be met. If all requirements are not met then information gained during the investigation will not be protected from release. The following sections provide detail of these requirements.

4.1 When can an RCA be conducted under Part 8 of the Act

For an RCA to be eligible for protection of information under Part 8 section 73 of the Act the incident being investigated must meet the definition of an adverse incident.

An adverse incident is an incident that occurred during the provision of health services and is within the class of incident specified by the Chief Executive by notice in the Government Gazette. The following class of incidents were specified in the Gazette on 21 May 2015:

- The death of a patient unrelated to the natural course of the person's illness and differing from the immediate expected outcome of the patient's health care management.
- Sentinel Events, namely:
  - procedures 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
  - haemolytic blood transfusion reaction resulting from ABO blood type incompatibility
  - medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
  - maternal death associated with pregnancy, birth and the puerperium
  - discharge of an infant to the wrong family.
- The abduction of an infant/child from a hospital facility.
- An intrauterine death that may be related to a system failure in health care delivery.
- The stillbirth[1] of an infant that may be related to a system failure in health care delivery.
- The suspected:
  - homicide or suicide, or
  - attempted homicide or suicide,

  committed by a person who has received care or treatment from a health service entity where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the entity.
- The suspected suicide or suspected attempted suicide of a person in custody applying the definition of 'custody' in the Coroners Act 2003 (SA).
- An incident where a patient:
  - suffers a major permanent loss of function (sensory, motor, physiologic or intellectual) unrelated to the natural course of the patient's illness and differing from the expected outcome of the patient's health care management
  - suffers significant disfigurement as a result of the incident

[1] as defined by section 4 of the *Births, Deaths and Marriages Registration Act 1996* (SA)

- is or was at significant risk due to being absent against medical advice
- who, whilst detained, has:
  - without leave, left the place at which he or she has been detained, or
  - having been absent with leave from the place at which he or she has been detained, failed to return at the conclusion of the period of leave

  and has been at significant risk during the period of absence or unauthorised absence.

- An incident or occurrence where the incident or occurrence has 'system wide safety implications', namely one that involves a systems failure[2] or multiple systems failure that does or has the potential to compromise the safety of a patient.

and otherwise an incident or occurrence which is not consistent with the routine health care of a patient or client or the routine operation of the health services entity providing the health care and which does or has the potential to result in harm to a person or persons receiving health care.

4.2 When must an RCA not be conducted

An RCA must not be conducted if it is believed that the sole underlying cause of the incident was related to the skills or abilities of a staff member who provided the health service. If it is believed that there was also systems issues that contributed to the incident an RCA may be conducted in relation to these issues but must not investigate the staff related aspect.

4.3 When must an RCA be suspended

The RCA team must suspend its activities if the RCA team suspects that its investigation relates to an adverse incident that involves a 'prescribed act' that:

- is illegal under State law and appears to have been committed by a member of staff
- is attributable to a member of staff, or any other person involved in the adverse incident, being medically unfit
- constitutes the abuse of a patient
- appears to be a deliberately unsafe act (other than an act that might be reasonably undertaken in the provision of a health service).

If an RCA is suspended, the *Health Care Regulations 2008* require:

- the RCA team to notify the designated authority (see section 4.4) in writing of the suspected prescribed act and the reasons for the team's suspicion
- the team immediately notify the designated authority if they believe a prescribed act of the same kind is, or may be, imminent
- the team to not continue with its investigation unless authorised to do so in writing by the designated authority
- the designated authority not to authorise the team to continue its investigation unless satisfied that the suspected prescribed act either did not occur or can be investigated independently of the adverse incident.

[2] A fault, breakdown, or dysfunction within operational methods, processes, or infrastructure, EXPLANATORY NOTES—Patient Safety Management Systems—Australian Council for Safety and Quality in Health Care, May 2005.

4.4 How is an RCA commissioned

If it is decided to commission an RCA under Part 8 of the Act, the RCA team must be appointed by a designated authority. Designated authorities are:

- the General Manager of a hospital
- the Chief Executive Officer of a LHN
- the Chief Executive Officer of the SA Ambulance Service
- a person appointed by the hospital, LHN or SA Ambulance Service to exercise the powers of a designated authority
- a person (including committees) authorised under Part 7 section 64(1)(b) of the Act.

The designated authority has discretion as to who will be appointed to the RCA team, but the team must consist of:

- a team leader who has completed a formal training course in RCA, this training should have been completed within the last 5 years
- at least one member who has a formal tertiary qualification or significant experience in a health related field relevant to the investigation
- members who understand their obligations under Parts 7 and 8 of the Act
- not less than three members.

The designated authority must ensure that a written record is kept of the persons appointed as members of the RCA team.

Any decision to conduct an RCA into an adverse incident without the protection of Part 8 of the Act must be discussed with the Director of Safety and Quality, Systems Performance and Service Delivery, prior to commencing the investigation.

4.5 Conducting the RCA investigation

4.5.1 Timeframes

An RCA should be commissioned within 14 days of the designated authority becoming aware of the adverse incident. The RCA team must commence their investigation within 14 days of being appointed. The date of appointment is the commissioning date.

The RCA team must complete the investigation and provide Report 2 (see section 6) to the Adverse Incident Team of the Department for Health and Ageing, Safety and Quality Unit within 10 weeks (70 calendar days) of commencing its investigation unless an extension has been granted.

4.5.1.1 Extensions

In some circumstances an extension may be obtained from the Safety and Quality Unit of the Department for Health and Ageing.

The request for an extension must be made by sending an email from within the Safety Learning System (SLS) to HealthSentinelEvents@sa.gov.au providing detail of why an extension is required and the proposed date that Report 2 will be delivered.

The request for an extension must be received before the date that Report 2 is due. If an extension has not been granted, on or **before that date, protection under Part 8 of the Act will be lost**.

The Safety and Quality Unit will confirm that an extension has been granted via an email generated from within the SLS. The email will include the new due date for Report 2.

4.5.2 Conflict of interest

If an RCA team member becomes aware that they, their spouse, domestic partner or a relative has or may have a direct or indirect personal or financial interest in the incident being investigated they must:

- as soon as reasonably practicable after becoming aware of the interest, disclose in writing to the designated authority full and accurate details of the interest
- not take any further part in the investigation or the preparation of reports unless it is determined by the designated authority that they may do so.

4.6 Protection of information

Information gained in connection with the activities of an RCA team is protected by Part 8 (section 73) of the Act.

A person who:

- is, or has been a member of the RCA team
- provides, or has provided, expert, technical, administrative or secretarial assistance to an RCA team or in connection with its activities, including the receiving and gathering of information on behalf of the RCA team
- receives an RCA report that contains protected information

must not make a record of, use or disclosure information gained in connection with the activities of the RCA team. Except:

- to the extent necessary for the proper performance of those activities
- to fulfil any reporting requirements of a prescribed kind
- to the extent allowed by the regulations.

See section 6 Reporting for detail about who may receive what information.

4.7 Liabilities

If a person acts in good faith for the purpose of the activities of an RCA team, or an activity that the person reasonably believes to be the activity of an RCA team, then no act or omission will give rise to any liability against the person, or against the entity involved in authorising the RCA team to act.

During the investigation people may provide the RCA team with information (including confidential information) without breaching any law or principle of professional ethics.

A person must not victimise and cause detriment to a person who has provided, or intends to provide, information or other assistance to an RCA team in connection with its activities. If victimisation does occur this may be dealt with under civil law or as if it were an act of victimisation under the *Equal Opportunities Act 1984*.

5. Roles and Responsibilities

5.1 SA Health Chief Executive (CE)

- Ensure that the conduct of RCA investigations across SA Health is in accordance with this policy and legislative requirements.
- Ensure that resources are available to enable the conduct of RCA investigations including the education and training of appropriate staff.

5.2 Director of Safety and Quality – System Performance and Service Delivery

- Establish, maintain and review the effectiveness of the Root Cause Analysis Policy Directive.
- Consider all requests for extensions to an RCA investigation and provide a timely response to the applicant.
- Support the implementation of this policy through facilitating the development, dissemination and implementation of training, tools, resource materials and evaluation of these.
- Provide advice to health services in response to specific queries about an RCA.
- Review RCA reports, conduct trend analysis and develop and disseminate statewide strategies for system improvement.

5.3 Local Health Network/SA Ambulance Service Chief Executive Officers

- Ensure the health services within their area of control have systems in place which facilitate the effective conduct of RCA investigations in accordance with this policy and legislative requirements.
- Allocate sufficient human and material resources to enable the effective conduct of RCA investigations across all areas within their area of control, and appropriate data capture and analysis to help inform the findings of the RCA team.
- Ensure a register is maintained of staff who have completed RCA training, that fulfils the requirement for a team leader.
- Delegate the day-to-day responsibility for establishing and monitoring the implementation of this policy to the relevant senior managers.

5.4 Directors, heads of service/departments and other senior managers

- Ensure that any incident meeting the definition of an adverse incident has been brought to the attention of a designated authority.
- Ensure that there are procedures in place to guide staff participation in an RCA investigation.
- Ensure that relevant staff have access to formal RCA training.
- Provide appropriately trained staff to support staff involved in an RCA investigation.

5.5 Designated authorities

- Make a decision as to whether an RCA will be conducted under Part 8 of the Act.
- Appoint the RCA team in accordance with this policy and legislative requirements.
- Ensure a written record of people appointed to the RCA team is kept.

5.6 RCA team leader

- Ensure that they have completed formal RCA training, within the last five years.
- Ensure they are fully aware of their obligations under the *Health Care Act 2008* and Health Care Regulations 2008.
- Ensure that the RCA is conducted in accordance with this policy and legislative requirements.

5.7 RCA team members

- Ensure they are fully aware of their obligations under the *Health Care Act 2008* and *Health Care Regulations 2008*.
- Ensure that the RCA is conducted in accordance with this policy and legislative requirements.

5.8 Safety and Quality Risk Managers / Clinical Governance

- Ensure that RCAs are being conducted where appropriate.
- ensure that records and processes are in place to confirm that:

- the person appointed as a team leader has completed formal RCA training within the last five years
- at least one member of the team has the required tertiary qualification or significant experience in a health related field relevant to the investigation.

- Ensure that patients and carers are supported to provide information to an RCA team.
- Ensure that the SLS is used to document the RCA processes.
- Ensure that any internal or external requests for information related to an RCA team's activities are considered for approval by LHN Safety and Quality Manager and/or Director Safety and Quality Unit, DHA, and are in accordance with Part 8 of the Act.
- collaborate with clinical education and external training provider to ensure that
  - relevant staff are aware of the protection of information related to an RCA team's activities under the *Health Care Act* and what this means for them
  - appropriate staff receive formal training in RCA that meets the training required to be an RCA team leader.
- maintain a record of all staff who have completed formal RCA training.

5.9 All SA Health employees

- provide information to an RCA team during an interview process when requested
- participate as a member of an RCA team as required
- participate in the implementation of recommendations arising from an RCA.

6. Reporting

When the RCA team has completed its investigation it must prepare two separate reports.

Report 1 contains a short description of the adverse incident based on facts known independent of their investigation and recommendations for changes or improvements in relation to a procedure or practice associated with the incident. This report may be released publicly and should be released to the patient/family affected, staff involved and health services.

Report 2 contains a description of the adverse incident based on facts determined during their investigation and recommendations for changes and improvements. The report may also include one or more of the following as the RCA team thinks fit:

- a flow diagram
- a cause and effect diagram
- a causation statement
- working documents associated with the RCA team's investigation and processes (incorporated as attachments)
- any other material considered relevant by the RCA team.

Report 2 may only be released in its entirety to:

- a person who has provided expert, technical, administrative or secretarial assistance to the RCA team or one of its members
- a person (including committees) authorised under Part 7 section 64(1)(b) of the Act.

If a designated authority (for example the CEO) is not a member of a committee authorised under Part 7 of the Act then they must only receive Report 1 and the causation statement.

The Adverse Incident Team of the Department for Health and Ageing, Safety and Quality Unit must receive the following parts of Report 2:

- any description of the adverse incident

- any causation statement
- the recommendations of the RCA team
- any other material considered relevant by the RCA team

within 10 weeks (70 calendar days) of commencing the investigation, unless an extension has been granted.

Both Report 1 and 2 are uploaded as Level 1 secure documents in the patient incident module of the SLS.

7. EPAS

EPAS and other medical records forms are used to document the care provided before during and after an incident, including results of any examination and/or tests relating to any injury or harm that was incurred. This information may need to be accessed by an RCA team during the course of its investigation into the incident.

8. Exemption

No exemption allowed for this policy directive.

9. National Safety and Quality Health Service Standards

 National Standard 1 Governance for Safety and Quality in Health Care	 National Standard 2 Partnering with Consumers	 National Standard 3 Preventing & Controlling Healthcare associated infections	 National Standard 4 Medication Safety	 National Standard 5 Patient Identification & Procedure Matching	 National Standard 6 Clinical Handover	 National Standard 7 Blood and Blood Products	 National Standard 8 Preventing & Managing Pressure Injuries	 National Standard 9 Recognising & Responding to Clinical Deterioration	 National Standard 10 Preventing Falls & Harm from Falls
☑	☑	☑	☑	☑	☑	☑	☑	☑	☑

This policy is relevant to all National Safety and Quality Health Service Standards that require services to have robust systems for investigating and change management to respond to an incident.

- Standards1.6 and 1.14 require that health services have a robust system for incident management and change management processes, as these are key enablers of any and all strategies for improving safety and quality of health services.
- Standard 1.4 requires that training is implemented in the assigned safety and quality roles and responsibilities.

10. Risk Management

There is the potential for considerable risk to the organisation if the commissioning, conduct and release of information related to RCA does not comply with all legislative requirements.

Organisational risk associated with non-compliance with this Directive includes, but is not limited to:

- the payment of a penalty of up to $60 000 if information protected under section 73 of the Act is released
- loss of protection of information gained as a result of, or in connection with, the activities of an RCA team
- information gained being required by a court, agency or other body for use in litigation and other proceedings
- loss of the opportunity to improve the safety and quality of care through learning from an RCA, as staff may be reluctant to be forthcoming with information and express their opinions during the RCA process if they cannot be sure it will not be released
- reduction in staff morale from inadequate governance; failure to improve safety and quality of care; and the experience of having their opinions given during an RCA released
- adverse media attention, loss of reputation and community confidence from single or groups of incidents.

11. Evaluation

Compliance with the delivery of reports within the required timeframes will be monitored by a member of the Adverse Incident Team of the Department for Health and Ageing, Safety and Quality Unit.

A member of the Adverse Incident Team will monitor the content of Report 1 to ensure that it does not contain any protected information.

The LHN Safety and Quality Risk Managers/Clinical Governance will routinely audit compliance with the maintenance of appointment and training records.

100 per cent compliance must be achieved for all legislative requirements.

12. Definitions

In the context of this document:

- **authorised activity** means an activity declared under section 64 of the *Health Care Act 2008* (SA);
- **authorised person** means a person declared under section 64 of the *Health Care Act 2008* (SA), including by being the member of a group (or committee) that has been declared under section 64;
- **confidential information** means information relating to a health service in which the identity of a patient or person providing the service is revealed;
- **court** includes a tribunal, authority, board or person having power to require the production of documents or the answering of questions;
- **designated authority** means
    - the General Manager of a hospital or CEO of a LHN/SAAS; or
    - a person who is appointed by the hospital or LHN/SAAS to exercise the powers of a designated authority; or
    - an authorised person as defined above;
- **disclose,** in relation to information, means to give, reveal or communicate in any way**;**
- **produce** includes permit access to.

13. Associated Policy Directives / Policy Guidelines

- Patient Incident Management and Open Disclosure Policy Directive (New)
- Coronial Process and Coroners Act 2003 Policy Directive and Policy Guideline, and the Coroners Inquest Procedure
- The *Health Care Act* 2008 Part 7 Committees Policy Directive

14. References, Resources and Related Documents

- *Civil Liability Act* 1936 (SA)
- *Coroners Act* 2003 (SA)
- *Equal Opportunities Act 1984*
- *Freedom of Information Act* 1991 (SA)
- *Health Care Act* 2008 (SA)
- Health Care Regulations 2008 (SA)
- *Health Practitioner Regulation National Law (South Australia) Act* 2010
- Root Cause Analysis (RCA) Reports and Documentation Requirements
- Information for interviewees contributing to a Root Cause Analysis (RCA) investigation conducted under Part 8 of the *Health Care Act 2008* (SA)
- Root cause analysis team member agreement
- Root cause analysis team leader agreement
- Checklist for root cause analysis (RCA) process to meet the requirements of the *Health Care Act 2008* (SA)