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Queensland Government Queensland Health	**Bundaberg Health Service District** **Policy & Procedure Document**	**QHEPS No. 21907**

Title:	Sentinel Events and Root Cause Analysis
Manual Name & No:	No. 2 - Leadership and Management
Section:	Section 2 – Risk Management
Policy Number: Manual/Section/Number	2.2.S1

Applicable to: All Staff

Effective Date: 01 June 2004

Last Review Date: New Policy

Next Review Date: 01 June 2007

Initiator: Director of Medical Services

Authorised:
Original signed by Peter Leck
District Manager

Ratified:
Original signed by Dr. Darren Keating
Director of Medical Services

Originals kept in the District Quality and Decision Support Unit

Replaces: New Policy

References:
- Department of Veterans Affairs, Veterans Affairs National Centre for Patient Safety Michigan, USA, February 2002
- The Clinicians Toolkit – for Improving Health Care – NSW Health 2001
- Sentinel Event Discussion Paper – QH Dec 2002
- QH Incident Management Policy – Draft – Oct 2003

Description

The identification, investigation and monitoring of sentinel events together with the health care facility's response is an important tool in developing safe, patient care and improving the safety of health care for consumers.

Definitions

Sentinel event: An incident in which serious harm resulted to a person receiving healthcare.

Root Cause Analysis: Root Cause is the most basic reason for an undesirable outcome, and Root Cause Analysis is a tool that enables us to learn as much as possible about what happened, why it happened and what can be done to prevent the same thing recurring in the future.

Policy Statement

Sentinel events are rare and serious events that signal the need for prompt multidisciplinary investigation and action. All sentinel events will be subject to a root cause analysis, conducted in an environment of support and learning to ensure that the appropriate actions are taken to prevent future recurrence.

When a sentinel event occurs in a health care facility of Bundaberg Health Service District, it is necessary that the District Manager, Director of Medical Services and the Director of Nursing Services and relevant Director are made aware of the event. The event must be investigated and the cause(s) that initiated the event understood; and changes made in the organisational systems and process to reduce the probability of such an event occurring in the future.

Outcome

- A positive impact in improving patient care.
- Focus attention of facility that experienced sentinel event on understanding the causes underlying the event, and on making changes in the care delivery systems and processes to reduce the probability of such an event in the future.
- Improve safety of health care for consumers and maintain the confidence of the public in the care provided.

Evaluation Method

- Sentinel Event Risk Register maintained by the District Quality and Decision Support Unit
- A six monthly report on trends and analysis to the Leadership & Management Committee; which is then made available to Heads of Department.
- Policies & procedures changed due to investigation of sentinel events on an annual basis.

Procedure

The following events are defined as sentinel events in the Bundaberg Health Service District (as per Australian Council for Safety and Quality in Health Care).

1. Procedures involving the wrong patient or the wrong body part
2. Retained instruments or other material after surgery requiring re-operation or further surgical procedure
3. Haemolytic blood transfusion reaction resulting from ABO incompatibility
4. Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
5. Infant discharge to wrong family
6. Maternal death or serious morbidity associated with labour or delivery
7. Intravascular gas embolism resulting in death or neurological damage
8. Suicide of a patient in an in-patient unit
9. Any serious and rare event

Upon identification of one of these events, immediate notification to one of the DM, DMS or DON must occur, preferably by the senior staff member involved in the incident. A verbal report should be received within 12hrs and a written notification within 48 hrs (see attachment A).

After this notification, immediate handling of the event is required. The designated executive member will be responsible for liaison with patient, family and staff in order to facilitate ongoing care; identify possible complaints and concerns and provide explanation of the investigation process. Liaison and notification of CZMU and Corporate Office Queensland Health will be required. Legal advice may also be required. (See Open Disclosure Policy 2.2.O1 for further information)

Upon notification of the sentinel event, an investigation and root cause analysis will be conducted. This investigation will be conducted by a team, headed by one of the executives noted above or by a senior staff member so duly appointed. The investigation will focus on systems and processes, not individual performance. It should encompass special causes in clinical process to common causes in organisational

process. The analysis should identify potential improvements in process or systems in order to decrease the likelihood of such events in the future. An action plan should be developed which identifies responsibility for implementation, mechanisms for oversight, time lines and strategies for measuring the effectiveness of the actions.

The report will be passed to the Leadership & Management Committee, in order that it undertakes the actions required in the facility to ensure the risk of a repeat event is reduced.

Goals of Root Cause Analysis

Root Cause

A root cause is the most fundamental reason an event has occurred

Contributing Factor

Contributing factors are additional reasons, not necessarily the most basic reason that an event has occurred

Root Cause Analysis (RCA)

Root Cause Analysis is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. RCAs have the following characteristics:

- The review is interdisciplinary in nature with involvement of those closest to the process.
- The analysis focuses primarily on systems and processes rather than individual performance.
- The analysis digs deeper by asking *what* and *why* until all aspects of the process are reviewed and all contributing factors are identified (progressing from looking at special causes to common causes).
- The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes or systems that would improve performance and reduce the risk of event or close call recurrence.

The goal of a **Root Cause Analysis** is to find out

- ***What happened?***
- ***Why did it happen?***
- ***What do you do to prevent it from happening again?***

By addressing the immediate causes at a unit or clinical level, you will reduce the likelihood that the same incident will occur again. However, by addressing the underlying causes (i.e. root causes) this will reduce the likelihood of a similar incident occurring throughout the organisation.

Root Cause Analysis is a *tool* for identifying prevention strategies. It is a process that is part of the effort to build a *culture of safety* and move beyond the culture of blame.

In **Root Cause Analysis**, basic and contributing causes are discovered in a process similar to diagnosis of disease - with the goal always in mind of preventing recurrence.

Root Cause Analysis is

1. inter-disciplinary, involving experts from the frontline services
2. involving of those who are the most familiar with the situation
3. continually digging deeper by asking why, why, why at each level of cause and effect.
4. a process that identifies changes that need to be made to systems
5. a process that is as impartial as possible

To be thorough, a Root Cause Analysis must include:

1. determination of human & other factors,
2. determination of related processes and systems,
3. analysis of underlying cause and effect systems through a series of ***why*** questions,
4. identification of risks & their potential contributions, and
5. determination of potential improvement in processes or systems.

To be credible a Root Cause Analysis must:

1. include participation by the leadership of the organisation & those most closely involved in the processes & systems,
2. be internally consistent, and
3. include consideration of relevant literature.

Documentation

Sentinel Event Report Form (Appendix A)
Root Cause Analysis Report (Appendix B)

Appendix A

Queensland Government
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Bundaberg Health Service District

Sentinel Event Report Form

Sentinel events are rare and serious events that require prompt and in-depth investigation
Sentinel events must be reported verbally to the District Manager, Director of Medical Services, Director of Nursing and other relevant Director within 12 hours.
This written report forwarded to DQDSU within 48 hours

Please print clearly using a **black** pen

Site	☐ Bundaberg	☐ Childers	☐ Gin Gin	☐ Mt. Perry

Details of the subject of the sentinel event (fill in applicable details)

Last Name:	Or affix Patient Label	Sex of Patient:	☐ Male ☐ Female ☐ Not stated
First Name:		IMHS Clients:	☐ Voluntary ☐ Involuntary ☐ Unknown
JR Number:		Unit	Inpatient Unit
OB/Age:			Unit where event occurred
Reporters Details	**Name:**	**Signature**	
	Contact No.	**Date**	

Reporters Classification: ☐ Nurse ☐ Medical Officer ☐ Allied Health Professional ☐ Other - specify

Sentinel Event

Please indicate which Sentinel Event has occurred:

- ☐ Procedures involving the wrong patient or the wrong body part
- ☐ Retained instruments or other material after surgery requiring re-operation or further surgical procedure
- ☐ Haemolytic blood transfusion reaction resulting from ABO incompatibility
- ☐ Medication error leading to death of a patient reasonably believed to be due to incorrect administration of drugs
- ☐ Infant discharge to wrong family
- ☐ Maternal death or serious morbidity associated with labour or delivery
- ☐ Intravascular gas embolism resulting in death or neurological damage
- ☐ Suicide of a patient in an in-patient unit
- ☐ Any serious and rare event

te of Event				Time of Event	**hours**
Reported to:	☐ DM	☐ DMS	☐ DON	Time reported	**hours**
Also reported to:	☐ DCAHS	☐ DCS	☐ Service Director IMHS	Time reported	

Narrative
Provide details of how this event occurred, including people involved, outcomes etc Attach additional sheets if insufficient space

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Appendix B

TRIGGERING QUESTIONS

(Adapted from the VA National Centre for Patient Safety Triage Questions)

Human Factors – Communication In this section address all questions	Yes	No
Was the patient correctly identified?	☐	☐
Was information from various patient assessments shared and used by members of the treatment team on a timely basis?	☐	☐
If "No" – This could be a Root Cause/Contributing Factor		
Did existing documentation provide a clear picture of the work-up, the treatment plan and the patient's response to treatment?	☐	☐
Assessments & Consultations	☐	☐
Orders & Treatment team notes	☐	☐
Progress notes	☐	☐
Medication administration record	☐	☐
X-ray & Pathology reports	☐	☐
If "No" – This could be a Root Cause/Contributing Factor		
Was communication between management/supervisors and front line staff adequate? Was it:	☐	☐
Accurate & Complete	☐	☐
Using standard vocabulary and no jargon & Unambiguous	☐	☐
If "No" -- Describe how management/supervisors and front line communications are not adequate.		
Was communication between front line team members adequate?	☐	☐
If "No" -- Describe how communications between team members were not adequate		
Were policies and procedures communicated adequately?	☐	☐
If "No" -- Describe how policies and procedures were not communicated adequately.		
If this is an issue, see the questions.		
Was the correct technical information adequately communicated 24 hours a day to the people who needed it?	☐	☐
If "No" -- Describe how communication about technical information is not adequate.		
Were there methods for monitoring adequacy of staff communication? Were there methods for:	☐	☐
Confirmation messages, Debriefs etc	☐	☐
If "No" -- This could be a Root Cause/Contributing Factor.		
Was the communication of potential risk factors free from obstacles?	☐	☐
If "No" -- This could be a Root Cause/Contributing Factor.		
Was there manufacturer's recall/alert/bulletin on file for equipment, medication, or transfusion related elements at the time of the event or close call?	☐	☐

Human Factors – Communication In this section address all questions	Yes	No
If this is an issue, consider ***questions***		
Were relevant staff members aware of the recall/alert/bulletin?	☐	☐
If relevant, were the patient and their family/significant others actively included in the assessment and treatment planning?	☐	☐
Did management establish adequate methods to provide information to employees who needed it in a manner that was easy to access/use, and timely?	☐	☐
If "No" -- This could be a Root Cause/ Contributing Factor.		
Did the overall culture of the facility encourage or welcome observations, suggestions, or "early warnings" from staff about risky situations and risk reduction?	☐	☐
Also, has this happened before and was anything done to prevent it from happening again?	☐	☐
Did adequate communication across organizational boundaries occur?	☐	☐

Notes/Additional Information

Human Factors – Training In this section, address all questions	Yes	No
Was there a program to identify what is actually needed for training of staff?	☐	☐
If "No" -- This could be a Root Cause/Contributing Factor.		
Was training provided prior to the start of the work process?	☐	☐
If "No" -- This could be a Root Cause/Contributing Factor		
Were the results of training monitored over time?	☐	☐
If "No" -- This could be a Root Cause/Contributing Factor		
Was the training adequate? If not, consider the following factors:	☐	☐
Supervisory responsibility	☐	☐
Procedure omission	☐	☐
Flawed training	☐	☐
Flawed rules, policy, or procedure -	☐	☐
If yes, go to the questions.		
Were training programs for staff designed up-front with the intent of helping staff perform their tasks without errors?	☐	☐
If "No" – This could be a Root Cause/Contributing Factor		
Had procedures and equipment been reviewed to ensure that there was a good match between people and the tasks they did; or people and the equipment they used?	☐	☐
If procedures were not followed as intended, see the questions		
Were all staff trained in the use of relevant barriers and controls?	☐	☐
If yes, see the questions		
If equipment was involved, did it work smoothly in the context of:	☐	☐
Staff needs and experience	☐	☐
Existing procedures, requirements, and workload	☐	☐
Physical space and location	☐	☐
If equipment was involved, see the questions		

Notes/Additional Information

Human Factors – Fatigue and Scheduling	Yes	No
Were the levels of vibration, noise, or other environmental conditions appropriate?	☐	☐
If applicable, were environmental stressors properly anticipated?	☐	☐
If stressors were anticipated, see the *questions.* ***If stressors were not anticipated, why weren't they anticipated?***		
Did personnel have adequate sleep?	☐	☐
Did scheduling allow personnel adequate sleep?	☐	☐
Was fatigue properly anticipated?	☐	☐
Was the environment free of distractions?	☐	☐
Was there sufficient staff on-hand for the workload at the time? (i.e., Workload is too high, too low, or wrong mix of staff.) ***If yes, see the*** ***questions***	☐	☐
Was the level of automation appropriate? i.e. Neither too much nor not enough ***f yes, see the*** ***questions***	☐	☐

Notes/Additional Information

Environment and Equipment In this section, address all questions	Yes	No

Environment		
Was the work area/environment designed to support the function it was being used for?	☐	☐
Had there been an environmental risk assessment (i.e., safety audit) of the area?	☐	☐
If no, consider reviewing the and questions.		
Were the work environment stress levels (either physical or psychological) appropriate? (e.g. Temperature, space, noise, intra-facility transfers, construction projects.) *If yes, go to the questions.)*	☐	☐
Had appropriate safety evaluations and disaster drills been conducted?	☐	☐
Did the work area/environment meet current codes, specifications, and regulations?	☐	☐
Equipment (If training was an issue go to .)		
Was equipment designed to properly accomplish its intended purpose?	☐	☐
Did the equipment involved meet current codes, specifications, and regulations?	☐	☐
Was there a documented safety review performed on the equipment involved?	☐	☐
If relevant, were recommendations for service/recall/maintenance completed in a timely manner?	☐	☐
Was there a maintenance program in place to maintain the equipment involved?	☐	☐
If no, go to .		
If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?	☐	☐
If previous inspections pointed to equipment problems, what corrective actions were implemented and were they effective?	☐	☐
Were adequate time and resources allowed for physical plant and equipment upgrades, if problems were identified?	☐	☐
Was there adequate equipment to perform the work processes?	☐	☐
Were emergency provisions and back-up systems available in case of equipment failure?	☐	☐
Had this type of equipment worked correctly and been used appropriately in the past?		
Was the equipment designed such that usage mistakes would be unlikely to happen?		
Was the design specification adhered to?		
If yes, go to the questions.		
Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy?	☐	☐
Were personnel trained appropriately, to operate the equipment involved in the adverse event/close call?	☐	☐
If no, see the questions.		
Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?	☐	☐
Was the equipment designed so that corrective actions could be accomplished in a manner that minimized/eliminated any undesirable outcome?	☐	☐
Were equipment displays and controls working properly and interpreted correctly?	☐	☐
Was the medical equipment or device intended to be reused (e.g. not a Single Use Device)?	☐	☐
Notes/Additional Information		
Rules Policies and Procedures In this section, address all questions.	Yes	No

Was there an overall management plan for addressing risk and assigning responsibility for risk?	☐	☐
Did management have an audit or quality control system to inform them how key processes related to the adverse event are functioning?	☐	☐
Had a previous audit been done for a similar event, were the causes identified, and were effective interventions developed and implemented on a timely basis?	☐	☐
Would this problem have gone unidentified or uncorrected after an audit/review?	☐	☐
Was required care for the patient within the scope of the facility's mission, staff-expertise and availability, technical and support service resources?	☐	☐
Was the staff, involved in the adverse event or close call, properly qualified and trained to perform their functions?	☐	☐
Were all involved staff oriented to the job, facility, and unit policies regarding: safety, security, hazardous material management, emergency preparedness, life-safety-management, medical equipment, and utilities management?	☐	☐
Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?	☐	☐
Were these policies/procedures consistent with relevant federal and VHA policies, standards, and regulations?	☐	☐
Were relevant policies/procedures clear, understandable, and readily available to all staff?	☐	☐
If no, go to the questions.		
Were the relevant policies and procedures actually used on a day-to-day basis?	☐	☐
If the policies and procedures were not used, what got in the way of their usefulness to the staff?	☐	☐
If policies and procedures were not used, what positive and negative incentives were absent?	☐	☐

Notes/Additional Information

Barriers In this section, address all questions.	Yes	No