

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Indian Health Service

ALBUQUERQUE AREA INDIAN HEALTH SERVICE CIRCULAR NO. 2001-02

RECOGNITION, MANAGEMENT AND REPORTING
OF A SENTINEL EVENT

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1. Purpose
 2. Policy
 3. Definitions
 4. Criteria/Reviewable Events
 5. Procedure
 6. Near Miss Events for Root Cause Analysis
 7. Reporting
 8. Effective Date
- Exhibit

1. **PURPOSE.** This circular establishes a policy for the Albuquerque Area Indian Health Service (AAIHS) on the appropriate response when Sentinel Events are identified at the Service Units.

2. **POLICY.** The policy of the AAIHS is to ensure that policies and procedures in this circular are used as a guide to help identify a sentinel event. The goals and objectives will be to:

- Have a positive impact in improving patient care.
- Focus the attention of an organization which has experienced a sentinel event on understanding the root causes of the event and identify ways to prevent a future similar event.
- Increase the general knowledge about sentinel events, their cause and prevention.
- Maintain public confidence in the accreditation process.

3. **DEFINITIONS.**

Sentinel Event: is an unexpected occurrence involving death or serious permanent loss of function not related to the natural course of the patient's illness or underlying condition. physical or psychological injury, or the risk thereof. Serious injury specifically includes the loss of limb or function. The phrase, "or the risk thereof", includes any

Page 2. ALBUQUERQUE AREA INDIAN HEALTH SERVICE CIRCULAR NO. 2001-02

process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

---Events are called sentinel because they signal the need for immediate documentation investigation and response.

---The event is associated with significant deviation from the usual processes for providing healthcare service or managing the organization.

---The event has undermined, or has the significant potential for undermining the public confidence in the organization.

4. CRITERIA/REVIEWABLE EVENTS.

The subset of sentinel events that is subject to review by the Joint Commission on Accreditation of Health Care Organization (JCAHO) includes any occurrence that meets any of the following criteria:

A. The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition.

B. The event is one of the following (even if the outcome was not death or major permanent loss of function):

---Suicide of a patient in a setting where the patient receives around-the-clock care (for example, hospital, residential treatment center, crisis stabilization center);

---Infant abduction or discharge the wrong family;

---Rape in the facility setting;

---Hemolytic transfusion reaction involving administration of blood products having major blood group incompatibilities;

--- Event resulted in unanticipated death or major permanent loss of function not related to the natural course of an illness.

---Surgery on the wrong patient or wrong body part (all events of surgery on the wrong patient or wrong body part are reviewable under the policy, regardless of the magnitude of the procedure).

5. **PROCEDURE.**

A) PROCESS FOR REPORTING THE EVENT

1. The Area Director, Executive Officer, Chief Medical Officer, and Director of Clinical Quality will review the RCA and discuss any questions with the CEO on where the RCA originated.
2. Hospital staff with knowledge of a sentinel event that has occurred will immediately notify the Chief Executive Officer (CEO) and/or the Risk Manager/Quality Manager. The Nursing Supervisor shall be contacted if the event occurs after hours. He/she shall notify CEO, Risk Manager and Quality Manager on the next scheduled workday. The CEO will notify the AAO Chief Medical Officer of the potential sentinel event and/or near miss, with 24 working hours of learning the event occurred.
3. Administrative Representative is responsible for immediately securing all materials relating to the event in a secure locked file.

B) The Area Chief Medical Officer in consultation with the Service Unit Clinical Director is responsible to see that the following steps be taken at the service unit level if a suspected sentinel event occurs.

- 1) Review the event relative to the intent (PI 4.3 and PI 4.3.1) of the Joint Commission Accreditation Manual for Hospitals to assess whether a sentinel event may have occurred.
- 2) Review the event by performing a Root Cause Analysis (RCA) (Exhibit I)
 - a. A RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.
 - b. RCA is will focus primarily on systems and processes, not individual performance. A Root Cause Analysis must be completed within 45 days of the event or of the organization's leadership becoming aware of the event.
 - c. The analysis repeatedly digs deeper by asking "Why?", then, when answered, "Why?" again, and so on.

- d. The analysis identifies changes which could be made in systems and processes – either through redesign or development of new systems or processes – that would reduce the risk of such events occurring in the future.
 - e. The analysis must be thorough and credible.
- 3) To be thorough, the root cause analysis must include:
- a. A determination of the human and other factors most directly associated with the sentinel event, and the process(es) and systems related to its occurrence;
 - b. Analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk;
 - c. Identification of risk points and their potential contributions to this type of event;
 - d. A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.
- 4) To be *credible*, the root cause analysis must:
- a. Include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review;
 - b. Be internally consistent, ie.,not contradict itself or leave obvious questions unanswered; and
 - c. Include consideration of any relevant literature.
- 5) The product of a RCA is an action plan. An action plan will be developed for each sentinel event. The plan will:
- a. Identify changes that can be implemented to reduce the risk, of similar events occurring in the future or formulates a rationale for not undertaking such changes; and

- b. Where improvement actions are planned, identify who is responsible for implementation, when the action will be implemented (including any pilot testing), timelines and strategies for measuring the effectiveness of the actions.
- 6) Service Unit Executive Committee shall review the RCA's, Performance Improvement Plan, within 45 days of the initial event, and recommend to the CEO that the findings be reported to the Area Chief Medical Officer and Director of Clinical Quality for review.
 - a. The Service Unit Risk Managers and Quality Managers will maintain a file of confidential information (i.e. incident reporting sentinel events and RCA) for purposes of tracking, trending, education and prevention activities.

6. **NEAR MISS EVENTS FOR ROOT CAUSE ANALYSIS.**

Clinical and non-clinical conditions may arise which can benefit from the RCA process as a performance improvement tool. Such events that place the organization or clients at risk for litigation such as fraud and abuse of billing processes, accounting discrepancies, operations of the facility (such as failures of utilities, equipment, etc.), theft, etc. can be evaluated using the RCA process to identify opportunities for improvement. Potentially dangerous medication errors, molestation, anesthesia related incidents, and prenatal paralysis should be analyzed with the RCA process.

7. **REPORTING.**

Healthcare organizations are encouraged but not required to report to JCAHO on sentinel events.

- When the decision is made to report a sentinel event, the RCA (Exhibit I) will be sent to the JCAHO Office of Quality Monitoring by mail or fax transmission.
- In the event the RCA is sent to JCAHO, the CMO will send notification to the CEO of the originating RCA.
- Requests for additional service unit generated data supporting the implementation of the RCA process from JCAHO, will be sent to the CMO, Executive Officer, and Regional Attorney, prior to the Service Unit sending data to JCAHO.

8. **EFFECTIVE DATE.** This circular is effective upon date of signature and shall remain in effect until canceled or superseded.

A handwritten signature in black ink, appearing to read "James L. Toya". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

James L. Toya
Director, Albuquerque Area IHS

A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event

Level of Analysis	Sentinel event	Questions	Findings	Root cause?	Ask "Why?"	Take action?
		What are the details of the event? (Brief description) When did the event occur? (Date, day of week, time) What area/service was impacted?				
Why did it happen? What were the most proximate factors? (Typically "special cause" variations)	The process or activity in which the event occurred	What are the steps in the process, as designed? (A flow diagram may be helpful here) What steps were involved in (contributed to) the event?				
	Human factors	What human factors were relevant to the outcome?				
	Equipment factors	How did the equipment performance affect the outcome?				
	Controllable environmental factors	What factors directly affected the outcome?				
	Uncontrollable external factors	Are they truly beyond the organization's control?				
	Other	Are there any other factors that have directly influenced this outcome?				
		What other areas or services are impacted?				

This three-page template is provided as an aid in organizing the steps in a root cause analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest for "root causes" and risk reduction.

As an aid to avoiding "loose ends," the three columns on the right are provided to be checked off for later reference:

"Root cause?" should be answered "yes" or "no" for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a "Why?" question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.

"Ask Why?" should be checked off whenever it is reasonable to ask why the particular finding occurred (or didn't occur when it should have) - in other words, to drill down further. Each item checked in this column should be addressed later in the analysis with a "Why?" question. It is expected that any significant findings that are not identified as root causes will have check marks in this column. Also, items that are identified as root causes will often be checked in this column, since many root causes themselves have "roots."

"Take action?" should be checked for any finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated Action Item on page 3 in the "Take Action?" column for each of the Findings that requires an action.

Framework for a Root Cause Analysis (continued)

Level of Analysis	Questions	Findings	Root cause? "Why?"	Ask "Why?"	Take action?
<p>Why did that happen What systems and processes underlie those proximate factors? (Common cause variation here may lead to special cause variation in dependent processes.)</p>	Human resource issues	<p>To what degree are staff properly qualified and currently competent for their responsibilities? How did actual staffing compare with ideal levels?</p>			
	<p>Information management issues</p>	<p>What are the plans for dealing with contingencies that would tend to reduce effective staffing levels? To what degree is staff performance in the operant process(es) addressed?</p>			
		<p>How can orientation & in-service training be improved?</p>			
		<p>To what degree is all necessary information available when needed? accurate? complete? unambiguous? To what degree is communication among participants adequate?</p>			
	Environmental management issues	<p>To what degree was the physical environment appropriate for the processes being carried out? What systems are in place to identify environmental risks?</p>			
	Leadership issues: Corporate culture	<p>To what degree is the culture conducive to risk identification and reduction?</p>			
	Encouragement of communication	<p>What are the barriers to communication of potential risk factors?</p>			
	Clear communication of priorities	<p>To what degree is the prevention of adverse outcomes communicated as a high priority? How?</p>			
	Uncontrollable factors	<p>What can be done to protect against the effects of these uncontrollable factors?</p>			



	Risk Reduction Strategies	Measures of Effectiveness
<p>For each of the findings identified in the analysis as needing an action, indicate the planned action, expected implementation date, and associated measure of effectiveness, OR...</p>	<p>Action Item #1:</p>	<p>Measure:</p>
<p>If, after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time.</p>	<p>Action Item #2:</p>	<p>Measure:</p>
<p>Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action.</p>	<p>Action Item #3:</p>	<p>Measure:</p>
<p>Consider whether pilot testing of a planned improvement should be conducted.</p>	<p>Action Item #4:</p>	<p>Measure:</p>
<p>Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented.</p>	<p>Action Item #5:</p>	<p>Measure:</p>
	<p>Action Item #6:</p>	<p>Measure:</p>
	<p>Action Item #7:</p>	<p>Measure:</p>
	<p>Action Item #8:</p>	<p>Measure:</p>

Cite any books or journal articles that were considered in developing this analysis and action plan: