RCA

Root Cause Analysis Tool Kit

California Correctional Health Care Services

RCA Tool Kit – DRAFT

Overview

In health care and other industries, such as aviation, it is common practice to conduct a Root Cause Analysis (RCA) when an adverse event or "near miss" occurs. In a Root Cause Analysis (RCA), a team uses a structured method to analyze an event, determine the fundamental causes of what went wrong, and take action to prevent the event from occurring in the future. This tool kit includes tools and techniques used by other healthcare organizations, like the Joint Commission and Department of Veterans Affairs, which may have been modified slightly to fit our correctional healthcare environment.

The RCA Tool Kit explains how to complete an RCA in 6 basic steps:

Step 1: Create an RCA Team
Step 2: Gather Information
Step 3: Brainstorm
Step 4: Identify Root Causes
Step 5: Design and Implement the Action Plan
Step 6: Measure Results and Modify the Action Plans as Appropriate

It includes tips and tools to help you complete the RCA process.

Definitions

Root Cause Analysis (RCA): A process for identifying the basic or causal factors that underlie variation in performance. An RCA:

- Focuses primarily on systems and processes, not on individual performance.
- Progresses from special cause to common causes in organizational processes and systems.
- Identifies potential improvements that will decrease the likelihood of such events in the future.

Root Cause: The most basic factor or factors that, if corrected or removed, will reduce the risk or prevent recurrence of a situation.

- It is a fundamental reason a failure has occurred.
- Human error is not a root cause.

Before you begin the RCA process:

- Review current policy requirements governing RCAs. The Patient Safety Program Policy and Procedures require that institutions complete an RCA for certain types of events. Click here to see a summary of current RCA requirements.
- Read the CCHCS Performance Improvement Culture Statement, which emphasizes a guiding principle of the RCA process – the focus is primarily on systems and processes, not individual performance. Click here to view the CCHCS Performance Improvement Culture Statement.
- Understand the criteria for a thorough and credible RCA. Click here to view the criteria for a Thorough and Credible RCA.

If the event you are reviewing requires an RCA per policy, you will also need to comply with the timeline below:

RCA Process Timeline						
	Adverse/Sentinel Event Identified	Complete RCA Steps 1-6	Submit RCA Report within 45 Days	Adverse Sentinel Event Committee (ASEC) Reviews the RCA Report	ASEC Monitors Improvement Activities for 4 Months	ASEC Closes Case or Refer to the Patient Safety Committee if Warranted
	RCA Process			**Implement the Improvement Activity**		

1 Assemble Team

To meet criteria for a thorough and credible RCA:

- ✓ *Complete the RCA process in a timely manner.*
- ✓ *Include people closely involved with the systems and processes under review.*
- ✓ *Obtain the support of institution leadership.*

Assemble the RCA Team

A. Assemble an RCA Team, ensuring that it:

1. Is interdisciplinary. Team members should understand that each member's knowledge and experience is critical to a successful RCA – and each team member has an equal place at the table, regardless of reporting level.

2. Includes, at a minimum, the following members:
   - i. **Team Leader** – An institution manager or leader who understands and supports the RCA process.
   - ii. **Team Facilitator** – A staff member trained in the RCA process who has hands-on experience participating in or conducting RCAs and managing workgroups.
   - iii. **Team Members** (4-6) – Individuals with firsthand knowledge of the event and processes/systems surrounding the event.

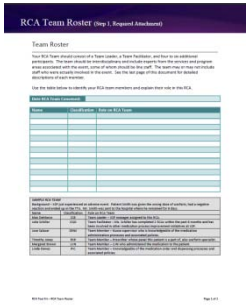
Use the "RCA Team Roster" (required for RCA report) to help you understand the roles of each team member and to document the members of your team and their roles. *See the Tools section to access this document.*

B. Set meeting dates, times and locations. Accomplish the RCA as quickly as possible while recall of event details is optimal.

C. Commit sufficient time for the RCA. Determining the actual facts of the event and brainstorming contributing factors and roots causes may require hours of dedicated attention from the team.

D. Understand and respect confidentiality. Review the "Confidentiality Statement" with team members. *See the Tools section to access this document.*

Tools


RCA Team Roster (Step 1, Required Attachment)

Team Roster

RCA Team Roster

Use this template to identify each member on your team

Includes information on the roles and responsibilities of RCA team members.


Confidentiality Statement (Step 1, Reference Only)

Confidentiality Statement

Confidentiality Statement

Review a summary of confidentiality provisions in state and federal law and general guidelines for handling information during the RCA process.

Use this information to help team members understand their responsibilities during the RCA.

2

Understand What Happened

Gather Information/Understand What Happened

Gather information and ascertain the facts of the event, including what led up to the event, what happened during the event, and what occurred immediately afterwards.

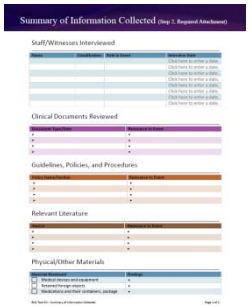
A. Collect information and data. The "Summary of Information Collected" document (required for RCA report) serves as a log of the information reviewed by the RCA Team during the RCA. *See the Tools section to access this document.*

1. Interview involved staff/witnesses.
    i. Often 1-2 RCA Team members are assigned to interview designated staff/witnesses and bring the information back at the next team meeting.
    ii. It is important to put the staff member/witness at ease and ask open-ended questions. The "Interviewing Techniques" document should be reviewed with the RCA Team prior to interviews. *See the Tools section to access this document.*
2. Review relevant clinical documents including health records, clinic logs, and medication administration records.
3. Identify and review guidelines, systems, processes, policies, and procedures relevant to the event.
4. Review health care literature for national practices, community standards, evidence-based guidelines and process studies that may be applicable to the event.
5. Examine any physical materials, such as equipment, medication containers, etc., that are relevant to the event.
6. Visit the location where the event occurred.
    i. Whenever possible, the RCA Team or selected members should visit the site of the event in order to observe and understand the environment and processes relevant to the event.
7. Review any/all other information that may be relevant.

B. Understand what happened: Using the information above, the RCA Team should achieve a common understanding of what happened. The RCA Team should:

1. Develop a chronological timeline from the first known fact to the actual

Tools


Summary of Information Collected (Step 2, Required Attachment)

Staff/Witnesses Interviewed

Clinical Documents Reviewed

Guidelines, Policies, and Procedures

Relevant Literature

Physical/Other Materials

Summary of Information Collected

Document all data and information collected and reviewed by the RCA Team.


Interviewing Techniques (Step 2, Reference Only)

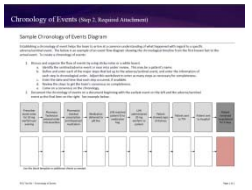
Overview

Do...

Do Not...

Interviewing Techniques

Review helpful hints to prepare for a witness interview.


Chronology of Events (Step 2, Required Attachment)

Sample Chronology of Events Diagram

Chronology of Events

Document a chronology of events leading up to the adverse/sentinel event.

event and create an event flow diagram. See the "Chronology of Events" document. *See the Tools section to access this document.*

i. It is often helpful to use sticky notes or a white board for this process as edits will occur as additional steps in each process are identified.

ii. Once the team agrees chronology is complete it should be recorded on the attachment for inclusion in the RCA report.

2. Ensure understanding of relevant processes:

i. As designed. (How they are meant to work per policy.)

ii. As usually implemented. (How they work day to day.)

iii. As implemented when Adverse/Sentinel Event occurred. (How the system/process worked the day of the event.)

3. Identify gaps in systems/processes.

To meet criteria for a thorough and credible RCA:

✓ *Consider all relevant literature.*

3 Brainstorm

Brainstorm Contributing Factors

A. Begin brainstorming by setting some "ground rules". These guidelines should provide the RCA Team a framework to ensure open, respectful dialogue and maximum participation. *See the Tools section to access this document.*

B. Identify factors that contributed to the event through group brainstorming. There are two approaches that can be used to facilitate the brainstorming process and ensure that all related contributing factors have been considered by the group. Either approach can be chosen by the facilitator/team; the choice of approach may vary based on type of event.

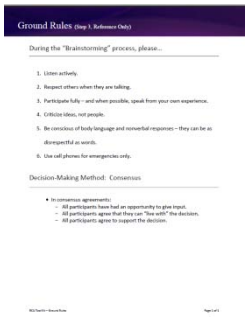
Approach 1. Work backwards from the event, asking "Why".

1. In this approach, the team starts with a brief statement of what happened (the occurrence that you don't want to happen again), such as "patient received wrong dose of warfarin". The team then considers all of the potential reasons why the event occurred. Refer to the "Tree Diagram" to see how one problem/event can have many potential contributing factors. *See the Tools section to access this document.*

2. A list of factors contributing to the event are identified.

3. The facilitator then takes each contributing factor and asks the team to

Tools


Ground Rules (Step 3, Reference Only)

During the "Brainstorming" process, please…

1. Listen actively.
2. Respect others when they are talking.
3. Participate fully – and when possible, speak from your own experience.
4. Criticize ideas, not people.
5. Be conscious of body language and nonverbal responses – they can be as disrespectful as words.
6. Use cell phones for emergencies only.

Decision-Making Method: Consensus

- In consensus agreements:
  - All participants have had an opportunity to give input.
  - All participants agree that they can "live with" the decision.
  - All participants agree to support the decision.

Sample Ground Rules

Provides a list of "ground rules" that might be helpful in creating a work environment conducive to effective brainstorming.


Tree Diagram (Step 3, Reference Only)

Sample Tree Diagram

Tree Diagram

Shows a sample cause and effect diagram to help the RCA Team visualize contributing factors.

To meet criteria for a thorough and credible RCA:

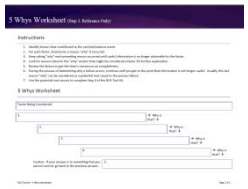
- ✓ *Determine human and other factors most directly associated with the event.*
- ✓ *Determine related systems or processes.*
- ✓ *Brainstorm and analyze systems and processes by asking "Why?" repeatedly.*
- ✓ *Inquire into all areas appropriate to this type of event.*
- ✓ *Identify risks and their potential contribution to this type of event.*

identify "why" that factor occurred (Refer to "5 Whys Worksheet" – *See the Tools section to access this document.*) The facilitator continues to ask the team "why" each preceding factor occurred until no further useful information is obtained. Usually "why" can be asked about five times before coming to an end-point, thus this process is known as the "5 Whys".

4. At the end of this process, the facilitator can quickly review the "Trigger Questions List" to ensure that all possible categories have been covered by the team. *See the Tools section to access this document.*

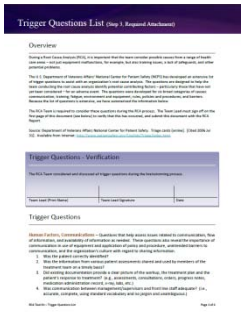
Approach 2. Start with a review of Trigger Questions.

1. In this approach, the RCA Team goes through the Trigger Questions List, question by question, to systematically review and consider all contributing factors in 6 broad categories (also known as Process Variables).
   i. Human Factors-Communication
   ii. Human Factors-Training
   iii. Human Factors-Fatigue/Scheduling
   iv. Environment and Equipment
   v. Rules, Policies, and Procedures
   vi. Barriers
2. The facilitator then takes each contributing factor and asks the team to identify "why" that factor occurred (Refer to "5 Whys Worksheet" – *See the Tools section to access this document.*) The facilitator continues to ask the team "why" each preceding factor occurred until no further useful information is obtained. Usually "why" can be asked about five times before coming to an end-point, thus this process is known as the "5 Whys".


5 Whys Worksheet (Step 3, Reference Only)

Instructions

5 Whys Worksheet


Trigger Questions List (Step 3, Required Attachment)

Overview

Trigger Questions – Verification

Trigger Questions

5 Whys Worksheet

Helps the RCA Team dig deeper into each factor by asking "Why?"

Trigger Questions List

Provides a complete list of questions, referencing a variety of health care areas and program aspects, to help an RCA Team explore potential contributing factors.

4

Identify Root Causes

To meet criteria for a thorough and credible RCA:

- ✓ *Present findings that are internally consistent (does not contradict itself or leave obvious questions unanswered).*
- ✓ *Explain all findings noted as "not applicable" or "no problem".*

Identify Root Causes

A. Once the team has completed the brainstorming process, identify which of the multiple contributing factors identified is actually a root cause.

1. If the RCA Team has identified a significant number of contributing factors (e.g., 20-30 factors), the team may wish to vote on the top 5-8 most likely to be a "root cause" before moving to the next step.
2. Restate each contributing factor as full sentences using the "Five Rules of Causation" summarized below (with full text available). *See the Tools section to access this document.*
   - i. Rule 1: Clearly show the cause-and-effect relationship.
   - ii. Rule 2: Use specific and accurate descriptors for what happened, rather than negative or vague words.
   - iii. Rule 3: Identify the preceding cause, not the human error.
   - iv. Rule 4: Violations of procedure are not root causes; they must have a preceding cause.
   - v. Rule 5: Failure to act is causal only when there was preexisting duty to act.

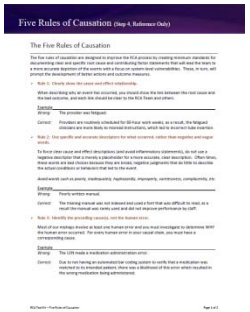
B. Enter each contributing factor statement into the "Identifying a Root Cause Worksheet" to test each contributing factor against the following criteria:

- i. Would the problem have occurred if this cause had not been present?
- ii. Will the problem recur due to the same casual factors if this cause is corrected or eliminated?
- iii. Will correction or elimination of the cause still allow similar events?

If the answer to any of the above is "no", then the factor is a root cause; otherwise, the factor is a contributing cause.

Note: There is usually more than one root cause; identifying more than six root causes may be evidence of too broad a definition of a root cause. *See the Tools section to access this document.*

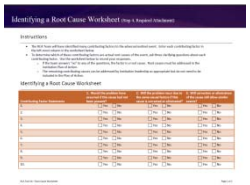
Tools


Five Rules of Causation (Step 4, Reference Only)

The Five Rules of Causation

Five Rules of Causation

Detailed explanation of each rule of causation.


Identifying a Root Cause Worksheet (Step 5, Required Attachment)

Instructions

Identifying a Root Cause Worksheet

Identifying a Root Cause Worksheet

Worksheet that helps the RCA Team determine if each contributing cause meets the criteria for a root cause.

5 Plan of Action

To meet criteria for a thorough and credible RCA:

- ✓ *Identify systems or process improvements to decrease the likelihood of the event happening in the future.*
- ✓ *Outline a plan of action that identifies the problem, actions to be taken, people responsible, deadlines, and methods for measuring success.*
- ✓ *If improvement opportunities are not apparent, explain why.*

Design and Implement a Plan of Action

A. Take each identified Root cause and select action(s) that will be implemented to ensure that the same event does not recur.

1. In choosing interventions, consider the information on the "Hierarchy of Actions". *See the Tools section to access this document.* In quality improvement literature, some types of interventions are known to be more effective and more likely to result in sustained improvement (Stronger Actions – such as standardizing equipment) while other improvement strategies have proven to be much less reliable (Weaker Actions – such as training/education alone). For your Plan of Action, you might choose a mix of intervention types, but when possible choose the strongest possible intervention.

B. Document the improvement interventions you plan to implement in the "Plan of Action" template, which provides a standardized structure for documenting, managing, and monitoring actions resulting from the RCA. *See the Tools section to access this document.*

1. Make sure to include the following information in your Plan of Action:

i. Root cause(s) addressed for each intervention.
ii. Action steps that describe how the intervention will be implemented.
iii. Staff accountable for completing each action step.
iv. Due dates for each action step.
v. Data collection, analysis, and reporting required to regularly monitor the impact of interventions.
vi. Group that will oversee intervention(s) and receive performance reports.

C. Have the team consider what, if any, unintended consequences may result from the implementation of the proposed actions. For example, could a new process slow down workflow? Consider ways these unintended consequences might be lessened or eliminated.

Tools


Hierarchy of Actions (Step 5, Reference Only)

Overview

Recommended Hierarchy of Actions

Stronger Actions
- System design/redesign, including fail-safes and constraints
- Eliminating of look-alike, sound-alike situations
- "Forcing" function procedures creating a "hard stop" when a process isn't followed
- Automation and computerization of processes and tasks
- Architectural/physical plant changes and engineering controls
- Engaging staff in selecting/developing equipment or supply changes, P&P development or modification and usability testing
- Standardizing equipment, supplies and processes including protocols and preprinted orders
- Changing the roles/duties of staff involved in the process and documenting changes

Intermediate Actions
- Redundancy/backstop/cognitive aids
- Enhanced documentation/communications
- Engaging leadership in visible support for patient safety
- Reading back instructions and orders
- Increasing staffing/decrease workload
- Elimination/reduction of distractions
- Implementing redundancy with backups
- Software enhancements/modifications

Weaker Actions
- Rules and double checking
- Warnings and labels
- New procedures/memorandums/policy
- Training/education
- Additional study/analysis/audits
- Employee discipline

Hierarchy of Actions

Use this guide to develop intervention and action steps to improve systems and processes.


Plan of Action (Step 5, Required Attachment)

Plan of Action Template

Use this tool to document the plan of action that addresses identified root causes.

D. Identify performance measures for each intervention. To ensure that performance measures are useful in determining the success of an intervention, choose measures that:

1. Measure the effectiveness or outcome of an intervention, not completion or implementation of the intervention.
2. Are quantifiable, with a defined numerator and denominator (if appropriate).
3. Define the sampling strategy and timeframes for measurement.
4. Set realistic performance objectives.
5. Include a "panic value" – a threshold of substandard performance that, if reached, requires immediate action.

6

Submit

To meet criteria for a thorough and credible RCA:

✓ *Distribute findings to those who can benefit from the information [not mentioned in JC or VA].*

Submit the RCA Report to Headquarters

CCHCS requires RCA Teams to use the "RCA Report Template" to compile all information relating to this RCA process. The "RCA Process Checklist" will guide your team through the final preparations before submitting the report. *See the Tools section to access these documents.*

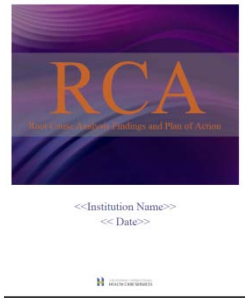
A. Include required attachments. As you complete the RCA Report Template, you will see that a number of attachments are required as part of the report submission – all of the required attachments are included in this tool kit, and should have been completed as the team moved step-by-step through this procedure.

B. Submit the RCA Report to appropriate oversight committees/leadership and the Institution Chief Executive Officer for review and approval.

C. Once approved, submit the report to the headquarters Adverse Sentinel Event Committee for final review. The Adverse Sentinel Event Committee will determine whether the institution has satisfied the criteria for a thorough and credible RCA.

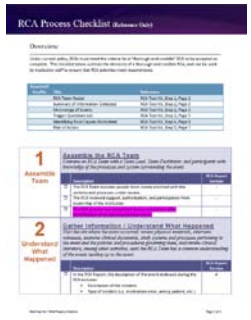
D. Send the report to: healthcareincidentreporting@cdcr.ca.gov

Tools



RCA Report Template

Use this template to document your RCA process.



RCA Process Checklist

This document may be used by the Team Facilitator as a guide for ensuring completion of the minimum RCA requirements during the RCA process.

7

Measure

Measure Results and Modify the Action Plan as Appropriate

A. Implement your Plan of Action immediately. You don't have to wait for formal approval from headquarters to move forward.

B. Update your plan as you go. Make changes to your plan to reflect current activities. For example, if you test out a new process in one clinic and find it to be effective, you may need to add action steps reflecting roll out of the process to the remaining clinics at the institution.

C. Consider adding RCA initiatives to your Institution's Performance Improvement Work Plan (PIWP), so that progress can be monitored by the Quality Management Committee on as ongoing basis, just as other improvement initiatives are monitored.

D. Stay tuned for feedback from the Adverse Sentinel Event Committee. The Adverse Sentinel Event Committee will be getting back to you upon review of your RCA Report and may provide recommendations or support to the institution.

Questions or comments about the RCA process or any of the information in this tool kit?
We want to hear from you!

Please contact Sarah Baker, analyst in the Quality Management Section at Sarah.Baker@cdcr.ca.gov.

RCA Requirements in Policy (Reference Only)

RCA Requirements

In 2012, California Correctional Health Care Services (CCHCS) issued the Patient Safety Program Policy and Procedures, which governs the Root Cause Analysis (RCA) process in our organization. You can find the full text of the Patient Safety Program Policy and Procedures in the **Inmate Medical Services Program (IMSP) Policies and Procedures, Volume 3, Chapter 7.**

Click here to view the full policy and procedures: http://www.cphcs.ca.gov/imspp.aspx

In brief, institutions are required to:

- **Conduct an RCA for adverse/sentinel events. RCAs are encouraged, but not required, for events that are considered near misses.** For the definition of an adverse/sentinel event and near miss, click here: http://www.cphcs.ca.gov/docs/imspp/IMSPP-v03-ch07_2.pdf
- Stop the RCA if the event is being investigated by an investigatory agency such as the Office of Internal Affairs (OIA). If a peer review referral has been made regarding the event, the RCA continues.
- Report an adverse/sentinel event within 24 hours to headquarters.
- Convene an RCA Team within 24 hours of an adverse/sentinel event.
- Ensure that the RCA Team reviews the CCHCS Performance Improvement Culture Statement prior to beginning the RCA to ensure that all members understand the context of the adverse/sentinel event review process.
- Follow the CCHCS RCA Procedure during the RCA.
- Complete the RCA process within 45 days of the adverse/sentinel event and submit a report to the Adverse/Sentinel Event Subcommittee.
- Make any changes to the RCA report requested by the Adverse/Sentinel Event Committee within 15 calendar days.
- Report progress on performance measures to the Adverse/Sentinel Event Committee monthly for at least four months.
- Ensure that all records of RCA proceedings of the adverse/sentinel event review process are maintained as confidential quality management deliberative process documents.
- Ensure that all staff participating in the RCA adhere to confidentiality provisions.
- Make additional reports to the California Department of Public Health as required by Title 22 or the Health and Safety Code.

The table on the following page provides you with specific language from the Patient Safety Program Policy and Procedures and citations.

RCA Requirements in Policy (Reference Only)

Requirement	IMSP Citation
The Institution Chief Executive Officer shall ensure that a root cause analysis is completed for adverse / sentinel events, including events that have been identified by staff at headquarters or by other stakeholder groups.	IMSP Volume 3, Chapter 7.5, Page 2
For all adverse/sentinel events involving blameworthy acts that must be referred to the hiring authority and the other appropriate investigatory agency, root cause analysis shall be deferred until the investigatory review is complete and the investigatory agency staff provides further direction to the institution. For adverse/sentinel events that result in peer review referrals or temporary redirection of health care staff from direct patient care, the root cause analysis continues without delay or deferral.	IMSP Volume 3, Chapter 7.5, Page 1 and 2, and Chapter 7.6, Page 3
Adverse/Sentinel events that are deaths will also receive a separate death review per current policy, which covers a different scope than the root cause analysis process.	IMSP Volume 3, Chapter 7.6, Page 3
As soon as possible and no later than 24 hours after the adverse/sentinel event, the CEO will convene a multi-disciplinary team to conduct a root cause analysis to identify the primary system or process lapses that contributed to the adverse/sentinel event and develop specific action steps to prevent similar events from occurring. The CEO will determine the scope and membership of the root cause analysis team.	IMSP Volume 3, Chapter 7.6, Page 3
The CEO or designee will assign a staff member to serve as the primary contact for information requests relative to the adverse/sentinel event.	IMSP Volume 3, Chapter 7.6, Page 3
Prior to beginning the root cause analysis process, the root cause analysis team will review the CCHCS Performance Improvement Culture Statement to ensure that all members understand the context of the adverse/sentinel event review process.	IMSP Volume 3, Chapter 7.6
The primary emphasis of the root cause analysis is system lapses, not behavior of individual staff.	IMSP Volume 3, Chapter 7.6, Page 4
The root cause analysis team shall adhere to the requirements in the CCHCS Root Cause Analysis (RCA) Procedure.	IMSP Volume 3, Chapter 7.6, Page 4
The CEO may request assistance with the RCA process from headquarters staff at any time by contacting the headquarters Adverse/Sentinel Event Committee, or by speaking to any committee member or designee.	IMSP Volume 3, Chapter 7.6, Page 4
If, at any point during the root cause analysis, the team determines that the circumstances surrounding the adverse/sentinel event meet criteria for a blameworthy act and referral to an appropriate investigatory agency, the team will immediately discontinue the root cause analysis and contact the appropriate investigatory agency for support.	IMSP Volume 3, Chapter 7.6, Page 4

RCA Requirements in Policy (Reference Only)

Requirement	IMSP Citation
If the RCA team identifies clinical practice issues that may merit a peer review referral, the team shall elevate this information to the appropriate clinical manager and the CEO for consideration and referral to headquarters as appropriate per current policy. The root cause analysis will continue regardless of peer review referral.	IMSP Volume 3, Chapter 7.6, Page 4
During the root cause analysis process and pending a final report, the institution shall implement concurrent improvements determined by the root cause analysis team to be appropriate.	IMSP Volume 3, Chapter 7.6, Page 4
The institution root cause analysis, including internal review, approval of the report by the CEO, and submission of a final Adverse/Sentinel Event Report to the headquarters Adverse/Sentinel Event Committee, shall be completed within 45 days of the adverse/sentinel event.	IMSP Volume 3, Chapter 7.6, Page 4
Additional reporting to the California Department of Public Health may be required.	IMSP Volume 3, Chapter 7.6, page 4
The Adverse/Sentinel Event Report shall contain the following elements (additional elements may be included at the discretion of the institution RCA committee): • A description of relevant facts and chronology of events, including immediate actions taken per this procedure to stabilize the patient, preserve documentation and physical materials, and support health care staff; • Classification and titles of staff who served on the root cause analysis team; • An overview of the process used to conduct the root cause analysis, including tools and techniques applied during analysis and relevant literature utilized in the review; • Findings from the root cause analysis, including local system and process lapses identified and appropriate referrals; and • An action plan to address the identified system and process lapses and prevent similar adverse/sentinel events in the future, including a specific timeframe for implementation of the action plan and measurable objectives.	IMSP Volume 3, Chapter 7.6, Pages 4 and 5
The Adverse/Sentinel Event Report must be reviewed by the institution Quality Management Committee and approved by the CEO prior to submission to the headquarters Adverse/Sentinel Event Committee. For institutions with a local Patient Safety Committee, the institution Quality Management Committee may delegate oversight of the root cause analysis and preliminary review of the Adverse/Sentinel Event Report to the Patient Safety Committee. For institutions without a local Patient Safety Committee, the institution Quality Management Committee shall conduct the root cause analysis and preliminary review of the	IMSP Volume 3, Chapter 7.6, Page 5

RCA Requirements in Policy (Reference Only)

Requirement	IMSP Citation
Adverse/Sentinel Event Report.	
Unless instructed otherwise by headquarters, the CEO shall begin implementation of the action plan as soon as practicable, but no later than upon submission of the Adverse/Sentinel Event Report to headquarters. Changes to local practices and procedures shall be made to eliminate reoccurrence of the adverse/sentinel event.	IMSP Volume 3, Chapter 7.6, Page 5
If, upon review of the Adverse/Sentinel Event Report, the headquarters Adverse/Sentinel Event Committee requests clarification or revision of the report, the institution will make necessary clarifications or revisions to the report within 15 calendar days and submit the revised report to the headquarters Adverse/Sentinel Event Committee.	IMSP Volume 3, Chapter 7.6, Page 5
The institution shall submit a monthly status report of activities conducted pursuant to the action plan to the headquarters Adverse/Sentinel Event Committee. The status report shall also include performance measurement data and an analysis about the extent to which local systems or processes have improved.	IMSP Volume 3, Chapter 7.6, Page 5
The institution will submit monthly status reports to the Adverse/Sentinel Event Committee for at least 4 months, until the committee deems the event review process completed.	IMSP Volume 3, Chapter 7.6, Page 5
Protected Proceedings and Records • To ensure full, open and candid review of sentinel events, all records of proceedings of the adverse/sentinel event review process shall be maintained as confidential quality management deliberative process documents. • All staff participating in the adverse/sentinel event review process discussed in this procedure shall adhere to these provisions regarding confidentiality.	IMSP Volume 3, Chapter 7.6, Page 6

ATTACHMENT II

California Correctional Health Care Services

Performance Improvement Culture Statement

Patient safety is the fundamental responsibility of every individual in the correctional health care delivery system. To promote an effective performance improvement program, CCHCS actively cultivates a culture of continuous learning and improvement where all staff focus on making health care delivery processes and outcomes as safe and effective as possible and developing and implementing systems that support sustainable, high-quality performance.

CCHCS recognizes that . . .

- Human error is inevitable and we continually strive to monitor and improve systems to prevent errors.
- Most incidents of unfavorable variances from expected patient care involve process or system breakdowns that must be addressed before performance can reliably improve.
- A punitive environment does not fully take into account systems issues, nor does a blame-free environment hold individuals appropriately accountable.
- A culture of learning and improvement recognizes that people operate within processes and systems and can make mistakes; acknowledges that even competent people can develop erroneous patterns of behavior, yet has zero tolerance for reckless behavior, blameworthy acts and delayed reporting of care incidents.
- To effectively identify opportunities for improvement and resolve system problems, CCHCS staff at all reporting levels must be able to report care incidents without being subject to unjust punitive investigation and penalties.

CCHCS staff will . . .

- Support a learning environment that encourages and fosters the reporting and review of all errors, near-misses, adverse events, and system weaknesses.
- Critically analyze existing processes to proactively identify potential problem areas and opportunities for improvement.
- Proactively analyze processes, design and improve systems to support a safe patient care environment.
- Promote collaboration across ranks and disciplines to find sustainable solutions to patient safety issues.
- Respond quickly and reasonably to actions, decisions, and behaviors that may result in unsafe acts, realizing that most actions, decisions, and behaviors do not warrant corrective or adverse action. The most severe penalties, such as demotion, reduction in pay, suspension with or without pay, and termination, are reserved for reckless behavior and blameworthy acts and, as warranted, delayed reporting.
- Report discovered patient care incidents within the timeframes prescribed in relevant Policies and Procedures.
- Use standardized algorithms based upon learning and improvement concepts to determine individual accountability.

A Blameworthy Act . . .

Although performance improvement processes will primarily target the identification and resolution of process breakdowns, reckless behavior and blameworthy acts discovered in this context will be appropriately addressed to ensure patient and staff safety. Reckless behavior includes situations in which an individual takes a substantial and unjustifiable risk that may result in patient harm. A blameworthy patient care act possesses one of the following three characteristics: it involves a criminal act, a purposefully unsafe act, or events involving patient abuse of any kind. Reckless behavior, a blameworthy act, intentionally withholding information, or providing misleading or false information may result in adverse action in accordance with the Disciplinary Matrix.

Thorough and Credible RCA (Reference Only)

Overview

An RCA must meet minimum requirements for acceptability:

1. Focuses primarily on systems and processes, not individual performance.
2. Is interdisciplinary and involves those who are the most familiar with the situation.
3. Progresses from special causes in clinical processes to common causes in organizational processes.
4. Repeatedly digs deeper by asking "Why?" and when the question is answered, asks "Why?" again, until a fundamental cause is identified.
5. Identifies changes that could be made in systems and processes (either through redesign or development of new systems or processes) that will reduce the risk of such events occurring in the future.
6. Meets the criteria for a thorough and credible RCA. See checklist below.

Thorough and Credible RCA Checklist

Use the checklists below to determine if your RCA has met the criteria for being thorough and credible.

	A Thorough Root Cause Analysis:
☐	Identifies human and other factors most directly associated with the event.
☐	Identifies related systems or processes.
☐	Brainstorms and analyzes underlying systems or processes through a series of "Why?" questions.
☐	Inquires into all areas appropriate to the this type of event.
☐	Identifies risks and their potential contributions to this type of event.
☐	Arrives at potential improvements in systems or processes to decrease the likelihood of such events in the future.
☐	Outlines a plan to address opportunities to improve systems or processes, and, if none are apparent, can explain why.
☐	When improvement plans are justified, explains:
☐	• Who will carry out the plan.
☐	• When that person(s) will carry out the plan.
☐	• The methods for measuring results.

	A Credible Root Cause Analysis:
☐	Is completed timely after identification of an adverse/sentinel event [Not explicit in JC or VA; CCHCS policy already requires timeliness].
☐	Receives support, authorization, and participation from leadership of the institution.
☐	Includes people most closely involved with the systems and processes under review.
☐	Presents findings that are consistent (not contradict itself or leave obvious questions unanswered) and conclusions all RCA team members endorse.
☐	Provides an explanation for all findings of "not applicable" or "no problem".
☐	Considers relevant literature.
☐	Is distributed to anyone who can benefit from the findings [Not mentinoed in JC or VA].

RCA Team Roster (Step 1, Required Attachment)

Team Roster

Your RCA Team should consist of a Team Leader, a Team Facilitator, and four to six additional participants. The team should be interdisciplinary and include experts from the services and program areas associated with the event, some of whom should be line staff. The team may or may not include staff who were actually involved in the event. See the last page of this document for detailed descriptions of each member.

Use the table below to identify your RCA team members and explain their role in this RCA.

Date RCA Team Convened:	

Name	Classification	Role on RCA Team

SAMPLE RCA TEAM Background – XSP just experienced an adverse event. Patient Smith was given the wrong dose of warfarin, had a negative reaction and ended up in the TTA. Mr. Smith was sent to the hospital where he remained for 9 days.		
Name	Classification	Role on RCA Team
Max DeMarco	CSE	Team Leader – XSP manager assigned to this RCA.
Julie Schiller	CQO	Team Facilitator – Ms. Schiller has completed 2 RCAs within the past 6 months and has been involved in other medication process improvement initiatives at XSP.
Jose Salazar	SRNII	Team Member – Nurse supervisor who is knowledgeable of the medication administration processes and associated policies.
Timothy Jones	PCP	Team Member – Prescriber whose panel this patient is a part of, also warfarin specialist.
Margaret Brown	LVN	Team Member – LVN who administered the medication to the patient.
Linda Dawes	PIC	Team Member – Knowledgeable of the medication order and dispensing processes and associated policies.

RCA Team Roster (Step 1, Required Attachment)

The RCA Team

- Team Leader – The project manager for the RCA, the person responsible for accomplishing a thorough and credible analysis, following the RCA process, and identifying and addressing barriers to completing the RCA. The Team Leader understands and supports the RCA, keeps the team focused, provides organizational support, has some subject-matter knowledge, and also acts as a contact person between the improvement team and institution health care leadership. The Team Leader ensures that appropriate time is allotted to the RCA process, an RCA Plan of Action is implemented, and the RCA findings are communicated appropriately. This person may also serve as the Team Facilitator.

- Team Facilitator – Should have hands-on experience in conducting an RCA and has expertise in RCA tools/techniques, facilitating teams, managing group dynamics, delegation, and group consensus building. Ideally, the Team Facilitator would be a staff member who facilitates or manages quality improvement or risk management activities as part of their day-to-day work. The Team Facilitator is responsible for orienting team members to the RCA process and guiding the team in the use of standardized improvement tools, such as flowcharts, brainstorming, and work plans. The Team Facilitator covers logistical functions, such as scheduling meetings.

- Team Members (4-6) – Individuals with firsthand knowledge of the event and subject matter expertise regarding the processes/systems surrounding the event. Team Members are responsible for identifying underlying system and process issues that contributed to the event, ensuring that all aspects of the event are thoroughly explored; recommendations for improvement will significantly reduce the likelihood of the event occurring again; and maintaining confidentiality.

    - Individuals Familiar with the Event and Event Subject Matter – Clinical and nonclinical staff with firsthand knowledge of the event and related processes/systems and who may be either involved or uninvolved but knowledgeable of the event.

    - Other Staff or Outside Consultants – Has relevant knowledge to provide additional information regarding the event or processes/systems relating to the event. This may be a staff member from the regional or headquarters levels of our organization. This person may also serve as the Team Facilitator.

Confidentiality Statement

You have been asked to participate as a member of a Root Cause Analysis (RCA) Team. During the RCA, you will be examining one or more specific health care events to determine:

- What happened.
- Why it happened.
- Actions to prevent the event from happening again.

You will be given access to materials, records, and information to help you analyze the event in question. Information associated with the RCA process is privileged under state and federal law – this means that legal provisions are in place to protect you from having to disclose information about the RCA process or findings as part of a lawsuit.

As an RCA Team member, you have a responsibility to keep RCA information confidential. There are many ways you can protect RCA information:

- Only discuss the patient case(s) with members of your RCA Team. When discussing the RCA case, make sure you are doing it in a place where other staff will not overhear the conversation.

- Be careful with RCA documents.
    - Store hard copies of documents in a locked file cabinet or other secure area of the office, where other staff will not have access to them.
    - If you are reviewing electronic files as part of the RCA, keep these files in a shared folder on the Local Area Network with access limited to RCA Team members. Don't move files to your personal computer.
    - When e-mailing RCA documents, make sure you are sending the documents only to members of the RCA Team. Send any e-mails with patient information to the team members' official CDCR e-mail address. In the event that you need to send information to a non-CDCR e-mail address, encrypt any information that is e-mailed.
    - In reports or documents shared with staff outside the RCA Team, replace the patient's name and CDCR number with a confidential identifier; do the same for any staff members included in the document.

- Store any physical materials, such as medical equipment involved in the incident or photographs, in a secure location accessible only to the RCA Team.

- Clearly define which oversight groups will have access to RCA findings, and make sure these are the only staff receiving RCA reports.

- If the institution decides to share RCA findings broadly to health care staff, provide a broad case description (e.g. “because of problems in our patient identification processes, the wrong patient received a specialty procedure”), and limit information to findings and the actions to address those findings, not the specific details of the case.

By keeping all proceedings, records, data, reports, information, and other materials used in the RCA process in the strictest confidence, you are helping to build an environment where staff will feel comfortable identifying system problems and developing ways to fix those problems. Your RCA Team will be most successful if all members commit to making the team a safe place to discuss information and ideas, knowing that the discussion is confidential.

Thank you for participating in this important effort to protect patient safety and improve our health care system, and for your efforts to protect the confidentiality of RCA proceedings.

Summary of Information Collected (Step 2, Required Attachment)

Staff/Witnesses Interviewed

Name	Classification	Role in Event	Interview Date
			Click here to enter a date.
			Click here to enter a date.
			Click here to enter a date.
			Click here to enter a date.
			Click here to enter a date.
			Click here to enter a date.
			Click here to enter a date.
			Click here to enter a date.

Clinical Documents Reviewed

Document Type/Date	Relevance to Event
➢	•
➢	•
➢	•
➢	•

Guidelines, Policies, and Procedures

Policy Name/Section	Relevance to Event
➢	•
➢	•
➢	•
➢	•

Relevant Literature

Source	Relevance to Event
➢	•
➢	•
➢	•
➢	•

Physical/Other Materials

Material Reviewed	Findings
☐ Medical devices and equipment	•
☐ Retained foreign objects	•
☐ Medications and their containers, package	•

Summary of Information Collected (Step 2, Required Attachment)

	labels, or inserts	
☐	Intravenous bags and tubing	•
☐	Syringes	•
☐	Supply containers and packaging	•
☐	Laboratory or pathology specimens	•
☐	Photographs	•

Other Materials Gathered and Reviewed	Findings
➢	•
➢	•
➢	•
➢	•

Visit to Event Site

☐	Location:	Date: Click here to enter a date.

Other Relevant Information

•
•
•
•
•
•
•
•

Interviewing Techniques (Step 2, Reference Only)

Overview

If you were not at the scene at the time, asking questions is a straightforward approach to finding out what happened in a health care event. The purpose of the interview is to establish an understanding with the witness and to obtain his or her own words describing the event. Obviously, care must be taken to assess the credibility of any statements made in interviews. Answers to a few initial questions will generally show how well the witness could actually observe what happened.

The actual questions you ask the witness will naturally vary with each event, but there are some general questions that should be asked each time:

- Where were you at the time of the adverse/sentinel event?
- What were you doing at the time?
- What did you see, hear?
- What were the environmental conditions (weather, light, noise, etc.) at the time?
- What was (were) the staff/patient(s) doing at the time?
- In your opinion, what caused the adverse/sentinel event?
- How might similar accidents be prevented in the future?

Interviewing is an art that cannot be given justice in a brief document such as this, but a few dos and don'ts can be mentioned.

Do…

- Put the witness, who is probably upset, at ease.
- Emphasize the larger purpose behind the RCA: not to fix blame on any individual person, but to address system problems and prevent the event from happening again.
- **Ask open-ended questions that cannot be answered by simply "yes" or "no".**
- Let the witness talk, and be attentive.
- Confirm that you have the witness's statements correct by repeating information back to the witness.
- Try to sense any underlying feelings of the witness.
- Make short notes or ask someone else on the team to take them during the interview.
- Ask if it is okay to record the interview, if you are doing so.
- Close on a positive note.

Do Not…

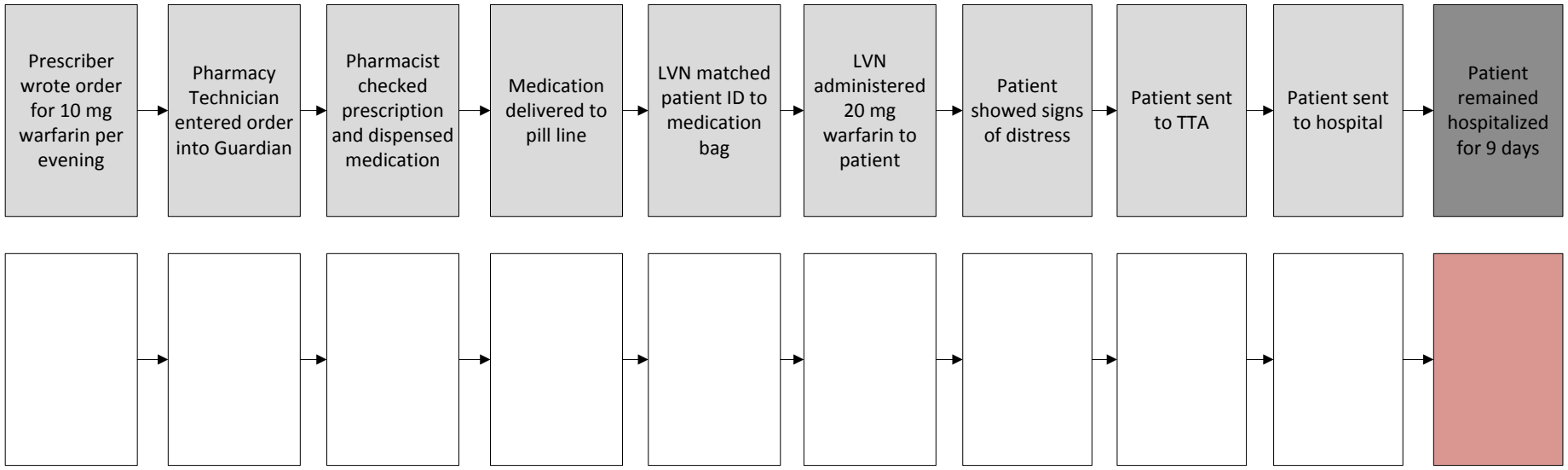
- Intimidate the witness.
- Interrupt.
- Prompt the witness or ask leading questions.
- Show your own emotions.
- Jump to conclusions.

Chronology of Events (Step 2, Required Attachment)

Sample Chronology of Events Diagram

Establishing a chronology of event helps the team to arrive at a common understanding of what happened with regard to a specific adverse/sentinel event. The below is an example of an event flow diagram showing the chronological timeline from the first known fact to the actual event. To create a chronology of events:

1. Discuss and organize the flow of events by using sticky notes or a white board.
    a. Identify the sentinel/adverse event or near miss under review. This may be a patient's name.
    b. Define and enter each of the major steps that led up to the adverse/sentinel event, and enter the information of each step in chronological order. Adjust this worksheet to enter as many steps as necessary for completeness.
    c. Enter the date and time that each step occurred, if available.
    d. Review the steps to get the team's consensus on completeness.
    e. Come on a consensus on the chronology.
2. Document the chronology of events on a document beginning with the earliest event on the left and the adverse/sentinel event as the final item on the right. See example below.



Use this blank template or additional sheets as needed.

Ground Rules (Step 3, Reference Only)

During the "Brainstorming" process, please…

1. Listen actively.
2. Respect others when they are talking.
3. Participate fully – and when possible, speak from your own experience.
4. Criticize ideas, not people.
5. Be conscious of body language and nonverbal responses – they can be as disrespectful as words.
6. Use cell phones for emergencies only.

Decision-Making Method: Consensus

- In consensus agreements:
  - All participants have had an opportunity to give input.
  - All participants agree that they can "live with" the decision.
  - All participants agree to support the decision.

Tree Diagram (Step 3, Reference Only)

Overview

Brainstorming technique:

- In this technique the RCA team starts with the “Problem Statement” (what happened) then works backwards to ask what were the factors that contributed to the event happening.
- This helps the team go from an understanding of what happened to “why” it happened.
- RCA Teams can use the tree diagram to help clarify the contributing reasons (factors) for why a gap in services, process malfunction, or episode of non-compliance occurred.

Instructions

Below are instructions for brainstorming cause and effects and how it can be shown in a tree diagram (see example on the next page).

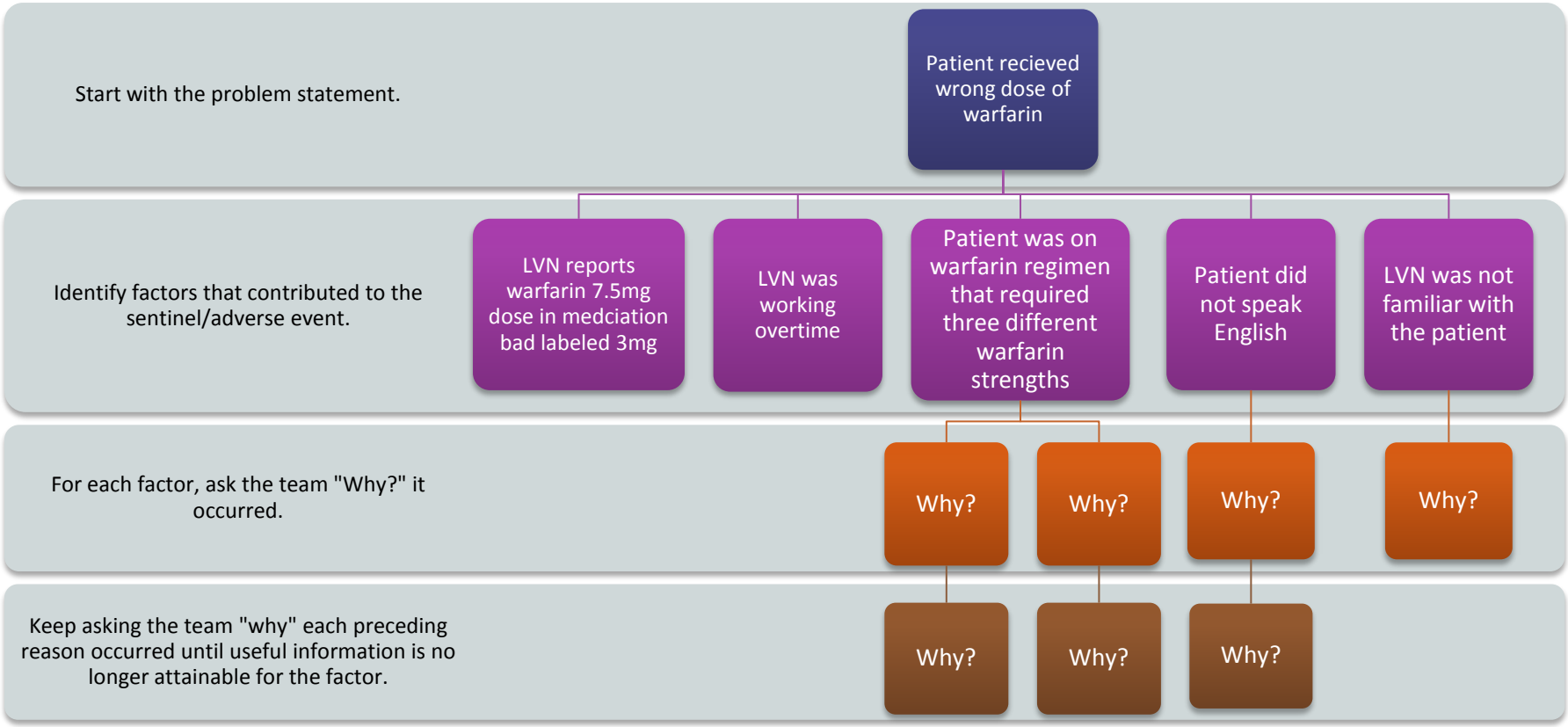
1. Identify factors that contributed to the sentinel/adverse event.

2. For each factor, brainstorm a reason "why" it occurred.

3. Keep asking the team "why" each preceding reason occurred until useful information is no longer attainable for the factor. (It may e easier to document this on the “5 Whys Worksheet”). Usually, this last reason "why" is considered a root cause to the process failure.

Tree Diagram (Step 3, Reference Only)

Sample Tree Diagram



5 Whys Worksheet (Step 3, Reference Only)

Overview

Asking "Why?" is a way of identifying the underlying root cause of a problem. It's important to get to the root cause of a problem, rather than addressing superficial aspects of a problem, to prevent the problem from recurring.

The "5 Whys" process involves repeatedly asking "why?" until the answer is "because that's the way it is". At this point, it is likely that you have identified a root cause of the problem. If addressed and removed, the observed symptoms of the problem should also disappear.

For example:

1. "Patient received wrong dose of warfarin." – why?
2. "The LVN gave the patient three 7.5 m.g. pills instead of three 3 mg pills." – why?
3. "The bag containing the 7.5 mg pills was inside a container with a label for 3 mg pills." – why?
4. "Only the outside opaque red medication envelop contained a label. The small, clear baggie with the medication inside that envelop was not labeled." - why?
5. "This was the process for dispensing medications developed by health care staff when the previous method (one envelope only) resulted in torn bags and missing medications." – why?

Although called the "Five Whys" process, five is an arbitrary number - there may be more or less "why" questions depending on the particular situation. It is important to beware of channeling your analysis down one avenue and completely ignoring other root causes of the same problem.

5 Whys Worksheet (Step 3, Reference Only)

Instructions

1. Identify factors that contributed to the sentinel/adverse event.
2. For each factor, brainstorm a reason "why" it occurred.
3. Keep asking "why" each preceding reason occurred until useful information is no longer attainable for the factor.
4. Look for reasons listed in the "why" section that might be considered a factor for further exploration.
5. Review the factors to get the team's consensus on completeness.
6. During the process of determining why a failure occurs, continue until you get to the point that information is not longer useful. Usually, this last reason "why" can be considered as a potential root cause to the process failure.
7. Use the potential root causes to complete Step 4 of the RCA Tool Kit.

5 Whys Worksheet

Factor Being Considered:	
1.	→ Why is that? ↓
2.	→ Why is that? ↓
3.	→ Why is that? ↓
4.	→ Why is that? ↓
Caution: If your answer is to something that you cannot control, go back to the previous answer.	5.

5 Whys Worksheet (Step 3, Reference Only)

Factor Being Considered:

1. → Why is that? ↓

2. → Why is that? ↓

3. → Why is that? ↓

4. → Why is that? ↓

Caution: If your answer is to something that you cannot control, go back to the previous answer.

5.

Factor Being Considered:

1. → Why is that? ↓

2. → Why is that? ↓

3. → Why is that? ↓

4. → Why is that? ↓

Caution: If your answer is to something that you cannot control, go back to the previous answer.

5.

5 Whys Worksheet (Step 3, Reference Only)

Factor Being Considered:

1. → Why is that? ↓

2. → Why is that? ↓

3. → Why is that? ↓

4. → Why is that? ↓

Caution: If your answer is to something that you cannot control, go back to the previous answer.

5.

Factor Being Considered:

1. → Why is that? ↓

2. → Why is that? ↓

3. → Why is that? ↓

4. → Why is that? ↓

Caution: If your answer is to something that you cannot control, go back to the previous answer.

5.

Trigger Questions List (Step 3, Required Attachment)

Overview

During a Root Cause Analysis (RCA), it is important that the team consider possible causes from a range of health care areas – not just equipment malfunctions, for example, but also training issues, a lack of safeguards, and other potential problems.

The U.S. Department of Veterans Affairs' National Center for Patient Safety (NCPS) has developed an extensive list of trigger questions to assist with an organization's root cause analysis. The questions are designed to help the team conducting the root cause analysis identify potential contributing factors – particularly those that have not yet been considered – for an adverse event. The questions were developed for six broad categories of causes: communication; training; fatigue; environment and equipment; rules, policies and procedures; and barriers. Because the list of questions is extensive, we have summarized the information below.

The RCA Team is required to consider these questions during the RCA process. The Team Lead must sign off on the first page of this document (see below) to verify that this has occurred, and submit this document with the RCA Report.

Source: Department of Veterans Affairs National Center for Patient Safety. Triage cards {online]. [Cited 2006 Jul 31]. Available from Internet: http://www.patientsafety.gov/CogAids/Triage/index.html.

Trigger Questions - Verification

The RCA Team considered and discussed all trigger questions during the brainstorming process.

Team Lead (Print Name)	Team Lead Signature	Date

Trigger Questions

Human Factors, Communications – Questions that help assess issues related to communication, flow of information, and availability of information as needed. These questions also reveal the importance of communication in use of equipment and application of policy and procedure, unintended barriers to communication, and the organization's culture with regard to sharing information.

1. Was the patient correctly identified?
2. Was the information from various patient assessments shared and used by members of the treatment team on a timely basis?
3. Did existing documentation provide a clear picture of the workup, the treatment plan and the patient's response to treatment? (e.g., assessments, consultations, orders, progress notes, medication administration record, x-ray, labs, etc.)
4. Was communication between management/supervisors and front line staff adequate? (i.e., accurate, complete, using standard vocabulary and no jargon and unambiguous.)

5. Was communication between front line team members adequate?
6. Were policies and procedures communicated adequately?
7. Was the correct technical information adequately communicated 24 hours a day to the people who needed it?
8. Were there methods for monitoring the adequacy of staff communication? (e.g., "read back", confirmation messages, debriefs, etc.)
9. Was the communication of potential risk factors free from obstacles?
10. If there was a manufacturer's recall/alert/bulletin on file for equipment, medication or transfusion related elements at the time of the event or close call, were relevant staff members aware of the recall/alert/bulletin? (VA)
11. If relevant, were the patient and their family/significant others actively included in the assessment and treatment planning?
12. Did management establish adequate methods to provide information to employees who needed it in a manner that was easy to access/use and timely?
13. Did the overall culture of the facility encourage or welcome observations, suggestions, or "early warnings" from staff about risky situations and risk reduction?
14. Has this happened before and was anything done to prevent it from happening again?
15. Did adequate communication across organized boundaries occur?

Human Factors, Training – Questions that help assess issues related to routine job training, special training, and continuing education; including the timing of that training. Training issues may concern application of approved procedures, correct use of equipment, or appropriate manipulation of protective barriers. These questions also focus attention on the interfaces between people, workspace, and equipment.

1. Was there a program to identify what was actually needed for staff training?
2. Was training provided prior to the start of the work process?
3. Were the results of training monitored over time?
4. Was the training adequate? If not, consider the following factors: supervisory responsibility, procedure omissions, flawed training and flawed rules/policy/procedure.
5. Were training programs for staff designed up-front with the intent of helping staff perform their tasks without errors?
6. 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 (i.e., human factors, engineering)?
7. Were all staff trained in the use of relevant barriers and controls?
8. If equipment was involved, did it work smoothly in the context of:
    a. Staff needs and experience?
    b. Existing procedures, requirements and workload?
    c. Physical space and location?

Human Factors, Fatigue/Scheduling – Questions that weigh the influence of stress and fatigue that may result from change, scheduling and staffing issues, sleep deprivation, or environmental distractions such as noise. These questions also evaluate relationships to training issues, equipment use, management concern and involvement.

1. Were the levels of vibrations, noise or other environmental conditions appropriate?
2. If applicable, were the environmental stressors properly anticipated?
3. Did staff have adequate sleep?
4. Did scheduling allow staff adequate sleep?

5. Was fatigue properly anticipated?
6. Was the environment free of distractions?
7. 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.)
8. Was the level of automation appropriate? (i.e., neither too much nor not enough.)

Environment/Equipment – Questions to help evaluate factors related to use and location of equipment; fire protection and disaster drills; codes, specifications and regulations; the general suitability of the environment; and the possibility of recovery after an error has occurred. These questions show that what appears to be equipment failure may relate to human factors issues, policy and procedure questions and training needs.

1. Was the work area/environment designed to support the function it was being used for?
2. Had there been an environmental risk assessment (i.e., safety audit) of the area?
3. Were the work environment stress levels (either physical or psychological) appropriate? (e.g. temperature, space, noise, intra-facility transfers, construction, projects)
4. Had appropriate safety evaluations and disaster drills been conducted?
5. Did the work area/environment meet current codes, specification and regulations?
6. Was equipment designed to properly accomplish its intended purpose?
7. Did the equipment involved meet current codes, specifications and regulations?
8. Was there a documented safety review performed on the equipment involved?
9. Was there a maintenance program in place to maintain the equipment involved?
10. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?
11. If previous inspections pointed to equipment problems, what corrective actions were implemented and were they effective?
12. If problems were identified, were adequate time and resources allowed for physical plant and equipment upgrades?
13. Was there adequate equipment to perform the work process?
14. Were emergency provisions and back-up systems available in case of equipment failure?
15. Had this type of equipment worked correctly and been used appropriately in the past?
16. Was the equipment designed such that usage mistakes would be unlikely to happen?
17. Was the design specification adhered to?
18. Was the equipment produced to specification and operated in manner that the design was intended to satisfy?
19. Were staff trained appropriately to operate the equipment involved in the event?
20. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?
21. Was the equipment designed so that corrective actions could be accomplished in a manner that minimized/eliminated any undesirable outcomes?
22. Were equipment displays and controls working properly and interpreted correctly?
23. Was the equipment or device intended to be reused (e.g. not a Single Use Device)?

Rules/Policies/Procedures – Questions that help assess the existence and ready accessibility of directives including technical information for assessing risk, mechanisms for feedback on key processes, effective interventions developed after previous events, compliance with national policies, the usefulness of and incentives for compliance with codes, standards, and regulations. The qualifications of the facility and employees for the level of care provided; orientation and training for compliance with safety and security measures including handling of hazardous material and emergency preparedness;

and the availability of information to all part time, temporary, or voluntary workers and students are also considered.

1. Was there any overall management plan for addressing risk and assigning responsibility for risk?
2. Did management have an audit or quality control system to inform them how key processes related to the event are functioning?
3. If previous audits have been done for a similar event, were the causes identified and were effective interventions developed and implemented on a timely basis?
4. Would this problem have gone unidentified or uncorrected after an audit/review?
5. Was required care for the patient within the scope of the facility's mission, staff expertise and availability, and technical and support resources?
6. Were staff who were involved in the event properly qualified and trained to perform their functions?
7. 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?
8. Were there written up-to-date policies and procedures that addressed the work processes related to the event?
9. Were these policies/procedures consistent with relevant CCHCS/DHCS policies, standards and regulations?
10. Were relevant policies/procedures clear, understandable and readily available to all staff?
11. Were the relevant policies and procedures actually used on a day-to-day basis?
12. If the policies and procedures were not used, what got in the way of their usefulness to the staff? (VA)
13. If policies and procedures were not used, what positive and negative incentives were absent? (VA)

Barriers – Barriers protect people and property from adverse events. Questions assess barrier strength, fault tolerance, function and interaction/relationship to Rules/Policies/Procedures and Environment/Equipment.

1. What barriers and controls were involved in this event?
2. Were these barriers designed to protect patients, staff, equipment or environment?
3. Was patient risk considered when designing these barriers and controls?
4. Were these barriers and controls in place before the event happened?
5. Had these barriers and controls been evaluated for reliability?
6. Were there other barriers and controls for related work processes?
7. Was the concept of "fault tolerance" applied in system design?
8. Were relevant barriers and controls maintained and checked on a routine basis by design staff?
9. Would the event have been prevented if the existing barriers and controls functioned correctly?
10. Were the systems or processes tested before they were implemented?
11. Did audits/reviews related to the barriers include evaluation of plans, designs, installation, maintenance, and process changes?
12. Did management have a method for identifying what the results of the system changes would be before implementation?

Five Rules of Causation (Step 4, Reference Only)

The Five Rules of Causation

The five rules of causation are designed to improve the RCA process by creating minimum standards for documenting clear and specific root cause and contributing factor statements that will lead the team to a more accurate depiction of the events with a focus on system-level vulnerabilities. These, in turn, will prompt the development of better actions and outcome measures.

- **Rule 1: Clearly show the cause and effect relationship.**

  When describing why an event has occurred, you should show the link between the root cause and the bad outcome, and each link should be clear to the RCA Team and others.

  Example

  Wrong: The provider was fatigued.

  Correct: Providers are routinely scheduled for 80-hour work weeks; as a result, the fatigued clinicians are more likely to misread instructions, which led to 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 descriptions (and avoid inflammatory statements), do not use a negative descriptor that is merely a placeholder for a more accurate, clear description. Often times, these words are bad choices because they are broad, negative judgments that do little to describe the actual conditions or behaviors that led to the event.

  Avoid words such as poorly, inadequately, haphazardly, improperly, carelessness, complacently, etc.

  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 staff.

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

  Most of our mishaps involve at least one human error and you must investigate to determine WHY the human error occurred. For every human error in your causal chain, you must have a corresponding cause.

  Example

  Wrong: The LVN made a medication administration error.

  Correct: Due to not having an automated bar coding system to verify that a medication was matched to its intended patient; there was a likelihood of this error which resulted in the wrong medication being administered.

Five Rules of Causation (Step 4, Reference Only)

- **Rule 4: Violations of procedures are not root causes; they must have a preceding cause.**

  Understand and manage the cause of a violation in policy or procedures, not the violation itself. 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 nurse is missing steps in a procedure because he is not aware of the formal checklist, work on education.

  Example

  Wrong: The OT scheduler did not follow the correct procedure for hospital follow-up appointment scheduling.

  Correct: Noise and confusion on the clinic area and production pressure to schedule RN referrals and other patient appointments increased the probability of missing steps in the protocol resulting in patients being missed for follow-up appointments.

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

  We can all find ways in which the event would not have occurred – but this is not the purpose of causal investigation. Instead, we need to find out why this mishap occurred in our system as it is designed today. A provider'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 stat orders on the printout created the possibility of urgent orders not being administered; this resulted in the medication not being administered.

Adapted from: "Using the Five Rules of Causation", VA National Center for Patient Safety web site (www.patientsafety.gov/causation.html)
"Medication-Use Safety: A Practical Approach to FMEA and RCA", American Society of Health-System Pharmacists; Summer Meeting, 2003.

Source: Lee Murdaugh, Cardinal Health 2008

Identifying a Root Cause Worksheet (Step 4, Required Attachment)

Instructions

- The RCA Team will have identified many contributing factors to the adverse/sentinel event. Enter each contributing factor in the left-most column in the worksheet below.
- To determine which of these contributing factors are actual root causes of the event, ask three clarifying questions about each contributing factor. Use the worksheet below to record your responses.
    - If the team answers "no" to any of the questions, the factor is a root cause. Root causes must be addressed in the institution Plan of Action.
    - The remaining contributing causes can be addressed by institution leadership as appropriate but do not need to be included in the Plan of Action.

Identifying a Root Cause Worksheet

Contributing Factor Statements	1. Would the problem have occurred if this cause had not been present?	2. Will the problem recur due to the same casual factors if this cause is corrected or eliminated?	3. Will correction or elimination of the cause still allow similar events?
1.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
2.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
3.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
4.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
5.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
6.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
7.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
8.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
9.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
10.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Hierarchy of Actions (Step 5, Reference Only)

Overview

Your RCA Team will discuss many ideas as solutions that address the root causes of system or process breakdowns. **Prioritize and implement the strongest possible actions first or use interventions that involve a combination of actions.** At times, depending on the situation, "Stronger" actions may be less effective than "Weaker" or "Intermediate" actions. Use the below as a guide for discussion and consideration.

Recommended Hierarchy of Actions

Stronger Actions
• System design/redesign, including fail-safes and constraints
• Eliminating of look-alike, sound-alike situations
• "Forcing" function procedures creating a "hard stop" when a process isn't followed
• Automation and computerization of processes and tasks
• Architectural/physical plant changes and engineering controls
• Engaging staff in selecting/developing equipment or supply changes, P&P development or modification and usability testing
• Simplifying processes; removing unnecessary steps with staff input
• Standardizing equipment, supplies and processes including protocols and preprinted orders
• Changing the roles/duties of staff involved in the process and documenting changes

Intermediate Actions
• Reminders/checklists/cognitive aids
• Enhanced documentation/communications
• Engaging leadership in visible support for patient safety
• Reading back instructions and orders
• Increasing staffing/decrease workload
• Elimination/reduction of distractions
• Implementing redundancy with backups
• Software enhancements/modifications

Weaker Actions
• Rules and double-checking
• Warnings and labels
• New procedure/memorandum/policy
• Training/education
• Additional study/analysis/audits
• Employee discipline

Sources: "Selecting the Best Error-Prevention Tools for the Job" – ISMP, "Root Cause Analysis" – Healthcare Hazard Control, ECRI, "Root Cause Analysis in Healthcare: Tools and Techniques" – The Joint Commission

Plan of Action (Step 5, Required Attachment)

Root Cause / Issue to be Addressed –			
Summary of the Improvement Activity –			
Person Responsible for Implementation:		Person Responsible for Monitoring/Reporting Results:	
Action Step(s)	**Responsible**	**Deadline**	**Comments/Status**
•			•
•			•
•			•
•			•
•			•
•			•
Performance Measures:	**Date of Most Recent Measurement**		**Findings/Results Per Most Recent Data**
•			•
•			•

Root Cause / Issue to be Addressed –			
Summary of the Improvement Activity –			
Person Responsible for Implementation:		Person Responsible for Monitoring/Reporting Results:	
Action Step(s)	**Responsible**	**Deadline**	**Comments/Status**
•			•
•			•
•			•
•			•
•			•
•			•
Performance Measures:	**Date of Most Recent Measurement**		**Findings/Results Per Most Recent Data**
•			•
•			•

Root Cause / Issue to be Addressed –

Plan of Action (Step 5, Required Attachment)

Summary of the Improvement Activity –			
Person Responsible for Implementation:		**Person Responsible for Monitoring/Reporting Results:**	
Action Step(s)	**Responsible**	**Deadline**	**Comments/Status**
•			•
•			•
•			•
•			•
•			•
•			•
Performance Measures:	**Date of Most Recent Measurement**		**Findings/Results Per Most Recent Data**
•			•
•			•

Root Cause / Issue to be Addressed –			
Summary of the Improvement Activity –			
Person Responsible for Implementation:		**Person Responsible for Monitoring/Reporting Results:**	
Action Step(s)	**Responsible**	**Deadline**	**Comments/Status**
•			•
•			•
•			•
•			•
•			•
•			•
Performance Measures:	**Date of Most Recent Measurement**		**Findings/Results Per Most Recent Data**
•			•
•			•

RCA

Root Cause Analysis Findings and Plan of Action

<<Institution Name>>

<< Date>>

CALIFORNIA CORRECTIONAL
HEALTH CARE SERVICES

RCA Report

Patient CDC#:	Patient Last Name:
Institution:	Date of Birth:
Date of Incident:	Time of Incident:

A. Issue to be Addressed

Summarize the issue that is to be addressed by this root cause analysis in a few sentences.

B. Event Description

Provide details of the adverse/sentinel event, including:

- Description of the adverse/sentinel event.
- Date of the event.
- Type of event (i.e. medication error, fall, wrong patients, etc.).
- Healthcare specialty in which the event occurred.
- Actual effect on patient, staff, and/or service.
- Point of detection of the event.
- Additional information to further explain the event and surrounding circumstances.

C. Support of the Patient and Staff

Provide details of the following:

- Actions taken to stabilize patient and remove immediate risks.
- Support/assistance provided to involved staff.
- Involvement, communication and support of patient and/or relatives.

D. Findings – Contributing Factors and Root Causes

The RCA Team identified the following contributing factors during group brainstorming and analysis sessions:

Contributing Factors

-

Root Causes

The RCA Team found that these contributing causes were most likely the root causes of the event:

-

E. Summary of Actions to Address Root Causes

Root Cause	Actions to Address
➢	•
➢	•
➢	•
➢	•

F. Performance Measures

Our institution will report on the following measures to determine whether the identified risks to patients have been successfully addressed by process improvements and other interventions:

-

G. Required RCA Report Attachments

Check the box next to the required documents below that are attached to this report.

Attached? Yes/No	Title	Reference
	RCA Team Roster	RCA Tool Kit, Step 1, Page 2
	Summary of Information Collected	RCA Tool Kit, Step 2, Page 3
	Chronology of Events	RCA Tool Kit, Step 2, Page 3
	Trigger Questions List	RCA Tool Kit, Step 3, Page 5
	Identifying Root Causes Worksheet	RCA Tool Kit, Step 4, Page 6
	Plan of Action	RCA Tool Kit, Step 5, Page 7

RCA Process Checklist (Reference Only)

Overview

Under current policy, RCAs must meet the criteria for a "thorough and credible" RCA to be accepted as complete. The checklist below outlines the elements of a thorough and credible RCA, and can be used by institution staff to ensure that RCA activities meet requirements.

Attached?	Title	Reference
☐ Yes ☐ No	RCA Team Roster	RCA Tool Kit, Step 1, Page 2
☐ Yes ☐ No	Summary of Information Collected	RCA Tool Kit, Step 2, Page 3
☐ Yes ☐ No	Chronology of Events	RCA Tool Kit, Step 2, Page 3
☐ Yes ☐ No	Trigger Questions List	RCA Tool Kit, Step 3, Page 5
☐ Yes ☐ No	Identifying Root Causes Worksheet	RCA Tool Kit, Step 4, Page 6
☐ Yes ☐ No	Plan of Action	RCA Tool Kit, Step 5, Page 7

1 Assemble Team

Assemble the RCA Team

Convene an RCA Team with a Team Lead, Team Facilitator, and participants with knowledge of the processes and system surrounding the event.

	Description	RCA Report Section
☐	The RCA Team includes people most closely involved with the systems and processes under review.	-
☐	The RCA received support, authorization, and participation from leadership of the institution.	-
☐	The RCA process was completed timely completion after identification of an adverse/sentinel event.	-

2 Understand What Happened

Gather Information / Understand What Happened

Visit the site where the event occurred, review physical materials, interview witnesses, examine clinical documents, study systems and processes pertaining to the event and the policies and procedures governing them, and review clinical literature, among other activities, until the RCA Team has a common understanding of the events leading up to the event.

	Description	RCA Report Section
☐	In the RCA Report, the description of the event reviewed during the RCA includes: • Description of the incident. • Type of incident (i.e. medication error, wrong patient, etc.). • Date of the incident.	A

		• Healthcare specialty in which the incident occurred. • Actual effect on patient, staff, and/or service. • Point of detection of the incident. • Additional information to further explain the incident and circumstances surrounding the incident. • Actions taken to stabilize patient and remove immediate risks. • Support/assistance provided to involved staff. • Involvement, communication and support of patient and/or relatives.	
	☐	The RCA Team reviewed and considered relevant literature.	-

3 Brainstorm

Brainstorm Contributing Factors

Determine all possible causes of the event by having the RCA Team ask "what happened" and "why it happened" continually until all factors/causes are exhausted.

	Description	RCA Report Section
☐	During the RCA, the team identified human and other factors most directly associated with the event.	-
☐	The RCA Team reviewed all related systems or processes.	-
☐	The RCA Team brainstormed and analyzed underlying systems or processes through a series of "Why?" questions.	-
☐	The RCA involved inquiry into all areas appropriate to the type of event.	-

4 Identify

Identify Root Causes

Describe root causes in the "Findings – Root Causes" section below, following the Five Rules of Causation guidelines.

	Description	RCA Report Section
☐	The RCA Team evaluated contributing factors.	D
☐	Root causes are presented in causal statements that meet all 5 rules for causation.	D
☐	The RCA Report presents findings that are consistent (not contradictory or leaving obvious questions unanswered) and all RCA team members endorse conclusions.	-
☐	The RCA Report provides an explanation for all findings of "not applicable" or "no problem".	-

RCA Process Checklist (Reference Only)

5

Plan

Design and Implement an Action Plan

Determine actions that will be implemented to improve systems and process and reduce the likelihood of the event occurring again.

	Description	RCA Report Section
☐	The RCA Team determined potential improvement in systems or processes to decrease the likelihood of such events in the future.	-
☐	The Plan of Action outlines actions to improve systems or processes, and if none are apparent, can explain why.	-
☐	The Plan of Action explains: • Who will carry out the plan. • When that person(s) will carry out the plan. • The methods for measuring results.	-