Institute for Healthcare Improvement

Root Cause Analyses and Actions (RCA²) Toolkit

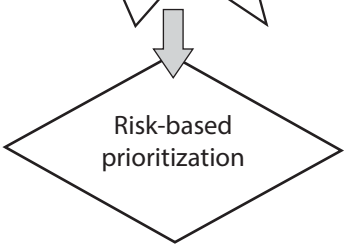
A resource for IHI's online course with coaching: *Redesigning Event Review with RCA²*

Please note: To ensure your work is saved, we recommend downloading worksheets to your desktop before filling them out.

This workbook is part of Redesigning Event Review with RCA², an online course in which participants receive tools, coaching, and community support to aid them in implementing RCA² at their organization. Learn more at ihi.org/RCA2course.

Timeline for RCA² Event Review Process

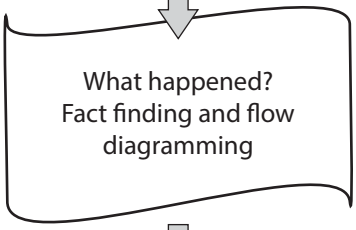
Immediate actions are taken to care for the patient, make the situation safe for others, and sequester equipment, products, or materials.



Applicable Tools:
- Safety Assessment Code Matrix Worksheet
- RCA² Roles Worksheet

Patient safety, risk or quality management is typically responsible for the prioritization; for consistency, one person is assigned responsibility for applying the risk matrix.

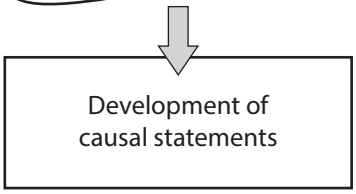
72 hours — ***72 hours***



Applicable Tools:
- Flow Diagram for RCA²
- Triggering Questions for RCA²
- RCA² Interview Tips

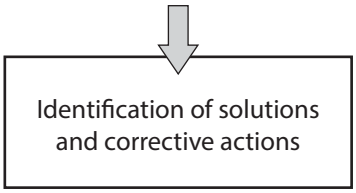
Multiple meetings of 1.5 to 2 hours may be required to: prepare and conduct interviews; visit the site; review equipment or devices; and prepare the report.
Managers/supervisors responsible for the processes or areas should be invited to provide feedback for the team's consideration.

Typically a single RCA² team is responsible for the entire review process; however, if different staff is used for these RCA² review phases, it is recommended that a core group of staff from the RCA² team participate in all phases for consistency and continuity.



Apply the Five Rules of Causation.

Applicable Tools:
- Cause and Effect Diagram for RCA²
- 5 Whys for RCA²
- Causal Statement Worksheet



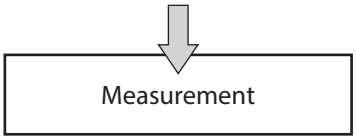
Applicable Tools:
- Action Hierarchy Worksheet
- Effective RCA² Checklist

Patients/families and managers/supervisors responsible for the process or area should be provided feedback and consulted for additional ideas; however they should not have final decision authority over the team's work.

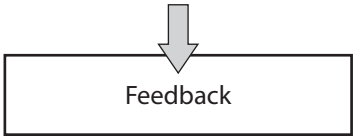
30–45 days — ***30–45 days***

Applicable Tool:
- Action Planning Worksheet

A responsible individual with the authority to act, not a team or committee, should be responsible for ensuring action implementation.



Each action should have a process or outcome measure identifying what will be measured, the expected compliance level, and the date it will be measured. An individual should be identified who will be responsible for measuring and reporting on action effectiveness.



Feedback should be provided to the CEO/board, service/department, staff involved, patient and/or patient's family, the organization, and the patient safety organization (if relevant).

The RCA² team is not usually responsible for these activities.

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Safety Assessment Code Matrix Worksheet

Use this worksheet to assess the potential severity (i.e., reasonable worst-case scenario) and probability of the type of event under review. For complete definitions of severity and probability categories — including **recommendations for assessing risks to visitors, staff, or property — see the RCA² report**.

SEVERITY and PROBABILITY	**Catastrophic** Death or major permanent loss of function	**Major** Permanent lessening of bodily functioning, disfigurement, or surgical intervention *or* for ≥ 3 patients increased length of stay or level of care	**Moderate** Increased length of stay or increased level of care for 1 or 2 patients	**Minor** No injury, increased length of stay, or increased level of care
Frequent Likely to occur immediately or within a short period (may happen several times in 1 year)	**3**	**3**	2	1
Occasional Probably will occur (may happen several times in 1 to 2 years)	**3**	2	1	1
Uncommon Possible to occur (may happen sometime in 2 to 5 years)	**3**	2	1	1
Remote Unlikely to occur (may happen sometime in 5 to 30 years)	**3**	2	1	1

Matrix score: _____ (Any event that scores a "3" should trigger RCA².)

Based on Department of Veterans Affairs, Veterans Health Administration, VHA Patient Safety Improvement Handbook 1050.01, May 23, 2008.
Available at http://cheps.engin.umich.edu/wp-content/uploads/sites/118/2015/04/Triaging-Adverse-Events-and-Close-Calls-SAC.pdf

RCA² Roles Worksheet

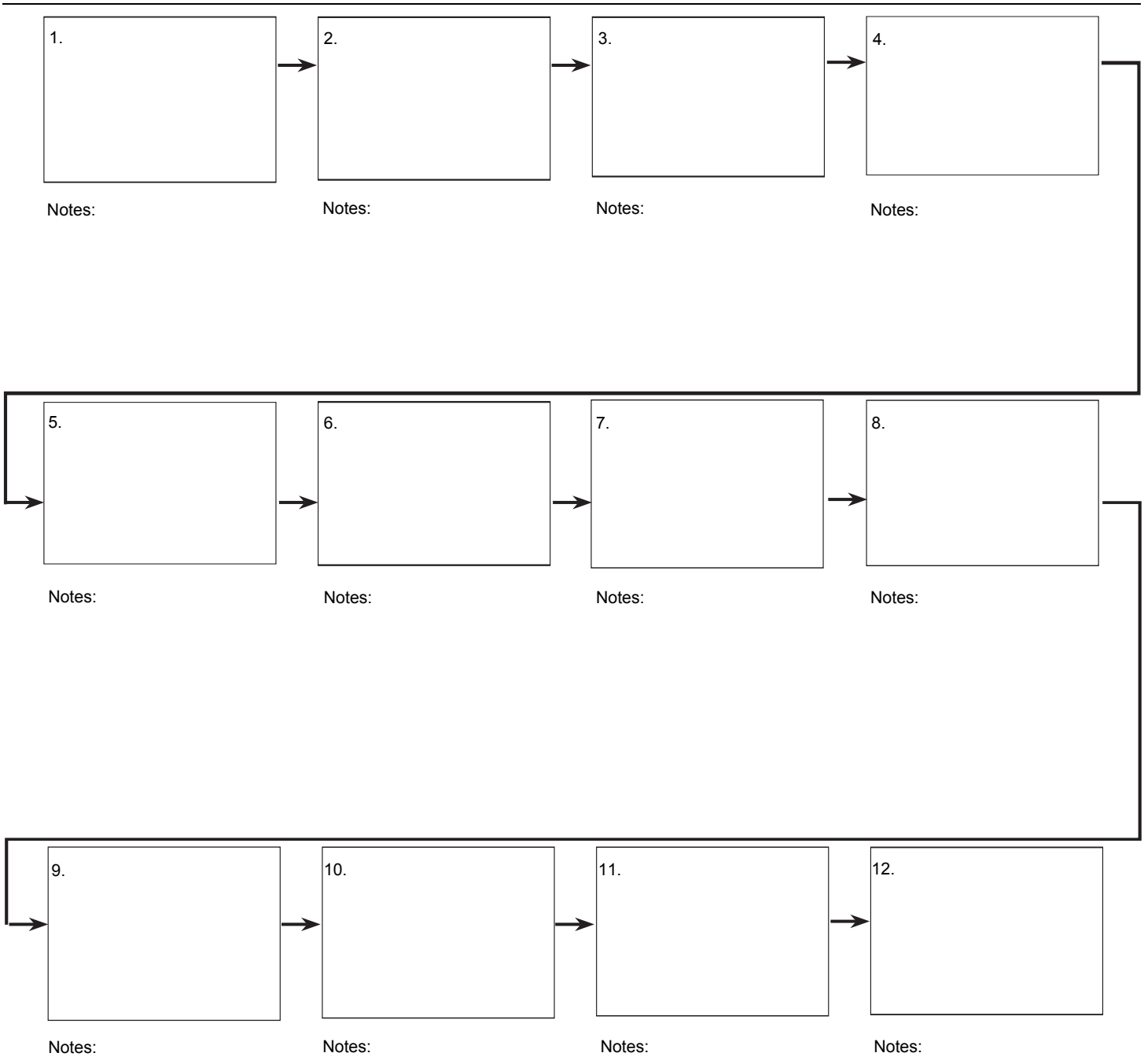
Use the chart below to ensure you're considering important perspectives in your RCA² review. Keep the following in mind:

- "Team members" are individuals who see the RCA² process through from beginning to end. In most cases, the team should include four to six people.
- The same individual may fulfill multiple roles.
- In some circumstances, an individual may be interviewed and also included on the RCA² team.

RCA² Roles	Team Member?	Interview?
Staff		
Staff directly involved in the event		
Front line staff working in the area/process being studied		
Staff who are not familiar with the process being studied		
Subject Matter Experts		
Subject matter expert(s) on the process being evaluated		
Subject matter expert on the RCA² process		
Patients and Families		
Patient involved in the event		
Family of patient involved in the event		
Patient representative		

Flowchart Diagram for RCA²

Use this tool with your RCA² team to create a chronological depiction of the steps within the event you're reviewing. It should help you: 1. Establish a shared understanding of what happened 2. Identify any gaps in knowledge. 3. Compare what happened with what should have happened. 4. Investigate why all deviations occurred. Refer to the **RCA² report** for an example.



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Triggering Questions for RCA²

Triggering Questions help RCA² teams consider important areas of inquiry. Answer each question as "yes," "no," or "not applicable" (N/A). For any questions to which the answer is "no," form a plan to investigate why not by interviewing staff and/or reviewing documentation (e.g., regulatory requirements, guidelines, publications, and/or codes and standards). Use the worksheet below to track your progress.

Communication

1. Was the patient correctly identified? ☐YES ☐NO ☐N/A
2. Was information from various patient assessments shared and used by members of the treatment team on a timely basis? ☐YES ☐NO ☐N/A
3. Did existing documentation provide a clear picture of the work-up, the treatment plan, and the patient's response to treatment? (e.g., Assessments, consultations, orders, progress notes, medication administration record, x-ray, labs, etc.) ☐YES ☐NO ☐N/A
4. Was communication between management/supervisors and front line staff adequate? (i.e., Accurate, complete, unambiguous, using standard vocabulary and no jargon) ☐YES ☐NO ☐N/A
5. Was communication between front line team members adequate? ☐YES ☐NO ☐N/A
6. Were policies and procedures communicated adequately? ☐YES ☐NO ☐N/A
7. Was the correct technical information adequately communicated 24 hours/day to the people who needed it? ☐YES ☐NO ☐N/A
8. Were there methods for monitoring the adequacy of staff communications? (e.g., Read back, repeat back, confirmation messages, debriefs) ☐YES ☐NO ☐N/A
9. Was the communication of potential risk factors free from obstacles? ☐YES ☐NO ☐N/A
10. Was there a manufacturer's recall/alert/bulletin issued on the medication, equipment, or product involved with the event or close call? If yes, were relevant staff members made aware of this recall/alert/bulletin, and were the specified corrective actions implemented? ☐YES ☐NO ☐N/A
11. Were the patient and their family/significant others actively included in the assessment and treatment planning? ☐YES ☐NO ☐N/A
12. Did management establish adequate methods to provide information to employees who needed it in a timely manner that was easy to access and use? ☐YES ☐NO ☐N/A
13. Did the overall culture of the department/work area encourage or welcome observations, suggestions, or "early warnings" from staff about risky situations and risk reduction? ☐YES ☐NO ☐N/A

- If this has happened before, consider: What was done to prevent it from happening again?

14. Did adequate communication across organizational boundaries occur? ☐YES ☐NO ☐N/A

Training

15. Was there an assessment done to identify what staff training was actually needed?
☐YES ☐NO ☐N/A

16. Was training provided prior to the start of the work process? ☐YES ☐NO ☐N/A

17. Were the results of training monitored over time? ☐YES ☐NO ☐N/A

18. Was the training adequate? ☐YES ☐NO ☐N/A

- Consider: supervisory responsibility, procedure omission, flawed training/policy/procedure.

19. Were training programs for staff designed upfront with the intent of helping staff perform their tasks without errors? ☐YES ☐NO ☐N/A

20. Were all staff trained in the use of relevant barriers and controls? ☐YES ☐NO ☐N/A

Fatigue/Scheduling

21. Were the levels of vibration, noise, or other environmental conditions appropriate?
☐YES ☐NO ☐N/A

22. Were environmental stressors properly anticipated? ☐YES ☐NO ☐N/A

23. Did personnel have adequate sleep? ☐YES ☐NO ☐N/A

24. Was fatigue properly anticipated? ☐YES ☐NO ☐N/A

25. Was the environment free of distractions? ☐YES ☐NO ☐N/A

26. Was there sufficient staff on-hand for the workload at the time? (i.e., Workload too high, too low, or wrong mix of staff.) ☐YES ☐NO ☐N/A

27. Was the level of automation appropriate? (i.e., Neither too much nor not enough.)
☐YES ☐NO ☐N/A

Environment/Equipment

28. Was the work area/environment designed to support the function it was being used for?
☐YES ☐ NO ☐N/A

29. Had there been an environmental risk assessment (i.e., safety audit) of the area?
☐YES ☐NO ☐N/A

30. Were the work environment stress levels (either physical or psychological) appropriate? (e.g., Temperature, space, noise, intra-facility transfers, construction projects) ☐YES ☐NO ☐N/A

31. Had appropriate safety evaluations and disaster drills been conducted? ☐YES ☐NO ☐N/A

32. Did the work area/environment meet current codes, specifications, and regulations?
☐YES ☐NO ☐N/A

33. Was the equipment designed to properly accomplish its intended purpose? ☐ YES ☐ NO ☐ N/A

34. Did the equipment work smoothly in the context of: staff needs and experience; existing procedures, requirements, and workload; and physical space and location? ☐ YES ☐ NO ☐ N/A

35. Did the equipment involved meet current codes, specifications, and regulations? ☐ YES ☐ NO ☐ N/A

36. Was there a documented safety review performed on the equipment involved? (If relevant, were recommendations for service/recall/maintenance, etc., completed in a timely manner?) ☐ YES ☐ NO ☐ N/A

37. Was there a maintenance program in place to maintain the equipment involved? ☐ YES ☐ NO ☐ N/A

38. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly? ☐ YES ☐ NO ☐ N/A

39. If previous inspections pointed to equipment problems, were corrective actions implemented effective? ☐ YES ☐ NO ☐ N/A

40. Had equipment and procedures been reviewed to ensure that there was a good match between people and the equipment they used or people and the tasks they did? ☐ YES ☐ NO ☐ N/A

41. Were adequate time and resources allowed for physical plant and equipment upgrades, if problems were identified? ☐ YES ☐ NO ☐ N/A

42. Was there adequate equipment to perform the work processes? ☐ YES ☐ NO ☐ N/A

43. Were emergency provisions and back-up systems available in case of equipment failure? ☐ YES ☐ NO ☐ N/A

44. Had this type of equipment worked correctly and been used appropriately in the past? ☐ YES ☐ NO ☐ N/A

45. Was the equipment designed such that usage mistakes would be unlikely to happen? ☐ YES ☐ NO ☐ N/A

46. Was the design specification adhered to? ☐ YES ☐ NO ☐ N/A

47. Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy? ☐ YES ☐ NO ☐ N/A

48. Were personnel trained appropriately to operate the equipment involved in the adverse event/ close call? ☐ YES ☐ NO ☐ N/A

49. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner? ☐ YES ☐ NO ☐ N/A

50. Was the equipment designed so that corrective actions could be accomplished in a manner that minimized/eliminated any undesirable outcome? ☐ YES ☐ NO ☐ N/A

51. Were equipment displays and controls working properly and interpreted correctly and were equipment settings including alarms appropriate? ☐ YES ☐ NO ☐ N/A

52. Was the medical equipment or device intended to be reused (i.e., not reuse of a single use device)? ☐ YES ☐ NO ☐ N/A

53. Was the medical equipment or device used in accordance with its design and manufacturer's instructions? ☐ YES ☐ NO ☐ N/A

Rules/Policies/Procedures

54. Was there an overall management plan for addressing risk and assigning responsibility for risk? ☐ YES ☐ NO ☐ N/A

55. Did management have an audit or quality control system to inform them how key processes related to the adverse event were functioning? ☐ YES ☐ NO ☐ N/A

56. Had a previous investigation been done for a similar event, were the causes identified, and were effective interventions developed and implemented on a timely basis? ☐ YES ☐ NO ☐ N/A

57. Would this problem have gone unidentified or uncorrected after an audit or review of the work process/equipment/area? ☐ YES ☐ NO ☐ N/A

58. Was required care for the patient within the scope of the facility's mission, staff expertise and availability, and technical and support service resources? ☐ YES ☐ NO ☐ N/A

59. Was the staff involved in the adverse event or close call properly qualified and trained to perform their function/duties? ☐ YES ☐ NO ☐ N/A

60. Did the equipment involved meet current codes, specifications, and regulations? ☐ YES ☐ NO ☐ N/A

61. Were all staff involved oriented to the job, department, and facility policies regarding: safety, security, hazardous material management, emergency preparedness, life safety management, medical equipment, and utilities management? ☐ YES ☐ NO ☐ N/A

62. Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call? ☐ YES ☐ NO ☐ N/A

63. Were these policies/procedures consistent with relevant state and national guidance, regulatory agency requirements, and/or recommendations from professional societies/organizations? ☐ YES ☐ NO ☐ N/A

64. Were relevant policies/procedures clear, understandable, and readily available to all staff? ☐ YES ☐ NO ☐ N/A

65. Were the relevant policies and procedures actually used on a day-to-day basis?
☐ YES ☐ NO ☐ N/A

• If the policies and procedures were not used, consider: What got in the way of their usefulness to staff? What positive and negative incentives were absent?

Barriers

Barriers protect people and property from adverse events and can be physical or procedural. Negative/positive pressure rooms are an example of a physical barrier that controls the spread of bacteria/viruses. The pin indexing system used on medical gas cylinders is another example of a physical barrier that prevents gas cylinders being misconnected. The "surgical time out" is an example of a procedural barrier that protects patients from wrong site, wrong patient, wrong procedure surgeries.

Before completing this section, consider: What barriers and controls were involved in this adverse event or close call? Were these barriers designed to protect patients, staff, equipment, or the environment?

66. Was patient risk considered when designing these barriers and controls? ☐ YES ☐ NO ☐ N/A
67. Were these barriers and controls in place before the adverse event or close call occurred?
☐ YES ☐ NO ☐ N/A
68. Had these barriers and controls been evaluated for reliability? ☐ YES ☐ NO ☐ N/A
69. Were there other barriers and controls for work processes? ☐ YES ☐ NO ☐ N/A
70. Was the concept of "fault tolerance" applied in the system design? (A fault tolerant system can withstand the failure of one or more barriers without the patient being harmed.)
☐ YES ☐ NO ☐ N/A
71. Were relevant barriers and controls maintained and checked on a routine basis by designated staff? ☐ YES ☐ NO ☐ N/A

QUESTIONS TO WHICH THE ANSWER IS "NO"	ANSWER TO: "WHY NOT?"

Developed by Department of Veterans Affairs National Center for Patient Safety

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RCA² Interview Tips

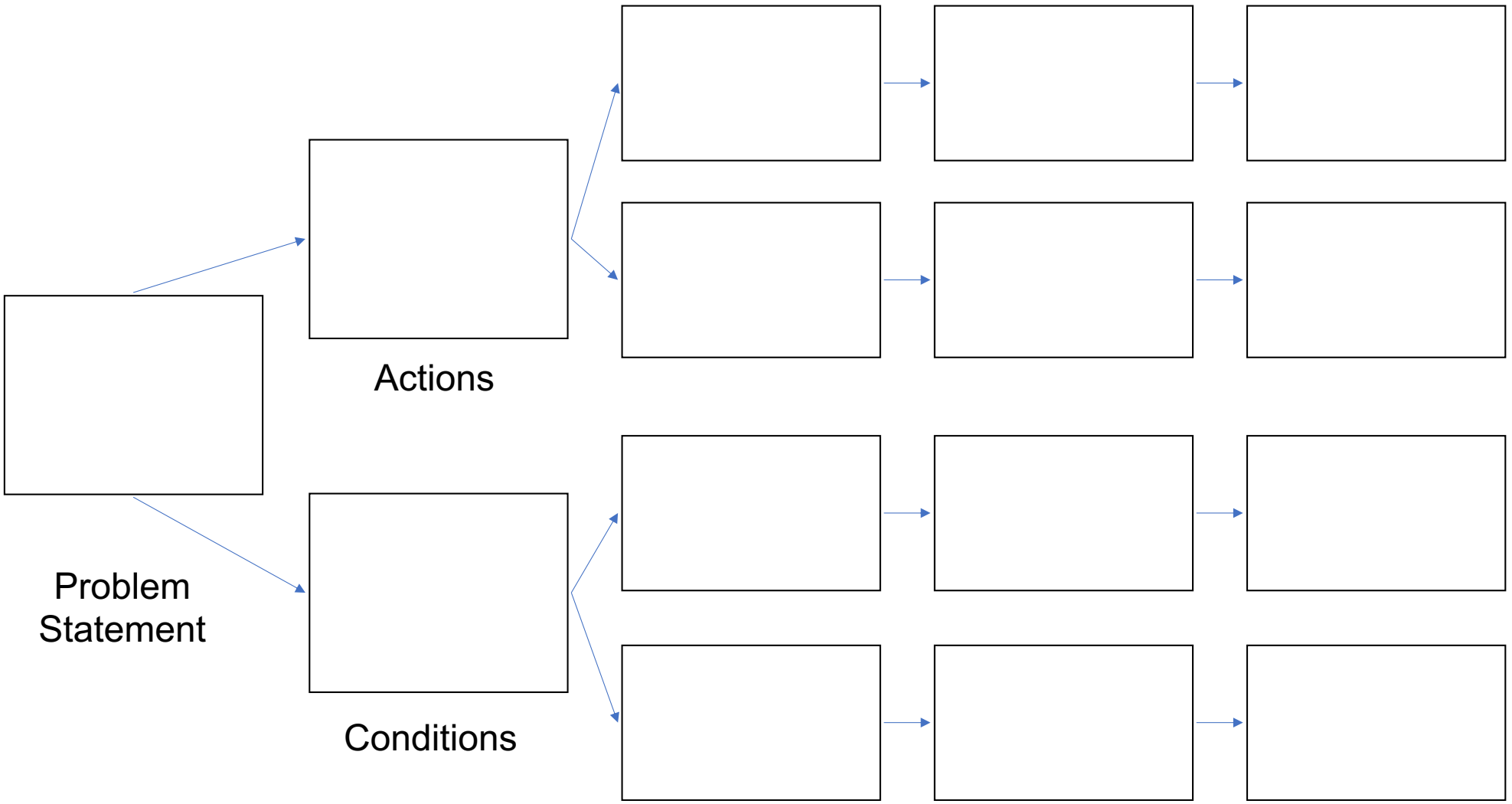
The goal of the RCA² interview process, which often involves the discussion of challenging and emotional topics, is to discover rich information about what happened leading up to an adverse event or near miss — in order to identify and facilitate appropriate corrective actions. Follow the recommendations below to help you conduct successful interviews.

- Interviews should be conducted by the RCA² team immediately after they have identified their interview questions. The preferred method is to conduct interviews in person. In some cases it may be necessary to conduct an interview via telephone. This may be acceptable if the individuals involved know and trust each other.
- After an adverse event, staff should be asked not to discuss the event among themselves, in order to promote the integrity and objectivity of the review process.
- If needed, notify the staff member/employee's immediate supervisor that the employee will be needed for an interview so that coverage can be arranged. Supervisors should not be present during the interview.
- Interview only one individual at a time, which will permit information to be compared and weighed. Expect differences between descriptions given by different staff when they describe what happened, and use additional information gathered by the team to support the final conclusions.
- Have the team's questions ready so that the required information may be obtained in one session.
- Ask only one or two RCA² team members to conduct the interview. Approaching the interviewee with a large group may be intimidating and potentially add to the stress of recounting the event.
- In some cases, staff members/employees may wish to have a representative or attorney present during the interview. The institution should set the ground rules for such participation.
- Patients may have family present during their interview.
- If the staff member/employee was involved in the adverse event, be sensitive to this. Let them know that no one is judging them and that the interview is being conducted to identify and implement systems-level sustainable corrective actions so a similar event does not happen again.
- Express to the patient and/or any family present that you are sorry the event occurred. Explain to them that the review is being conducted to identify system issues and implement sustainable and effective corrective actions, and that the team will not be assigning blame to anyone involved in the event.
- Conduct the interview in the staff member's/employee's area or in an area that may help them relax. Avoid the appearance of summoning them to a deposition or administrative review.
- For interviews of patients and/or family members, conduct the interview at a location that is acceptable to them.
- If practical, match your attire to that of the interviewee, while maintaining a level of professionalism. The goal is to avoid having them feel intimidated.
- Request permission to take notes and explain what the notes will be used for.

- Explain the purpose of the interview. Stress that the RCA^2 review team is seeking to identify system issues and not to assign blame to any individuals.
- Effective interview skills help make fact finding easier and the staff involved more comfortable with the process. Start with broad, open-ended questions and then narrow them down; move from general interrogatories, to specific clarifying questions, and then where appropriate, to closed questions to clarify your understanding of what has been shared. The process should not feel like an inquisition, and it is essential that you make the interviewee feel as safe as possible.
- Use active listening and reflect what is being said. Build confidence by restating and summarizing what you have heard. Keep an open body posture, good eye contact, and nod appropriately. Demonstrate empathy and be patient. Do not prejudge, lay blame, or interrupt. Tell them that the information obtained during the RCA^2 process is protected and confidential and will not be shared outside of the process. Union representatives, if present, should be informed that they are not permitted to talk about what was discussed with anyone other than the employee and RCA^2 team members.
- If the interviewee is having difficulty remembering the details surrounding the event, ask them to describe what they normally do when completing the task/procedure that was involved. Drawing a sketch of the process or work area may also trigger their memory.
- Thank the interviewee at the conclusion of the process, provide your contact information in case they have additional information that they remember, and if you sense they need emotional support, be aware of what resources are available to them.

Cause and Effect Diagram for RCA²

Use this tool with your RCA² team to explore causes that contributed to the adverse event or near miss you're reviewing. Input the problem you're seeking to address at the far left. Input the categories of primary causes (actions and conditions) as you see them. Then input causes within each category. As you identify causes, you may think of smaller causes that contribute to the larger causes; keep drilling down as much as it is helpful. (You may need more space than this template provides.) See the RCA² report for an example.



5 Whys for RCA²

Use this tool with your RCA² team to help you identify the root cause(s) of a problem — and generate potential change ideas — by asking "Why?" five times. See the **RCA² report** for an example.

EVENT. What happened? Define the problem as an event:

PATTERN. What's been happening? Define the problem as a *pattern* by selecting a poor performance factor:

STRUCTURE. Why is it happening? What are the tangible and intangible structures determining the results we see?

1.

Why is that?

2.

Why is that?

3.

Why is that?

4.

Why is that?

5.

ACTION. What are the implications for action? What can you do to change the results?

Causal Statement Worksheet

A causal statement links the causes an RCA² team identifies to the effects and then back to the main event that prompted the RCA² in the first place. A causal statement has three parts:

1. The cause: "This happened…"
2. The effect: "…which led to something else happening…"
3. The event: "…which caused this undesirable outcome."

For each causal statement you write, apply the Five Rules of Causation to ensure it focuses on systems issues and does not cite human error as a root cause.

Causal Statement #1:

- ☐ Clearly shows the "cause and effect" relationship.
- ☐ Uses specific and accurate descriptors for what occurred.
- ☐ Human errors have a preceding cause.
- ☐ Violations of procedure are not root causes.
- ☐ Failure to act is only causal if there is a pre-existing duty to act.

Causal Statement #2:

- ☐ Clearly shows the "cause and effect" relationship.
- ☐ Uses specific and accurate descriptors for what occurred.
- ☐ Human errors have a preceding cause.
- ☐ Violations of procedure are not root causes.
- ☐ Failure to act is only causal if there is a pre-existing duty to act.

Causal Statement #3:

- ☐ Clearly shows the "cause and effect" relationship.
- ☐ Uses specific and accurate descriptors for what occurred.
- ☐ Human errors have a preceding cause.
- ☐ Violations of procedure are not root causes.
- ☐ Failure to act is only causal if there is a pre-existing duty to act.

Action Hierarchy Worksheet

Discuss how you can apply the concept(s) below to the process you want to improve. Generate a list of ideas, focusing on the feasible actions that are the strongest. See the **RCA2 Report** for an example of each action category.

Actions	Ideas
Stronger Actions These tasks require less reliance on humans to remember to perform the task correctly.	
• Architectural/physical plant changes • New devices with usability testing • Engineering control (forcing function) • Simplify process • Standardize on equipment or process • Tangible involvement by leadership	
Intermediate Actions These tasks are less effective than the strongest level actions but more effective than the weakest level.	
• Redundancy • Increase in staffing/decrease in workload • Software enhancements, modifications • Eliminate/reduce distractions • Education using simulation-based training, with periodic refresher sessions and observations • Checklist/cognitive aids • Eliminate look- and sound-alikes • Standardized communication tools • Enhanced documentation, communication	
Weaker Actions These tasks require more reliance on humans to remember to perform the task correctly.	
• Double checks • Warnings • New procedure/memorandum/ policy • Trainings	

Action Hierarchy levels and categories are based on Root Cause Analysis Tools, VA National Center for Patient Safety, http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf

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RCA² Action Planning Worksheet

For RCA² to improve patient safety, causes must be identified, corrective actions must be implemented, and actions' effectiveness must be measured. Use the worksheet below to help your team take these steps.

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1. A causal statement has three parts: The cause: "This happened…" The effect: "…which led to something else happening…" The event: "…which caused this undesirable outcome."

Causal Statement #1	E.g. The lack of a ferromagnetic detection system at the entrance into the MRI room increased the likelihood that the patient's oxygen cylinder would be permitted in the room, resulting in the cylinder being drawn into the bore of the magnet, the magnet being quenched, and the room being out of service for five days.

2. Each causal statement should trigger at least one intermediate-level action recommendation (see the Action Hierarchy), which should be expressed as an aim statement. That is, it should clearly state "how good, by when, for whom."

Action(s)	E.g. Install a ferromagnetic detection system by September 30, 2019 at the entrance to all four MRI magnet rooms.
Person responsible	

3. A measurement plan, including what will be measured, how, and for how long, should be in place for each action. Measures may be process or outcome measures.

Measure(s)	E.g. On May 10, 2020, five ferrous objects including an oxygen cylinder will be passed by the ferromagnetic sensors of each detector and 100% will result in alarms sounding in the adjacent MR Control Room.
Person responsible	

Causal Statement #2	
Action(s)	
Person responsible	
Measure(s)	
Person responsible	

Causal Statement #3	
Action(s)	
Person responsible	
Measure(s)	
Person responsible	

Effective RCA² Checklist

After an RCA² event review, use this checklist to confirm your RCA² process is working. If any of the statements is false, then your specific RCA² review or your RCA² process in general needs to be re-examined and revised because it is failing.

☐ Contributing factors are identified and have supporting data or information.

☐ Individuals are NOT identified as causing the event; causal factors do NOT point to human error or blame.

☐ At least one stronger or intermediate strength action is identified.

☐ Causal statements comply with the Five Rules of Causation.

- Rule 1. Clearly show the "cause and effect" relationship.
- Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague.
- Rule 3. Human errors must have a preceding cause.
- Rule 4. Violations of procedure are not root causes but must have a preceding cause.
- Rule 5. Failure to act is only causal when there is a pre-existing duty to act.

☐ Corrective actions are identified and appear to address the system vulnerabilities identified by the contributing factors.

☐ Action follow-up is assigned to an individual and NOT a group or committee.

☐ Actions have completion dates and meaningful process and outcome measures.

☐ The event review took 45 days or fewer to complete.

☐ There is strong confidence that implementing and sustaining corrective action will significantly reduce the risk of future occurrences of similar events.