

**RCA<sup>2</sup>**  
**Improving Root Cause  
Analyses and Actions  
to Prevent Harm**

Version 2. January 2016

© Copyright 2015 by the National Patient Safety Foundation.

All rights reserved.

Second online publication, Version 2, January 2016.

First online publication June 2015.

This report is available for downloading on the Foundation's website, [www.npsf.org](http://www.npsf.org).

This report or parts of it may be printed for individual use or distributed for training purposes within your organization.

No one may alter the content in any way, or use the report in any commercial context, without written permission from the publisher:

National Patient Safety Foundation  
Attention: Director, Information Resources  
268 Summer Street, Sixth Floor  
Boston, MA 02210  
[info@npsf.org](mailto:info@npsf.org)

About the National Patient Safety Foundation®

The National Patient Safety Foundation's vision is to create a world where patients and those who care for them are free from harm. A central voice for patient safety since 1997, NPSF partners with patients and families, the health care community, and key stakeholders to advance patient safety and health care workforce safety and disseminate strategies to prevent harm.

NPSF is an independent, not-for-profit 501(c)(3) organization. Information about the work of the National Patient Safety Foundation may be found at [www.npsf.org](http://www.npsf.org).



# CONTENTS

Acknowledgments	<b>iv</b>
Endorsements	<b>vi</b>
Executive Summary	<b>vii</b>
Introduction	<b>1</b>
Objective	
Definitions	
I. Identifying and Classifying Events	<b>5</b>
Events Appropriate for RCA <sup>2</sup> Review versus Blameworthy Events	
Risk-Based Prioritization of Events, Hazards, and System Vulnerabilities	
Close Calls	
II. RCA <sup>2</sup> Timing and Team Membership	<b>9</b>
Timing	
Team Size	
Team Membership	
Interviewing	
III. The RCA <sup>2</sup> Event Review Process	<b>14</b>
Analysis Steps and Tools	
Actions	
Measuring Action Implementation and Effectiveness	
Feedback	
Leadership and Board Support	
Measuring the Effectiveness and Sustainability of the RCA <sup>2</sup> Process	
IV. Conclusion and Recommendations	<b>21</b>
Appendix 1. The Safety Assessment Code (SAC) Matrix	<b>23</b>
Appendix 2. Triggering Questions for Root Cause Analysis	<b>31</b>
Appendix 3. Interviewing Tips for RCA <sup>2</sup> Reviews	<b>35</b>
Appendix 4. Final Flow Diagram Example	<b>37</b>
Appendix 5. Cause and Effect Diagram Example	<b>38</b>
Appendix 6. The Five Rules of Causation	<b>39</b>
Appendix 7. Cause, Action, Process/Outcome Measure Table	<b>40</b>
References	<b>41</b>

## ACKNOWLEDGMENTS

### PANEL PARTICIPANTS

#### Core Working Group

**James P. Bagian, MD, PE**

**Project Co-Chair**

Director, Center for Health Engineering and Patient Safety, University of Michigan

**Doug Bonacum, CSP, CPPS**

**Project Co-Chair**

Vice President, Quality, Safety, and Resource Management, Kaiser Permanente

**Joseph DeRosier, PE, CSP**

Program Manager, Center for Health Engineering and Patient Safety, University of Michigan

**John Frost**

President, Safety Engineering Services Inc.  
Member, Aerospace Safety Advisory Panel (ASAP)  
National Aeronautics and Space Administration (NASA)  
Member, Board of Directors, APT Inc.

**Rollin J. “Terry” Fairbanks MD, MS, FACEP, CPPS**

Director, National Center for Human Factors in Healthcare and Simulation Training & Education Lab, MedStar Institute for Innovation, MedStar Health  
Associate Professor of Emergency Medicine, Georgetown University

**Tejal Gandhi, MD, MPH, CPPS**

President and Chief Executive Officer, National Patient Safety Foundation

**Helen Haskell, MA**

Founder, Mothers Against Medical Error  
President, Consumers Advancing Patient Safety

**Patricia McGaffigan, RN, MS**

Chief Operating Officer and Senior Vice President, Program Strategy, National Patient Safety Foundation

**Faye Sheppard RN, MSN, JD, CPPS**

Principal, Patient Safety Resources

#### Expert Advisory Group

**John S. Carroll**

Professor of Organization Studies and Engineering Systems, Massachusetts Institute of Technology  
Co-Director, Lean Advancement Initiative at MIT

**Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon)**

President, Institute for Safe Medication Practices

**Thomas W. Diller, MD, MMM**

Vice President and System Chief Medical Officer, CHRISTUS Health

**Noel Eldridge, MS**

Senior Advisor, Public Health Specialist, Center for Quality Improvement and Patient Safety, Agency for Healthcare Research and Quality

**Andrew R. Hallahan, MD**

Medical Lead, Patient Safety, Children’s Health Queensland Hospital and Health Service

**Robin Hemphill, MD, MPH**

Director, National Center for Patient Safety, US Department of Veterans Affairs

**James P. Keller, Jr., MS**

Vice President, Health Technology Evaluation and Safety, ECRI Institute

**Carol Keohane, MS, RN**

Assistant Vice President, Academic Medical Center’s Patient Safety Organization, CRICO

**Maria Lombardi, RN, MSN, CCRN**

Clinical Nursing Director, Tufts Medical Center

**Robert Schreiber, MD**

Medical Director of Evidence-Based Programs, Hebrew Senior Life Department of Medicine  
Medical Director, Healthy Living Center for Excellence  
Clinical Instructor of Medicine, Harvard Medical School

**Julie Spencer, RN, CPHRM**

System Director of Risk Management, BSWH Risk Management

**Mary J. Tharayil, MD, MPH**

Staff Physician  
Brigham and Women’s Hospital

**Ailish Wilkie, MS, CPHQ, CPHRM**

Patient Safety and Risk Management  
Atrius Health

**Ronald M. Wyatt, MD, MHA, DMS (hon.)**

Medical Director, Healthcare Improvement, Office of the Chief Medical Officer, The Joint Commission

## ACKNOWLEDGMENTS *(cont)*

### NPSF STAFF

**Tejal K. Gandhi, MD, MPH, CPPS**  
President and Chief Executive Officer

**Patricia McGaffigan, RN, MS**  
Chief Operating Officer and  
Senior Vice President, Program Strategy

**Joellen Huebner**  
Program Coordinator, Special Projects

**Patricia McTiernan, MS**  
Assistant Vice President, Communications

**Elma Sanders, PhD**  
Communications Manager

---

The National Patient Safety Foundation gratefully acknowledges James Bagian, MD, PE, and Doug Bonacum, CSP, CPPS, for their work as co-chairs of this project.

Special thanks are due to Joseph DeRosier, PE, CSP, for lead authorship of this report, and to Mary Tharayil, MD, MPH, for preparatory research.

The National Patient Safety Foundation gratefully acknowledges The Doctors Company Foundation for its critical and generous support of this project.



## ENDORSEMENTS

The following organizations have endorsed the use of this document as a valuable resource in efforts to create a more effective event analysis and improvement system:

AAMI  
AAMI Foundation  
Alliance for Quality Improvement and Patient Safety (AQIPS)  
American Society of Health-System Pharmacists (ASHP)  
Association of Occupational Health Professionals in Healthcare (AOHP)  
Atrius Health  
Aurora Health Care  
Canadian Patient Safety Institute  
Children’s Health Queensland Hospital and Health Service  
CHRISTUS Health  
Citizens for Patient Safety  
CRICO | Risk Management Foundation of the Harvard Medical Institutions  
The Doctors Company  
ECRI Institute  
HCA Patient Safety Organization, LLC  
Institute for Healthcare Improvement  
Institute for Safe Medication Practices  
The Joint Commission  
Kaiser Permanente  
MHA Keystone Center  
National Association for Healthcare Quality (NAHQ)  
National Council of State Boards of Nursing (NCSBN®)  
Tufts Medical Center and Floating Hospital for Children



## EXECUTIVE SUMMARY

Millions of patients in the United States are harmed every year as a result of the health care they receive.<sup>(1)</sup> The National Patient Safety Foundation (NPSF), with support from The Doctors Company Foundation, convened a panel of subject matter experts and stakeholders to produce recommended practices to improve the manner in which we can learn from adverse events and unsafe conditions and take action to prevent their occurrence in the future. Traditionally, the process employed to accomplish this learning has been called root cause analysis (RCA), but it has had inconsistent success. To improve the effectiveness and utility of these efforts, we have concentrated on the ultimate objective: preventing future harm. Prevention requires actions to be taken, and so we have renamed the process Root Cause Analysis and Action, RCA<sup>2</sup> (RCA “squared”) to emphasize this point. This document describes methodologies and techniques that an organization or individuals involved in performing an RCA<sup>2</sup> can credibly and effectively use to prioritize the events, hazards, and vulnerabilities in their systems of care to accomplish the real objective, which is to understand what happened, why it happened, and then take positive action to prevent it from happening again. It cannot be over-emphasized that if actions resulting from an RCA<sup>2</sup> are not implemented and measured to demonstrate their success in preventing or reducing the risk of patient harm in an effective and sustainable way, then the entire RCA<sup>2</sup> activity will have been a waste of time and resources.

The purpose of this document is to ensure that efforts undertaken in performing RCA<sup>2</sup> will result in the identification and implementation of sustainable systems-based improvements that make patient care safer in settings across the continuum of care. The approach is two-pronged. The first goal is to identify methodologies and techniques that will lead to more effective and efficient RCA<sup>2</sup>. The second is to provide tools to evaluate individual RCA<sup>2</sup> reviews so that significant flaws can be identified and remediated to achieve the ultimate objective of improving patient safety. The purpose of an RCA<sup>2</sup> review is to identify system vulnerabilities so that they can be eliminated or mitigated; the review is not to be used to focus on or address individual performance, since individual performance is a symptom of larger systems-based issues. Root cause analysis and action team findings must not be used to discipline or punish staff, so that the trust in the system is not undermined. The maximum benefit for the safety of the patient population occurs when system-based vulnerabilities are addressed, and this can be compromised if the root cause

analysis and action process is viewed as a witch hunt. It is critical that each organization define blameworthy events and actions that fall outside the purview of the safety system and define how and under what circumstances they will be handled or dealt with using administrative or human resource systems.

Just as a well-performed and well-executed RCA<sup>2</sup> must take a systems-based approach, the same approach is important in formulating a methodology that will achieve these desired objectives. Since unlimited resources are not available to identify, analyze, and remediate hazards, it is essential that an explicit risk-based prioritization system be utilized to credibly and efficiently determine what hazards should be addressed first. A risk-based approach that considers both the potential harm and the probability of it impacting a patient—as opposed to a solely harm-based approach—allows efforts to be focused in a manner that achieves the greatest benefit possible for the patient population as a whole and allows learning and preventive action to be taken without having to experience patient harm before addressing a problem. This prioritization system must be a transparent, formal, and explicit one that is communicated with both internal and external stakeholders.

The most important step in the RCA<sup>2</sup> process is the identification of actions to eliminate or control system hazards or vulnerabilities identified in the causal statements. Teams should strive to identify stronger actions that prevent the event from recurring and, if that is not possible, reduce the likelihood that it will occur or that the severity or consequences are reduced if it should recur. Using a tool such as the Action Hierarchy will assist teams in identifying stronger actions that provide effective and sustained system improvement.

The success of any patient safety effort lies in its integration into the fabric of the organization at all levels. This cannot happen without the active participation of leaders and managers at all levels. For example, strength of actions should be actively reviewed by leadership to ensure that teams are identifying strong actions that provide effective and sustained system improvement. Their participation demonstrates the importance of activities related to patient safety not just by words but by tangible actions and involvement.

This document answers questions integral to patient safety and the root cause analysis process including how to:

- Triage adverse events and close calls/near misses
- Identify the appropriate RCA<sup>2</sup> team size and membership
- Establish RCA<sup>2</sup> schedules for execution
- Use tools provided here to facilitate the RCA<sup>2</sup> analysis
- Identify effective actions to control or eliminate system vulnerabilities
- Develop Process/Outcome Measures to verify that actions worked as planned
- Use tools provided here for leadership to assess the quality of the RCA<sup>2</sup> process



## Recommendations

1. Leadership (e.g., CEO, board of directors) should be actively involved in the root cause analysis and action (RCA<sup>2</sup>) process. This should be accomplished by supporting the process, approving and periodically reviewing the status of actions, understanding what a thorough RCA<sup>2</sup> report should include, and acting when reviews do not meet minimum requirements.
2. Leadership should review the RCA<sup>2</sup> process at least annually for effectiveness.
3. Blameworthy events that are not appropriate for RCA<sup>2</sup> review should be defined.
4. Facilities should use a transparent, formal, and explicit risk-based prioritization system to identify adverse events, close calls, and system vulnerabilities requiring RCA<sup>2</sup> review.
5. An RCA<sup>2</sup> review should be started within 72 hours of recognizing that a review is needed.
6. RCA<sup>2</sup> teams should be composed of 4 to 6 people. The team should include process experts as well as other individuals drawn from all levels of the organization, and inclusion of a patient representative unrelated to the event should be considered. Team membership *should not* include individuals who were involved in the event or close call being reviewed, but those individuals should be interviewed for information.
7. Time should be provided during the normal work shift for staff to serve on an RCA<sup>2</sup> team, including attending meetings, researching, and conducting interviews.
8. RCA<sup>2</sup> tools (e.g., interviewing techniques, Flow Diagramming, Cause and Effect Diagramming, Five Rules of Causation, Action Hierarchy, Process/Outcome Measures) should be used by teams to assist in the investigation process and the identification of strong and intermediate strength corrective actions.
9. Feedback should be provided to staff involved in the event as well as to patients and/or their family members regarding the findings of the RCA<sup>2</sup> process.

The National Patient Safety Foundation strongly recommends that organizations across the continuum of care adopt the recommendations of this report in order to improve their root cause analyses and bring them to the next level, that of root cause analysis and action, RCA<sup>2</sup>, to ensure the most effective prevention of future harm.





## INTRODUCTION

Millions of patients are harmed in the United States every year as a result of the health care they receive.<sup>(1)</sup> Virtually all health care providers and organizations respond to some events where patient harm has occurred by investigating the event in question with the intent of eliminating the possibility or reducing the likelihood of a future similar event. This activity is commonly referred to as root cause analysis (RCA), although other terms are sometimes used to describe this process, such as focused review, incident review, and comprehensive system analysis. Some health care organizations have robust RCA processes and have made huge strides toward improving patient safety, including sharing lessons widely, both internally and externally, so others can learn from their experience. This is, however, more the exception than the rule.<sup>(2)</sup> Currently the activities that constitute an RCA in health care are not standardized or well defined, which can result in the identification of corrective actions that are not effective—as demonstrated by the documented recurrence of the same or similar events in the same facility/organization after completion of an RCA. Some of the underlying reasons for lack of effectiveness of RCAs in improving patient safety include the lack of standardized and explicit processes and techniques to:

- Identify hazards and vulnerabilities that impact patient safety and then prioritize them to determine if action is required
- Identify systems-based corrective actions
- Ensure the timely execution of an RCA and formulation of effective sustainable improvements and corrective actions
- Ensure follow-through to implement recommendations
- Measure whether corrective actions were successful
- Ensure that leadership at all levels of the organization participate in making certain that RCAs are performed when appropriate, in a timely manner, and that corrective actions are implemented to improve patient safety

The National Patient Safety Foundation (NPSF), with support from The Doctors Company Foundation, convened a panel of subject matter experts and stakeholders to recommend practices to improve the RCA process in settings across the continuum of care. The term

RCA itself is problematic and does not describe the activity's intended purpose. First, the term implies that there is *one* root cause, which is counter to the fact that health care is complex and that there are generally many contributing factors that must be considered in understanding why an event occurred. In light of this complexity, there is seldom one magic bullet that will address the various hazards and systems vulnerabilities, which means that there generally needs to be more than one corrective action. Second, the term RCA only identifies its purpose as *analysis*, which is clearly not its only or principal objective, as evidenced by existing regulatory requirements for what an RCA is to accomplish. The ultimate purpose of an RCA is to identify hazards and systems vulnerabilities so that *actions* can be taken that improve patient safety by preventing future harm. The term RCA also seems to violate the Chinese proverb "The beginning of wisdom is to call things by their right names," and this may itself be part of the underlying reason why the effectiveness of RCAs is so variable. While it might be better not to use the term RCA, it is so imbedded in the patient safety culture that completely renaming the process could cause confusion.

We introduce a more accurate term to describe what is really intended by performing an RCA, and that is Root Cause Analysis and Action, RCA<sup>2</sup> (RCA "squared"), which is the term used throughout this document. Our discussion describes methodologies and techniques that an organization or individuals can credibly and effectively use to prioritize the events, hazards, and vulnerabilities in their systems of care that should receive an RCA<sup>2</sup>, and then accomplish the real objective, which is to understand what happened, why it happened, and what needs to be done<sup>(3)</sup> to correct the problem, and then to take positive action to prevent it from happening again.

The actions of an RCA<sup>2</sup> must concentrate on systems-level type causations and contributing factors. If the greatest benefit to patients is to be realized, the resulting corrective actions that address these systems-level issues must not result in individual blaming or punitive actions. The determination of individual culpability is not the function of a patient safety system and lies elsewhere in an organization. "Preventing errors means designing the health care system at all levels to make it safer. Building safety into processes of care is a much more effective way to reduce errors than blaming individuals."<sup>(4)</sup>

If actions resulting from an RCA<sup>2</sup> review are not implemented, or are not measured to determine their effectiveness in preventing harm, then the entire RCA<sup>2</sup> activity may be pointless.

Many organizations do not provide timely feedback to the parties who brought an issue to the attention of the patient safety organization or those who were personally impacted by a particular event. When this feedback loop is broken, the staff and patients involved can easily come to the conclusion that the event either was ignored or that no meaningful action was taken. In other words, the report of the event, hazard, or vulnerability fell into a "black hole." The lack of feedback can have a negative impact on the future involvement of staff and patients, who may become cynical and distrustful in the belief that their efforts or experience will not be used to effect change. To reap the greatest benefit for patients everywhere, the lessons learned from RCA<sup>2</sup>—including contributing factors and hazards that were identified, as well as the corrective actions—should be shared as openly as possible, both within and outside the organization.

Finally, an RCA<sup>2</sup> process cannot be successful and have lasting positive effect without active and tangible leadership support with involvement at all levels, including board involvement. Leadership demonstrates the real importance that they attach to patient safety by their level of personal involvement and support.

## Objective

The purpose of this document is to provide guidance for performing RCA<sup>2</sup> reviews that will result in the identification and implementation of sustainable and effective systems-based improvements to make health care safer. The RCA<sup>2</sup> approach described in this document was developed for hospitals, but it is applicable to settings that range from nursing homes to acute care, doctors' offices to care units, and from single health care organizations to large health care systems and patient safety organizations (PSOs).<sup>(5)</sup> While root cause analysis has typically been used at the hospital level, RCA<sup>2</sup> is also applicable at the unit level and as part of comprehensive unit-based safety programs (CUSP).<sup>(6)</sup>

The approach presented is two-pronged. The first goal is to identify methodologies and techniques that will lead to more effective and efficient use of RCA<sup>2</sup>. The second goal is to provide tools to health care leaders to evaluate RCA<sup>2</sup> reviews so that significant flaws in individual RCA<sup>2</sup> reports can be identified and remediated to achieve the ultimate objective of improving patient safety. Just as a well-performed, well-executed RCA<sup>2</sup> must take a systems-based approach, the same approach is important in formulating a methodology that will achieve these desired objectives.

There are many other activities that may need to take place at the same time as RCA<sup>2</sup>. One of these is disclosure to the patient or family that an adverse event has occurred. Although the disclosure may be for the same adverse event for which an RCA<sup>2</sup> is being undertaken, these two processes are independent activities. The disclosure activities should in no way interfere with the initiation or performance of the RCA<sup>2</sup> and, accordingly, further discussion of disclosure is not addressed in this document since it is outside the scope of RCA improvement.

## Definitions

The following definitions were adopted for the discussions and recommendations presented in this paper:

- Hazard: Potential for harm;<sup>(7)</sup> a condition precursor to a mishap (adverse event).
- Safety: Freedom from those conditions that can cause death, injury, illness, damage to or loss of equipment or property, or damage to the environment.<sup>(7)</sup>
- Quality: The degree to which a set of inherent characteristics fulfills a set of requirements.<sup>(8)</sup>
- Risk: A measure of the expected loss from a given hazard or group of hazards. Risk is a combined expression of loss severity and probability (or likelihood).<sup>(7)</sup>

- System: A set of interrelated or interacting elements<sup>(8)</sup> any one of which, if changed, can impact overall outcome. Some examples of system elements are organizational culture, technical and equipment related factors, physical environment, organizational goals and incentives, and professional performance and standards.
- Close Call/Near Miss: A close call is an event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention. Sometimes referred to as near miss incidents.<sup>(9)</sup>
- Adverse Event: Untoward incident, therapeutic misadventure, iatrogenic injury, or other occurrence of harm or potential harm directly associated with care or services provided.<sup>(7)</sup>



## I. IDENTIFYING AND CLASSIFYING EVENTS

### **Events Appropriate for RCA<sup>2</sup> Review versus Blameworthy Events**

The purpose of an RCA<sup>2</sup> review is to identify system vulnerabilities so that they can be eliminated or mitigated. RCA<sup>2</sup> processes are not to be used to focus on or address individual health care worker performance as the primary cause of an adverse event, but instead to look for the underlying systems-level causations that were manifest in personnel-related performance issues. Findings from an RCA<sup>2</sup> must not be used to discipline, shame, or punish staff.

In a 2015 report, the NASA Aerospace Safety Advisory Panel cautions about the inadvisability of focusing on individuals and assigning blame:

The releasable nature of NASA mishap reports also creates a vulnerability to focusing on blame. Generally speaking, all organizations in public view are subject to pressures of answering for errors. These pressures can lead to a focus on fault and assigning blame in a mishap investigation that will inherently inhibit the robustness of an investigation. Such investigations have two shortcomings: (1) filtered or less-than-transparent reporting of information, and (2) the inability to discover the true root and contributing causes. The first can affect the culture of mishap investigation, because the desire to protect an individual, program, or organization in the short term hinders risk reduction in the long term. In the second case, disciplinary action associated with the resultant blame gives a false sense of confidence where it rids the organization of the problem; however, the root cause likely remains, and latent risk waits patiently for the next opportunity to strike. . . . In addition, when blame is the focus of the investigation, the true cause of a mishap can be missed or hidden, thus increasing the risk of repeating the mishap. This danger is introduced when releasable information is “spun” to appease short-term public interest. It can contribute to second and third order negative cultural effects in other areas such as misinterpreting risk and subsequent incorrect resolution.<sup>(10)</sup>

### Developing Trust within the Organization and in the Community

Reports of hazards, vulnerabilities, and adverse events are the fuel for the safety improvement engine. An organization is made up of people, and if the people in an organization aren't motivated to report, then the organization is at a definite disadvantage. An organization cannot fix a problem if they don't know that it exists.

One of the barriers or disincentives to people reporting is fear of negative results for themselves or their colleagues and organization. Adoption of a clear and transparent organizational policy and absolute adherence by the organization to faithfully following it provides staff clarity as to how reports that they make will be used and the ramifications for them personally. It is critical to gain the trust of the members of the organization. Implementing such policies where employees perceive that they are being treated in a fair and consistent manner is an essential part of developing that trust. Policies that achieve these goals often include discussions of what activities are viewed as at risk or blameworthy and often are characterized as promoting a just culture.

Clear policies and the rationale behind them that are openly communicated to the community also are essential to gain the trust and support of the community at large, which includes patients. When an organization publicly and concretely states what it will do to promote patient safety, it makes itself accountable to the community it serves. ♦

***It is critical that each organization define blameworthy events and actions that will be handled or dealt with using administrative or human resource systems.*** A common definition of blameworthy events includes events that are the result of criminal acts, patient abuse, alcohol or substance abuse on the part of the provider, or acts defined by the organization as being intentionally or deliberately unsafe.<sup>(9,11,12)</sup> In the unlikely event that during a review an RCA<sup>2</sup> team discovers that the event is or may be blameworthy, the team should notify the convening authority and refer the event to the convening authority to be handled as dictated by the local policy. Referral of an event to the convening authority does not mean that the opportunity to learn from it has been lost or that no action will ultimately be taken. Referral just means that the primary responsibility to fully look into the event and formulate and implement corrective actions is assumed by a different organizational entity that will not only look for systems-based solutions, as should be the case with any safety investigation, but may also take actions that are directed at a specific individual. Doing so preserves the integrity of a safety system that has committed to using safety activities for system improvement, not for individual punitive action. This is important because even the perception that an RCA<sup>2</sup> review has led to punitive actions can permanently and negatively impact the effectiveness of future reviews, as has been demonstrated in other industries.<sup>(13)</sup>

To be effective, a risk-based prioritization system must receive reports of adverse events, close calls, hazards, or system vulnerabilities from staff. Not receiving reports can negatively impact the ability to estimate the probability that an event or hazard may occur. Solutions to this include educating staff about reporting, making it easy for staff to report, taking visible action as a result of reports, and providing feedback to reporters when



they submit reports. When staff members realize that their input makes a difference, they are more likely to report to improve safety. Reports that do not end up being reviewed through the RCA<sup>2</sup> process still have significant value in improving patient safety.

## **Risk-Based Prioritization of Events, Hazards, and System Vulnerabilities**

***As resources necessary to identify, analyze, and remediate hazards are not unlimited, it is essential that an explicit, risk-based prioritization system be utilized so that an organization can credibly and efficiently determine what hazards should be addressed first.***

An explicit, risk-based RCA<sup>2</sup> prioritization system is superior to one based solely on the harm or injury that a patient experienced. In a harm-based approach, currently the most commonly used, an event must cause harm to a patient to warrant an RCA. A risk-based system prioritizes hazards and vulnerabilities that may not yet have caused harm so that these hazards and vulnerabilities can then be mitigated or eliminated before harm occurs. This thinking is consistent with successful practices in many high-reliability industries, such as aviation, as well as the recommended approaches of various health care accreditation organizations.<sup>(14,15)</sup> (Methodology and examples of risk-based prioritization systems are shown in Appendix 1.)

Establishing a risk-based prioritization system—and making it transparent to all stakeholders—allows an organization to concentrate on eliminating or mitigating hazards rather than being distracted by having to explain why they will or will not conduct an RCA. Use of an explicit, risk-based prioritization methodology lends credibility and objectivity to the process and reduces the chance of misperception by both internal and external stakeholders that decisions to conduct an RCA are inappropriately influenced by political pressure or other factors to cover up problems rather than discover what is in the best interests of the patient.

Risk-based selection criteria should incorporate both the outcome severity or consequence and its probability of occurrence.<sup>(16)</sup> An efficient way of doing this is to develop a risk matrix (see Appendix 1) that has predefined and agreed-upon definitions for the levels of severity or consequence as well as the probability of occurrence, along with predefined steps that will be taken when matrix thresholds established by the organization are reached.\* When the definitions for severity or consequence also incorporate events or outcomes that mandate root cause analysis by accrediting organizations, use of the matrix will ensure compliance with their standards and make the process easier to communicate and operationalize. The source (e.g., safety reports) of the information related to events, hazards, or vulnerabilities is not important as long as enough information is received to allow prioritization using an explicit risk-based prioritization tool.

The actual implementation of the prioritization system should be performed by an individual and not a committee; an explicit, well-devised prioritization system should not require group deliberation. Also, the efficiency of the process is enhanced and needless inertia is

---

\* Risk-based selection criteria must meet the requirements of applicable accrediting and regulatory organizations.

eliminated when prioritization for hazards does not have to wait for a group to be convened and to deliberate. Periodically (e.g., quarterly, semiannually) reviewing a summary of the recently scored/prioritized events as part of the facility's quality assurance program will ensure that scoring does not deviate from the approved prioritization system.

Finally, the prevention of harm is the goal of these efforts. The organization should not be distracted from taking immediate actions to minimize risk of harm while it is engaged in the more formal RCA<sup>2</sup> process.

## Close Calls

**Close calls (also called near misses or good catches) should also be prioritized using the risk matrix** by asking what is a plausible severity or consequence for the event, hazard, or vulnerability, coupled with the likelihood or probability of the event/hazard scenario occurring. This plausible outcome is then used as the severity or consequence when applying the risk matrix to determine the appropriate response (RCA<sup>2</sup> or other actions). Some may believe that since there was no patient injury, close calls do not need to be reported or investigated. However, close calls occur 10 to 300 times<sup>(17)</sup> more frequently than the actual harm events they are the precursors of and provide an organization the opportunity to identify and correct system vulnerabilities before injury or death occurs. A concern sometimes expressed is that reviewing close calls will increase the workload to an unmanageable level. This concern is unwarranted since the organization can construct a risk matrix (such as the one provided in Appendix 1) to prioritize all events, hazards, and system vulnerabilities that also accounts for the level of resources required for RCA<sup>2</sup> reviews.<sup>(11,18,19)</sup> Additionally, performance of an aggregated review of predefined and pre-selected categories of events that have the *potential* for a severe outcome can also ensure that the workload is kept to an acceptable level to provide value.

### Aggregated Review

Aggregated review is a process of analyzing similar events to look for common causes. For example, close call events in high frequency event categories that would typically require root cause analysis (e.g., falls, medication adverse events) are collected and reviewed as a group on a quarterly or semi-annual basis. Data and information on each event is collected as it occurs by front line staff who complete forms developed for this purpose. The review team looks for trends or recurring issues in the data or information associated with the events to identify system issues needing correction. ♦



## II. RCA<sup>2</sup> TIMING AND TEAM MEMBERSHIP

### Timing

When a hazard is first identified there needs to be a mechanism in place that promptly assesses if actions are required to mitigate the risk to the patient even before the formal RCA<sup>2</sup> process is under way. Immediate actions may include taking care of the patient, disclosure, making the situation safe, notifying police or security if appropriate, preserving evidence, and gathering relevant information to fully understand the situation. Also included may be tasks such as sequestering equipment, securing the scene as needed, and conducting fact finding. These immediate actions may be performed in parallel to the initiation of the RCA<sup>2</sup> process.

Immediate actions following the event include taking care of the patient, making the situation safe for others, and sequestering equipment, products, or devices that were involved. Within 72 hours of the event's occurrence, it should be scored using the facility's approved risk-based prioritization system. If an RCA<sup>2</sup> is required, the review needs to be initiated as soon as possible following the event in order to capture details while they are still fresh in the minds of those involved. ***Starting the event review promptly can be achieved if steps have been taken ahead of time to ensure staff and resources will be available.*** Techniques such as scheduling standing RCA<sup>2</sup> team meetings each week, which may be cancelled if not needed, establishes a placeholder and permits meeting space to be reserved. Requesting that each department or service identify at least one or two staff to be on call each week to serve on a review team will facilitate timeliness by allowing for the quick convening of a team if one is needed.

The more rapidly well-thought-out actions are implemented, the less exposure there is for additional patient injury to occur from the same type of event, hazard, or system vulnerability. A number of organizations have recommended that RCA<sup>2</sup> type activities be completed in no longer than 30–45 days.<sup>(9,14,20)</sup>

Several meetings will be required to complete the RCA<sup>2</sup> process. Meetings are typically 1.5 to 2 hours in length, with work required by individual members prior to and between meetings to complete interviews or locate and review publications and documents. It is critical that the organization provide adequate resources for the RCA<sup>2</sup> process.

## Team Size

For the purposes of this document the team is defined as those individuals who see the RCA<sup>2</sup> process through from beginning to end. The work of the team is certainly augmented and assisted through involvement with a myriad of other individuals (e.g., staff, patients, and subject matter experts) but the involvement of those individuals may not encompass all activities in which the team must engage. It is suggested that an RCA<sup>2</sup> review team be limited in size to 4 to 6 members. Rationales for doing so include the likelihood that larger review teams will use more person-hours to complete the review, increase the difficulty of scheduling team meetings, and add inertia that reduces the nimbleness of the RCA<sup>2</sup> process.

## Team Membership

For the purposes of this document, “team members” are those who are assigned by the organization’s leadership to officially serve on the team, participate in the process by attending meetings, conduct research and interviews, and identify root cause contributing factors. These team members also are the individuals who make the determination as to the final contents, findings, and recommendations of the RCA<sup>2</sup> report.

Team membership (see Figure 1) should include a subject matter expert and someone who is familiar with the RCA<sup>2</sup> process but is not familiar with (i.e., is naïve to) the event process being reviewed. Ideally a single team member will meet more than one team experience requirement; for example, the subject matter expert may be front line staff member who is also capable of serving as the team leader. This may require bringing in experts from the outside, provided confidentiality protection is not compromised. Managers and supervisors may serve as team members provided the event did not occur in their area of responsibility and their subordinates are not team members. This avoids the possibility of subordinates censoring themselves if their supervisor or manager is present, thus inhibiting free and open communication.

Team members should have a basic understanding of human factors to provide insight into how people can be set up to fail by improperly designed systems, equipment, devices, products, and processes. A patient representative, unrelated to any patient or family member of a patient who might be involved in the event undergoing analysis, should be considered to serve on each RCA<sup>2</sup> review team to represent the patient perspective and voice. Some organizations have experimented with including the patient involved in the adverse event or their family members on RCA teams, but data supporting this as an effective method are currently lacking. There are many organizations outside of and within health care that have prohibited the patient or family members being on RCA teams because of concern that it inhibits free and open communication.

One team member should be appointed as the team leader and charged with ensuring the team follows the RCA<sup>2</sup> process and completes the work on schedule. The leader needs to be skilled in the RCA<sup>2</sup> process and problem solving in general, and be an effective communicator. Another team member should be assigned to serve as the recorder. The recorder’s responsibilities include documenting team findings during the meetings. Less rework will

be required if the recorder uses an LCD projector or similar method to project the team’s work during the meeting so all team members can review and comment on what is being generated.

**Figure 1. RCA<sup>2</sup> Team Membership\* and Involvement**

<i><b>NOTE: An individual may serve in multiple capacities</b></i>	<b>Team Member?</b>	<b>Interview?</b>
Subject matter expert(s) on the event or close call process being evaluated	Yes	Yes, if not on the team
Individual(s) not familiar with (naïve to) the event or close call process	Yes	No
Leader who is well versed in the RCA <sup>2</sup> process	Yes	No
Staff directly involved in the event	No	Yes
Front line staff working in the area/process	Yes	Yes
Patient involved in the event	No	Yes**
Family of patient involved in the event	No	Yes**
Patient representative	Yes	Yes
<p><i>*Strongly consider including facility engineering, biomedical engineering, information technology, or pharmacy staff on an RCA<sup>2</sup> team, as individuals in these disciplines tend to think in terms of systems and often have system-based mindsets. Including medical residents on a team when they are available is also suggested.</i></p> <p><i>** This might not be needed for some close calls or events that are far removed from the bedside (e.g., an incorrect reagent that is used in the lab).</i></p>		

Individuals who were involved in the event should not be on the team because they may feel guilty and insist on corrective measures that are above and beyond what is prudent, or they may steer the team away from their role in the event and activities that contributed to the event. It may also be hard for other team members to ask difficult questions and have frank discussions with these individuals present in the room. These same reasons apply to having patients or family members who were involved in the event serve on RCA<sup>2</sup> teams. However, it is certainly appropriate and usually vital that involved individuals (staff, patients, family members) should be interviewed by the team, in order to understand what happened and to solicit feedback on potential corrective actions. Outside individual and patient involvement with RCA<sup>2</sup> reviews should be considered with respect to “federal statutes, state statutes and case law as well as the readiness and availability of the patient/family member to participate in a productive manner with the shared goal of significantly reducing the risk of recurrence of the event and making the system safer.”<sup>(21)</sup>

It is important to remember that the team is convened to discover what happened, why it happened, and what can be done to prevent it from happening again. Staff may be drawn from across the organization and not just from the departments or services intimately involved with the close call or adverse event being reviewed. Having those intimately involved in the event on the review team creates a real or perceived conflict of interest that can negatively impact the success of the RCA<sup>2</sup> and must be avoided. It is important to remember that, in teaching institutions, trainees (e.g., nursing students and resident physicians) deliver a substantial portion of patient care, and their incorporation in the

RCA<sup>2</sup> process both as team members or as sources for information can be invaluable to understanding what happened. They may also contribute effectively to the formulation of effective and sustainable corrective actions. Their inclusion may provide a fresh look at existing systems and a deeper understanding for those involved with how the organization operates, and that can have future benefits.

***Serving on a review team should not be “additional work as assigned.” Serving on an RCA<sup>2</sup> review team is “real work” and it should be prioritized, acknowledged, and treated as such.*** Time within the normal work schedule needs to be provided for staff to participate in the review to send a clear message that management values and supports the activity to improve patient safety. Facilities may want to consider rotating RCA<sup>2</sup> team membership to include staff in all services/departments throughout the facility, including those working afternoons, nights, and weekends. Permitting all staff to have the opportunity to participate in the process exposes them to how and why adverse events occur and may bring about new understanding. In particular, staff may better understand the way that systems influence how they complete their daily tasks as well as gain a better understanding of the value of the RCA<sup>2</sup> process.

### Patient and Family Involvement

The National Patient Safety Foundation's report *Safety Is Personal: Partnering with Patients and Families for the Safest Care* (2014) challenges leaders of health care systems to “involve patients and families as equal partners in the design and improvement of care across the organization and/or practice,” and health care clinicians and staff to not only “provide clear information, apologies, and support to patients and families when things go wrong” but also “engage patients as equal partners in safety improvement and care design activities.”

What might this level of involvement and engagement look like with respect to root cause analysis and action reviews? While there is little industry experience regarding the involvement of patients/families in the process of root cause analysis, an article by Zimmerman and Amori asserts that, when properly handled, involving patients in post-event analysis allows risk management professionals to further improve their organization's systems analysis process, while empowering patients to be part of the solution.<sup>21</sup> The article also acknowledges there are a number of legal and psychological issues to be considered.

Patients and families are among the most important witnesses for many adverse events, and organizations are encouraged to interview them if the patient and/or family are able and willing. This will enable the RCA<sup>2</sup> team to gain a more complete understanding of the circumstances surrounding the event under consideration and may offer additional perspectives on how to reduce the risk of recurrence. Consideration should be made to include an uninvolved patient representative as a member of the RCA<sup>2</sup> team. This will help protect the confidentiality of the process while broadening the perspective on how to further improve organizational performance. This representative may be a member of the organization's patient and family advisory council (or equivalent) or simply a patient representative selected for this specific RCA<sup>2</sup>. In either case, the representative should be unrelated to any patient or family member of a patient who is involved in the event, should have received education regarding quality and peer review protections, and should have a signed confidentiality form on file. This can help mitigate the legal and psychological barriers to direct patient/family involvement in the RCA<sup>2</sup> process, while obtaining the benefit that patient representatives can bring to improvement efforts. ♦

## **Interviewing**

Expertise required for the review that is not already represented or possessed by those on the team may be obtained through the interview process (tips for conducting these interviews are presented in Appendix 3). Individuals who were involved in the event should be interviewed by the team. Patients and/or the patient's family, as appropriate, should be among those interviewed unless they decline. Requesting information from the patient and family will enable the team to gain a more complete understanding of the circumstances surrounding the event under consideration. Patients and/or their family members provide a unique perspective that would otherwise be unavailable.



### III. THE RCA<sup>2</sup> EVENT REVIEW PROCESS

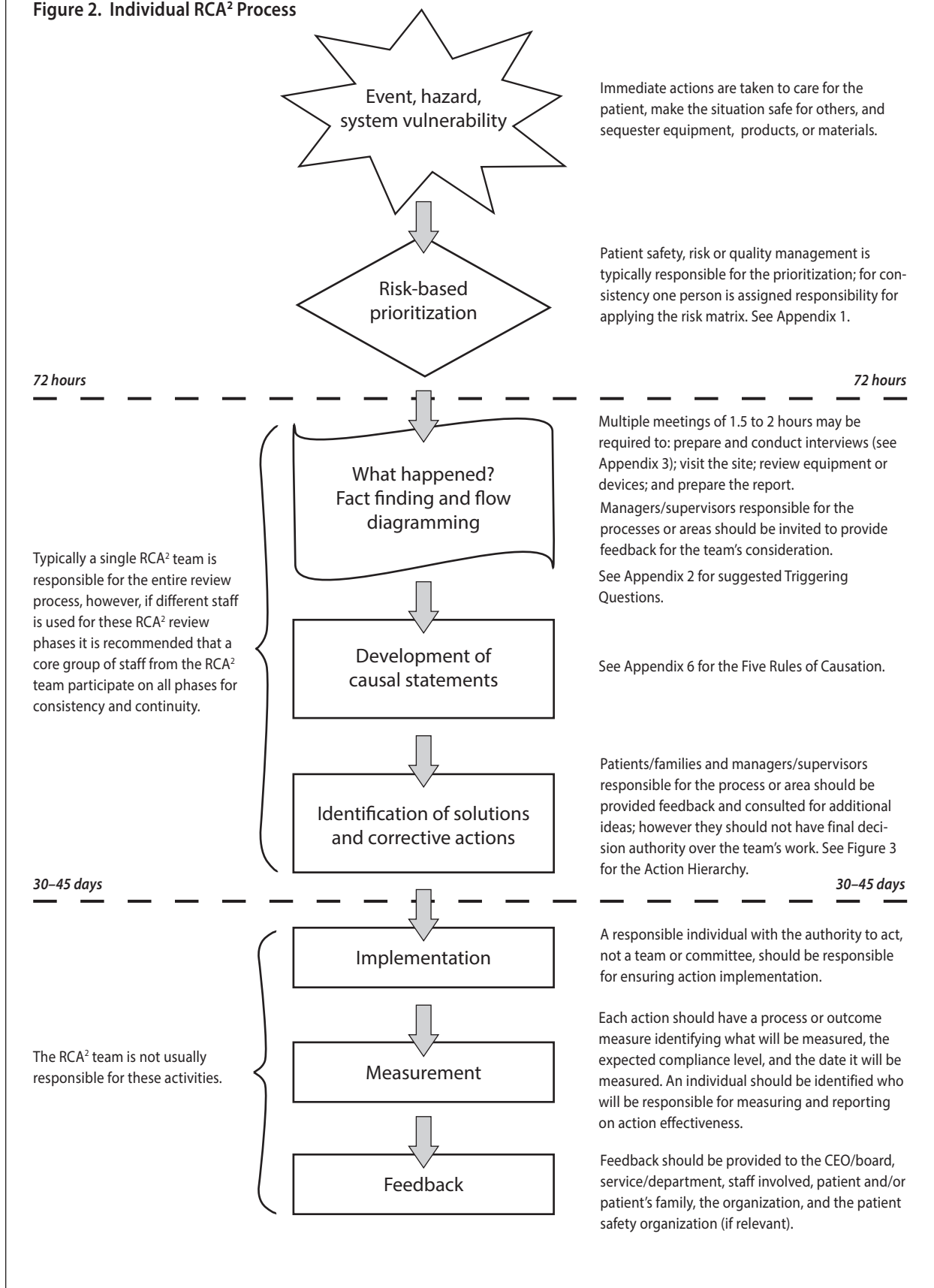
#### **Analysis Steps and Tools**

Figure 2 graphically describes the RCA<sup>2</sup> process from the occurrence of the event through fact finding, corrective action effectiveness measurement, and feedback to the patient and/or family, staff in the organization, and externally to the patient safety organization. The initial fact finding is used to discover what happened and why it happened. The review process should include the following actions:

- Graphically describe the event using a chronological Flow Diagram or timeline; identify gaps in knowledge about the event.
- Visit the location of the event to obtain firsthand knowledge about the workspace and environment.
- Evaluate equipment or products that were involved.
- Identify team-generated questions that need to be answered.
- Use Triggering Questions (see Appendix 2) and team-generated open-ended questions that can broaden the scope of the review by adding additional areas of inquiry.
- Identify staff who may have answers to the questions and conduct interviews (see the Interviewing Tips in Appendix 3) of involved parties including staff and affected patients.
- Include patients, family, or a patient representative as appropriate to ensure a thorough understanding of the facts.
- Identify internal documents to review (e.g., policies, procedures, medical records, maintenance records).
- Identify pertinent external documents or recommended practices to review (e.g., peer reviewed publications, manufacturers' literature, equipment manuals, professional organization guidance and publications).
- Identify and acquire appropriate expertise to understand the event under review. This may require interactions with internal and external sources of expertise (e.g., manufacturers, vendors, professional organizations, regulatory organizations).
- Enhance the Flow Diagram (see the sample in Appendix 4) or timeline to reflect the final understanding of events and where hazards or system vulnerabilities are located.
- Use the flow diagram to compare what happened with what should have happened and investigate why all deviations occurred.
- Provide feedback to the involved staff and patients, as well as feedback to the organization as a whole.



Figure 2. Individual RCA<sup>2</sup> Process



With the new information acquired through the review process, teams are in a position to identify contributing factors. Tools such as Cause and Effect Diagramming (a sample is presented in Appendix 5) and the “Five Whys,” best known as the Five Rules of Causation (see Appendix 6), may also be used to identify and document contributing factors, but their use is not mandatory. The Cause and Effect Diagram is an investigative tool as well as a means to improve communication to stakeholders. Health care processes are complex, and there are many contributing factors to adverse events or near misses that when identified and addressed will improve patient safety. Review teams should strive to identify the multiple contributing factors and not stop the analysis when only a single contributing factor is found. Once identified, contributing factors should be identified in a manner that focuses on system issues and does not assign blame to one or more individuals. Applying the Five Rules of Causation to each contributing factor statement will help ensure that this goal is met. It is important that supporting evidence or rationale be provided in the report to corroborate or substantiate why a contributing factor was selected.

#### Keeping Team Members Engaged and Involved

Projecting the RCA<sup>2</sup> team’s work using an LCD projector or displaying it on a large flat screen monitor during meetings is an effective way of keeping team members engaged. Also, using self-stick notes to construct Flow Diagrams and Cause and Effect Diagrams during meetings helps ensure everyone has the same level of knowledge about the event and allows efficient adjustment of diagrams as the understanding of facts changes with addition of new information. Both techniques reduce the need for rework after the meeting, thus saving everyone time. ♦

## Actions

***The most important step in the RCA<sup>2</sup> process is the identification and implementation of actions to eliminate or control system hazards or vulnerabilities that have been identified in the contributing factor statements.*** Therefore, review teams should strive to identify actions that prevent the event from recurring or, if that is not possible, reduce the severity or consequences if it should recur. Using a tool such as the Action Hierarchy (see Figure 3) will assist teams in identifying stronger actions that provide effective and sustained system improvement.<sup>(22)</sup> The Action Hierarchy developed by the US Department of Veterans Affairs National Center for Patient Safety in 2001 was modeled on the National Institute for Occupational Safety and Health Administration’s Hierarchy of Controls,<sup>(23)</sup> which has been used for decades in many other industries to improve worker safety.

***Teams should identify at least one stronger or intermediate strength action for each RCA<sup>2</sup> review.*** In some cases it may be necessary to recommend actions classified as weaker actions in the Action Hierarchy as temporary measures until stronger actions can be implemented. It should be understood that “weaker” actions such as training and policy changes are often necessary to establish proficiency and expectations, but when used alone are unlikely to be sufficient to provide sustained patient safety improvements.<sup>(24,25)</sup>

**Figure 3. Action Hierarchy**

	<b>Action Category</b>	<b>Example</b>
<b>Stronger Actions</b> (these tasks require less reliance on humans to remember to perform the task correctly)	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).
	Simplify process	Remove unnecessary steps in a process.
	Standardize on equipment or process	Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA <sup>2</sup> process; purchase needed equipment; ensure staffing and workload are balanced.
<b>Intermediate Actions</b>	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
	Education using simulation-based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room.
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.
<b>Weaker Actions</b> (these tasks require more reliance on humans to remember to perform the task correctly)	Double checks	One person calculates dosage, another person reviews their calculation.
	Warnings	Add audible alarms or caution labels.
	New procedure/memorandum/policy	Remember to check IV sites every 2 hours.
	Training	Demonstrate correct usage of hard-to-use medical equipment.

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](http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf). Examples are provided here.

### Why Is “Human Error” Not an Acceptable Root Cause?

While it may be true that a human error was involved in an adverse event, the very occurrence of a human error implies that it can happen again. Human error is inevitable. If one well-intentioned, well-trained provider working in his or her typical environment makes an error, there are system factors that facilitated the error. It is critical that we gain an understanding of those system factors so that we can find ways to remove them or mitigate their effects.

Our goal is to increase safety in the long term and not allow a similar event to occur. When the involved provider is disciplined, counseled, or re-trained, we may reduce the likelihood that the event will recur with that provider, but we don't address the probability that the event will occur with other providers in similar circumstances. Wider training is also not an effective solution; there is always turnover, and a high-profile event today may be forgotten in the future. This is reflected in Figure 3, the Action Hierarchy, which is based upon safety engineering principles used for over 50 years in safety-critical industries. Solutions that address human error directly (such as remediation, training, and implementation of policies) are all weaker solutions. Solutions that address the system (such as physical plant or device changes and process changes) are much stronger. This is why it's so important to understand the system factors facilitating human error and to develop system solutions.

Review teams should not censor themselves when it comes to identifying corrective actions. This is important because the team's job is to identify and recommend the most effective actions they can think of, and it is leadership's responsibility to decide if the benefit likely to be realized is worth the investment, in light of the opportunity cost and its impact on the system in general. Only the top leadership of an organization can accept risk for the organization, and this is a responsibility that should not be delegated to others. ♦

## Measuring Action Implementation and Effectiveness

***In order to improve patient safety, corrective actions must be implemented and their effectiveness measured. To ensure that actions are implemented, assign an individual, not a committee, the responsibility for each action, and set a date by which the action must be completed.*** This individual must have the authority to effect change and the resources or access to resources to implement the action. Multiple individuals or a committee should not be assigned this responsibility because to do so dilutes accountability and undermines the probability of successful implementation.

***Each action identified by the review team requires at least one measure, which may be either a process measure or an outcome measure.*** A process measure may be something as simple as documenting that the action was implemented. For the overall RCA<sup>2</sup> process, it is wise to have a combination of both process and outcome measures. Process measures confirm the action has been implemented, while outcome measures determine if the action was effective. The length of time required to implement the measure should also be considered. For example, if an action required beta testing of new technology to improve staff use of alcohol-based hand gel before and after each patient encounter, a potential process measure might be to observe 100 staff-patient encounters over a 7-day period with an expected compliance rate of 95%. A potential outcome measure for this same action might be a 20% reduction in hospital-acquired infections (HAI) transmitted by staff-patient contact. The data for the process measure may be collected more quickly

than the HAI data, and therefore the technology (if effective) may be implemented sooner to reduce future potential patient harm. Deciding what type of measures to employ is a risk-based decision. A balance must be struck between the precision and accuracy of measurement required and what conclusions it will permit as opposed to the downside if the effectiveness is inaccurately determined. Measures should identify what is being measured, by whom, what compliance level is expected, and a specific date that the measure will be assessed. An individual, not a committee or group, should be made responsible for ensuring the action effectiveness is reviewed. (Appendix 7 provides the Cause, Action, Process/Outcome Measure Table structure, plus a sample causal statement.) When actions have been measured, the CEO, review team, patient, and/or patient's family should be provided with feedback on its effectiveness.

## Feedback

***It is essential that involved staff as well as involved patients/families be provided feedback of the findings of the RCA<sup>2</sup> process, and be given the opportunity to comment on whether the proposed actions make sense to them.*** Feedback to the organization as a whole is also essential in order to create a culture of safety and reporting, permitting staff to see the improvements that result from these reports.

## Leadership and Board Support

***For the RCA<sup>2</sup> process to be successful it is critical that it be supported by all levels of the organization including the chief executive officer and the board of directors, as demonstrated by an appropriate investment of resources. Each action recommended by a review team should be approved or disapproved, preferably by the CEO or alternatively by another appropriate member of top management.*** If an action is disapproved, the reason for its disapproval should be documented and shared with the RCA<sup>2</sup> team so that the constraint preventing implementation can be understood and another action developed by the team to replace it, unless it is otherwise effectively addressed in the action plan.

***RCA<sup>2</sup> results on significant events as defined by the organization—including the hazards identified, their causes, and corresponding corrective actions—should be presented to the board of directors for their review and comment.*** Figures 3 and 4 present cognitive aids that may be used by CEOs and board members when reviewing RCA<sup>2</sup> reports. These tools will aid the CEO and board in making a qualitative assessment to determine whether a thorough RCA<sup>2</sup> review has been completed. Leaders then need to determine the applicability of the findings on a broader scale across their organization or beyond and take further action as appropriate if required. It is recommended that the review of RCA<sup>2</sup> reports be added to the board of directors meeting agenda as a recurring topic as part of efforts to address enterprise risk management. The visible and tangible involvement of leadership and the board demonstrates that the process of root cause analysis and action is important.

**Figure 4. Warning Signs of Ineffective RCA<sup>2</sup>**

If any one or more of the following factors are true, then your specific RCA<sup>2</sup> review or your RCA<sup>2</sup> process in general needs to be **re-examined** and **revised** because it is failing:

- There are no contributing factors identified, or the contributing factors lack supporting data or information.
- One or more individuals are identified as causing the event; causal factors point to human error or blame.
- No stronger or intermediate strength actions are identified.
- Causal statements do not comply with the Five Rules of Causation (see Appendix 6).
- No corrective actions are identified, or the corrective actions do not appear to address the system vulnerabilities identified by the contributing factors.
- Action follow-up is assigned to a group or committee and not to an individual.
- Actions do not have completion dates or meaningful process and outcome measures.
- The event review took longer than 45 days to complete.
- There is little confidence that implementing and sustaining corrective action will significantly reduce the risk of future occurrences of similar events.

## Measuring the Effectiveness and Sustainability of the RCA<sup>2</sup> Process

***It is recommended that the RCA<sup>2</sup> program be reviewed annually by senior leadership and the board for effectiveness and continued improvement.*** The following are examples of measures that may be useful:

- Percent of contributing factors written to meet the Five Rules of Causation
- Percent of RCA<sup>2</sup> reviews with at least one stronger or intermediate strength action
- Percent of actions that are classified as stronger or intermediate strength
- Percent of actions that are implemented on time
- Percent of actions completed
- Audits or other checks that independently verify that hazard mitigation has been sustained over time
- Staff and patient satisfaction with the RCA<sup>2</sup> review process (survey)
- Response to AHRQ survey questions pertinent to the RCA<sup>2</sup> review process
- Percent of RCA<sup>2</sup> results presented to the board



## IV. CONCLUSION AND RECOMMENDATIONS

### Conclusion

The key to establishing a successful root cause analysis and action process lies in leadership support. The components of a successful program include establishing a transparent risk-based methodology for triaging events, selecting the correct personnel to serve on the team, providing the team with the resources and time to complete the review, identifying at least one stronger or intermediate strength action in each review, and measuring the actions to assess if they were effective in mitigating the risk. Using tools such as risk-based prioritization matrices, Triggering Questions, the Five Rules of Causation, and the Action Hierarchy will aid the team in identifying and communicating causal factors and taking actions that will improve patient care and safety.

### Recommendations

1. Leadership (e.g., CEO, board of directors) should be actively involved in the root cause analysis and action (RCA<sup>2</sup>) process. This should be accomplished by supporting the process, approving and periodically reviewing the status of actions, understanding what a thorough RCA<sup>2</sup> report should include, and acting when reviews do not meet minimum requirements.
2. Leadership should review the RCA<sup>2</sup> process at least annually for effectiveness.
3. Blameworthy events that are not appropriate for RCA<sup>2</sup> review should be defined.
4. Facilities should use a transparent, formal, and explicit risk-based prioritization system to identify adverse events, close calls, and system vulnerabilities requiring RCA<sup>2</sup> review.
5. An RCA<sup>2</sup> review should be started within 72 hours of recognizing that a review is needed.

6. RCA<sup>2</sup> teams should be composed of 4 to 6 people. The team should include process experts as well as other individuals drawn from all levels of the organization, and inclusion of a patient representative unrelated to the event should be considered. Team membership *should not* include individuals who were involved in the event or close call being reviewed, but those individuals should be interviewed for information.
7. Time should be provided during the normal work shift for staff to serve on an RCA<sup>2</sup> team, including attending meetings, researching, and conducting interviews.
8. RCA<sup>2</sup> tools (e.g., interviewing techniques, Flow Diagramming, Cause and Effect Diagramming, Five Rules of Causation, Action Hierarchy, Process/Outcome Measures) should be used by teams to assist in the investigation process and the identification of strong and intermediate strength corrective actions.
9. Feedback should be provided to staff involved in the event as well as to patients and/or their family members regarding the findings of the RCA<sup>2</sup> process.





## APPENDIX 1. THE SAFETY ASSESSMENT CODE (SAC) MATRIX

This appendix reproduces a modified version of the VA National Center for Patient Safety’s Safety Assessment Code Matrix as an example of a risk-based prioritization methodology for ranking hazards, vulnerabilities, and events so that an organization can consistently and transparently decide how to utilize its available resources to determine which risks to study and mitigate first. Five sample scenarios and their assessments are provided on pages 25–30.

Any event prioritization tool such as the SAC Matrix presented in this appendix should meet local organizational regulatory requirements and standards as well as those of applicable accrediting and regulatory organizations. For a prioritization tool’s use to be successful, a system should be instituted to ensure that the tool is updated periodically to reflect changes in applicable requirements, regulations, and standards.

### THE SAFETY ASSESSMENT CODE (SAC) MATRIX

The Severity Categories and the Probability Categories that are used to develop the Safety Assessment Codes (SACs) for adverse events and close calls are presented in the following, and are followed by information on the SAC Matrix.

#### 1. SEVERITY CATEGORIES

a. Key factors for the severity categories are extent of injury, length of stay, level of care required for remedy, and actual or estimated physical plant costs. These four categories apply to actual adverse events and potential events (close calls). For **actual adverse events**, assign severity based on the patient’s actual condition.

b. If the event is a **close call**, assign severity based on a reasonable “worst case” systems level scenario. *NOTE: For example, if you entered a patient’s room before they were able to complete a lethal suicide attempt, the event is catastrophic, because the reasonable “worst case” is suicide.*

<p><b>Catastrophic</b>  <b>Patients with Actual or Potential:</b>                      Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) <b>not related to the natural course of the patient’s illness or underlying condition</b> (i.e., acts of commission or omission). This includes outcomes that are a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime. Any of the adverse events defined by the Joint Commission as reviewable “Sentinel Events” should also be considered in this category.</p> <p><b>Visitors:</b> A death; <b>or</b> hospitalization of three or more visitors  <b>Staff:</b> A death or hospitalization of three or more staff*</p>	<p><b>Major</b>  <b>Patients with Actual or Potential:</b>                      Permanent <b>lessening</b> of bodily functioning (sensory, motor, physiologic, or intellectual) <b>not related to the natural course of the patient’s illness or underlying conditions</b> (i.e., acts of commission or omission) <b>or</b> any of the following:                      a. Disfigurement                      b. Surgical intervention required                      c. Increased length of stay for three or more patients                      d. Increased level of care for three or more patients</p> <p><b>Visitors:</b> Hospitalization of one or two visitors  <b>Staff:</b> Hospitalization of one or two staff <b>or</b> three or more staff experiencing lost time or restricted duty injuries or illnesses</p> <p><b>Equipment or facility:</b> Damage equal to or more than \$100,000**.*</p>
<p><b>Moderate</b>  <b>Patients with Actual or Potential:</b> Increased length of stay <b>or</b> increased level of care for one or two patients  <b>Visitors:</b> Evaluation <b>and</b> treatment for one or two visitors (less than hospitalization)  <b>Staff:</b> Medical expenses, lost time or restricted duty injuries or illness for one or two staff  <b>Equipment or facility:</b> Damage more than \$10,000, but less than \$100,000**.*</p>	<p><b>Minor</b>  <b>Patients with Actual or Potential:</b> No injury, nor increased length of stay nor increased level of care  <b>Visitors:</b> Evaluated and no treatment required <b>or</b> refused treatment  <b>Staff:</b> First aid treatment only with no lost time, nor restricted duty injuries nor illnesses  <b>Equipment or facility:</b> Damage less than \$10,000 or loss of any utility without adverse patient outcome (e.g., power, natural gas, electricity, water, communications, transport, heat and/or air conditioning)**.*</p>

\*Title 29 Code of Federal Regulations (CFR) 1960.70 and 1904.8 requires each Federal agency to notify the Occupational Safety and Health Administration (OSHA) within 8 hours of a work-related incident that results in the death of an employee or the in-patient hospitalization of three or more employees. Volunteers are considered to be non-compensated employees.

\*\*The Safe Medical Devices Act of 1990 requires reporting of all incidents in which a medical device may have caused or contributed to the death, serious injury, or serious illness of a patient or another individual.

\*The effectiveness of the facilities disaster plan must be critiqued following each implementation to meet The Joint Commission’s Environment of Care Standards.

**2. PROBABILITY CATEGORIES**

a. Like the severity categories, the probability categories apply to actual adverse events and close calls.

b. In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at your facility. Sometimes the data will be easily available because they are routinely tracked (e.g., falls with injury, Adverse Drug Events (ADEs), etc.). Sometimes, getting a feel for the probability of events that are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

Like the severity categories, the probability categories apply to actual adverse events and close calls.

c. In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at your facility. Sometimes the data is easily available because the events are routinely tracked (e.g., falls with injury, ADEs, etc.). Sometimes, getting a feel for the probability of events that are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be the best educated guess.

(1) **Frequent** – Likely to occur immediately or within a short period (may happen several times in 1 year).

(2) **Occasional** – Probably will occur (may happen several times in 1 to 2 years).

(3) **Uncommon** – Possible to occur (may happen sometime in 2 to 5 years).

(4) **Remote** – Unlikely to occur (may happen sometime in 5 to 30 years).

**3. How the Safety Assessment Codes (SAC) Matrix Looks**

Probability and Severity	Catastrophic	Major	Moderate	Minor
<b>Frequent</b>	3	3	2	1
<b>Occasional</b>	3	2	1	1
<b>Uncommon</b>	3	2	1	1
<b>Remote</b>	3	2	1	1

**4. How the SAC Matrix Works.** When a severity category is paired with a probability category for either an actual event or close call, a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk) results. These ranks, or SACs, can then be used for doing comparative analysis and for deciding who needs to be notified about the event.

**5. Reporting**

a. All known reporters of events, regardless of SAC score (one, two, or three), must receive appropriate and timely feedback.

b. The Patient Safety Manager, or designee, must refer adverse events or close calls related solely to staff, visitors, or equipment and/or facility damage to relevant facility experts or services on a timely basis, for assessment and resolution of those situations.

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>

## Using the Safety Assessment Code Matrix: Five Examples

Excerpted and adapted from Bagian JP, Lee CZ, Cole JF, "A Method for Prioritizing Safety Related Actions," in *Strategies for Leadership: a Toolkit for Improving Patient Safety*, developed by the Department of Veterans Affairs National Center for Patient Safety, sponsored by the American Hospital Association.

---

### EXAMPLE 1

The nursing staff was providing the patient with routine a.m. care. This consisted of showering the patient in the shower room on the ward. The patient was seated in a chair being washed when he slid off the chair and hit his face, hip, and shoulder. The patient was examined by the doctor at 7:55 a.m. and transferred to the acute evaluation unit (AEU) for further evaluation. The AEU physician ordered x-rays. No fractures noted. The patient was returned to the ward where neuro checks were initiated as per policy and reported as normal.

#### Severity Determination

The first step in assigning the SAC score is determining the severity of the event. We can see from the report that no injury was reported after evaluation by x-ray and clinical evaluation on the ward. Therefore, the actual severity would be rated as minor.

**Actual Severity Score = MINOR**

However, when one considers the potential for injury, the evaluator could reasonably assess it as potentially catastrophic. This is true because their past experience with similar falls had demonstrated that the *most likely worst case scenario* could have resulted in a lethal injury. Therefore, while the *actual severity would be rated as minor the potential severity would be considered to be catastrophic*.

In general, the severity score assigned should be whichever one is the most severe when comparing the actual versus the potential/risk thereof (close call) assessment. In this way, the most conservative course will be selected, which will maximize the potential to prevent future events of this nature.

**Potential Severity Score = CATASTROPHIC**

#### Probability Determination

The probability determination should be made based on the situation that results in the most severe severity assessment. The evaluator should base the probability assessment on their own experience at their facility and locally generated data. This, in most cases, will be the most subjective portion of the SAC score determination. It should be noted that the SAC Matrix that is used has been constructed in such a way that it minimizes the impact of this subjectivity. The purpose of the SAC score process is to provide a framework to prioritize future actions. If the facility feels that there are circumstances that warrant a more in-depth follow-up than that which the SAC score indicates, they are free to pursue it.

Based on the experience of the evaluator, the probability of a catastrophic (using the SAC definition) outcome for a patient of this type whose head struck a hard object as the result of a

fall would be *occasional to uncommon*. Wanting to be conservative, the occasional assessment would be selected.

**Probability Score = OCCASIONAL**

**Example 1 SAC Matrix**

Severity and Probability	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	<b>3</b>	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

Using the SAC matrix one need only locate the severity rating and then follow down the column until reaching the row containing the probability score. In this case this would yield the SAC score of "3." Notice that even if the probability of the event had been rated as uncommon, the SAC score still would have been determined to be a "3."

**SAC Score = 3, therefore an RCA<sup>2</sup> review would be conducted.**

All actual SAC 3 and potential SAC 3 events require that a root cause analysis and action review be conducted.

---

**EXAMPLE 2**

XYZ monitor did not trigger an alarm in the Surgical ICU. The problem was observed by the nurses while they cared for a DNR patient who developed cardiac arrhythmias, but the monitor failed to trigger the alarm. Since the patient had a DNR order he was not resuscitated.

**Severity Determination**

The first step in assigning the SAC score is determining the actual severity score for the event. We can see from the report that the actual outcome of this event was the death of the patient. While this would definitely be thought of as a catastrophic event, there are other factors to be considered.

Since the patient was classified as a DNR, and the nurses who were caring for the patient witnessed the cardiac arrhythmias, the patient's death was not the result of the failure of the alarm to announce the cardiac abnormalities. Instead, there was an appropriate decision made not to resuscitate based on the DNR order. This then would mean that the actual outcome would be considered to be a result of the natural course of the patient's disease. As such, the *severity code based on the actual outcome would be N/A (not applicable)* and the case would not receive any further consideration if scoring were to stop at the actual severity.

However, such an action does not take into account the potential/risk thereof (close call) assessment and does not make common sense. It was purely serendipitous that the patient was a

DNR. Had this not been the case, the death would not have been placed in the natural course of the disease category. It was probably also serendipitous that the cardiac arrhythmias were witnessed. This would mean that had this happened in a patient that was not in DNR status, a catastrophic event may reasonably be construed to have occurred. For these reasons the severity for this event would be determined to be *catastrophic* from a potential perspective. Remember, the severity score assigned should be whichever one is the most severe when comparing the actual versus the potential/risk thereof (close call) assessment. In this way, the most conservative course will be selected, which will maximize the potential to prevent future events of this nature.

**Severity Score = CATASTROPHIC**

**Probability Determination**

The probability determination should be made based on the situation that results in the most severe severity assessment. The evaluator should base the probability assessment on their own experience at their facility. This, in most cases, will be the most subjective portion of the SAC score determination. It should be noted that the SAC Matrix that is used has been constructed in such a way that it minimizes the impact of this subjectivity. It must be remembered that the entire purpose of the SAC score process is to provide a framework within which to prioritize future actions and that a higher rating can be assigned if the facility feels that there are particular circumstances that warrant more in-depth follow-up.

The probability determination would rely on the experience of the evaluator. For the purposes of this illustration we will assume that the probability is thought to be *uncommon*.

**Probability Score = UNCOMMON**

**Example 2 SAC Matrix**

Severity and Probability	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	<b>3</b>	2	1	1
Remote	3	2	1	1

Using the SAC matrix one need only locate the severity rating and then follow down the column until reaching the row containing the probability score. In this case this would yield a "3." Notice that even if the probability of the event had been rated as remote, the SAC score still would have been determined to be a "3."

**SAC Score = 3, therefore an RCA<sup>2</sup> review would be conducted.**

### EXAMPLE 3

An outpatient received an MRI scan and brought his oxygen cylinder into the magnet room, where it was pulled into the bore of the magnet. The MR technician activated the emergency shutdown, which turned off all electrical power to the magnet and expelled the liquid helium cooling the magnet to atmosphere outside of the building. Neither the patient nor the tech was injured. The magnet sustained superficial damage but was out of service for 5 days until a contractor could be brought in to replace the helium. (Appendix 4 provides the Final Flow Diagram for this event.)

#### Severity Determination

The first step in assigning the SAC score is determining the actual severity score for the event. We can see from the report that the actual outcome of this event was no injury to either the patient or staff, superficial damage to the MRI, and loss of business income generated by the MRI for 5 days.

As such, the severity score based on the *actual severity for the patient is minor, for the staff member is minor, and for the equipment is moderate* when lost income is factored in.

**Actual Severity Score = MODERATE**

However, such an action does not take into account the potential/risk thereof (close call) assessment. It was by chance or luck that the patient or tech was not injured by the flying oxygen cylinder as it was pulled into the bore of the magnet or that the MR magnet did not crack. The most likely worst case scenario for this event is determined to be *major to catastrophic*. Had the oxygen cylinder struck the tech or patient in the head it likely would have resulted in death or permanent loss of function; a likely outcome for the magnet after quenching is cracking from the thermal shock, and a replacement magnet costs in excess of \$100,000. Based on the potential injury, a severity level of *catastrophic* was selected.

**Potential Severity Score = CATASTROPHIC**

#### Probability Determination

The probability determination should be based on the situation that results in the most severe severity assessment. In this case it is the probability of ferromagnetic objects being brought into the MRI magnet room that could result in catastrophic severity. Based on past experience at the facility, this was assessed to be *uncommon* (possible to occur, may happen sometime in 2 to 5 years).

**Probability Score = UNCOMMON**

**Example 3 SAC Matrix**

Severity and Probability	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	<b>3</b>	2	1	1
Remote	3	2	1	1

Using the SAC matrix the score is a "3" which would require that a root cause analysis and action review be completed.

**SAC Score = 3, therefore an RCA<sup>2</sup> review would be conducted.**

Refer to Appendix 4 for a sample Final Flow Diagram, and Appendix 5 for a Cause and Effect Diagram, of this (fictitious) MRI close call event.

## EXAMPLE 4

An employee working in Food and Nutrition Service was loading large cans of vegetables into a flow-through rack in the dry goods storage area. A can slipped and fell, hitting the employee on the toe. The employee sustained broken bones and was on medical leave for 5 days before returning to work in a light/limited duty position.

### Severity Determination

The first step in assigning the SAC score is determining the actual severity score for the event. We can see from the report that the actual outcome of this event was an injury that required time away from work and a limited/light duty assignment when the employee returned to work. The employee was not wearing safety shoes, which are required for employees performing this task.

The severity score based on the actual severity for the employee is *moderate*.

**Actual Severity Score = MODERATE**

The severity score for most likely worst case scenario for this event is determined to be *major* based on the possibility for permanent loss of function.

**Potential Severity Score = MAJOR**

### Probability Determination

The probability determination should be based on the situation that results in the most severe severity assessment. Based on past experience at the facility this was assessed to be *occasional* (probably will occur, may happen several times in 1 to 2 years).

**Probability Score = OCCASIONAL**

**Example 4 SAC Matrix**

Severity and Probability	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	<b>2</b>	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

**SAC Score = 2, therefore an RCA<sup>2</sup> review is not mandated.**

## EXAMPLE 5

An Environmental Management staff member was cleaning a waiting room in the pediatrics hospital and noticed that there were new potted philodendron plants on the end tables by the couches. Understanding that philodendrons can be poisonous if ingested, the staff member submitted a patient safety report.

### Severity Determination

The first step in assigning the SAC score is determining the actual severity score for the event. We can see from the report that the actual outcome of this event was no injury to patients or employees.

The severity score based on the actual severity for the employee or patient is *minor*.

**Actual Severity Score = MINOR**

The severity score for the most likely worst case scenario for this event is determined to be *moderate* since the risk of fatal poisonings is extremely rare in pediatric patients; however, the plants contain calcium oxalate, which if ingested could cause inflammation of the mucus membranes in the mouth or throat.

**Potential Severity Score = MODERATE**

### Probability Determination

The probability determination should be based on the situation that results the most severe severity assessment. There has been no experience with pediatric patients eating plants in the waiting rooms, but there have been reports of patients eating other objects. The best educated guess is that the probability is *remote to uncommon*.

**Probability Score = UNCOMMON**

**Example 5 SAC Matrix**

Severity and Probability	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	<b>1</b>	1
Remote	3	2	1	1

**SAC Score = 1, therefore an RCA<sup>2</sup> review is not mandated.**

However, just because no RCA<sup>2</sup> review was required, action to mitigate the risk was still thought to be appropriate. The plants were removed from the hospital, and the contract with the vendor was reviewed and modified to prevent a recurrence.





## APPENDIX 2. TRIGGERING QUESTIONS FOR ROOT CAUSE ANALYSIS

Developed by Department of Veterans Affairs National Center for Patient Safety. Available at <http://cheps.engin.umich.edu/wp-content/uploads/sites/118/2015/04/Triggering-Questions-for-Root-Cause-Analysis.pdf>

### Introduction

Triggering Questions are used by the RCA<sup>2</sup> team to help them consider areas of inquiry that might otherwise be missed. The questions are initially answered as “yes,” “no,” or “not applicable.” When questions are answered “no,” it is incumbent upon the team to investigate further to understand why and determine if corrective actions need to be identified and implemented.

### Instructions

- After reviewing the initial Flow Diagram (which is based on what is known about the event before the RCA<sup>2</sup> team’s first meeting), identify and document all questions team members have about the adverse event or close call. (These are referred to as the team questions.)
- Review the Triggering Questions as a team, with the goal of identifying those questions that are applicable to the adverse event being investigated.
- Combine the applicable Triggering Questions with the team questions, and as a team identify where the answers may be obtained. This may include: interviewing staff, reviewing documentation (e.g., policies, procedures, the medical record, equipment maintenance records), regulatory requirements (e.g., The Joint Commission, CMS, other accreditation or regulatory agencies) guidelines (e.g., AORN, ISMP, ECRI Institute), publications, and codes and standards.
- As the investigation progresses, the team may identify additional questions that will need to be answered.
- By the end of the investigation, the RCA team should be able to identify which Triggering Questions are not applicable and the answers to the remaining questions.

### Triggering Questions

#### Communication

1. Was the patient correctly identified?
2. Was 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 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.*)
4. Was communication between management/supervisors and front line staff adequate? (i.e., *Accurate, complete, unambiguous, using standard vocabulary and no jargon*)
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/day to the people who needed it?

8. Were there methods for monitoring the adequacy of staff communications? (*e.g., Read back, repeat back, confirmation messages, debriefs*)
9. Was the communication of potential risk factors free from obstacles?
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?
11. 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 timely manner that was easy to access and use?
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? (*Also, if this has happened before what was done to prevent it from happening again?*)
14. Did adequate communication across organizational boundaries occur?

### **Training**

15. Was there an assessment done to identify what staff training was actually needed?
16. Was training provided prior to the start of the work process?
17. Were the results of training monitored over time?
18. Was the training adequate? If not, consider the following factors: supervisory responsibility, procedure omission, flawed training, and flawed rules/policy/procedure.
19. Were training programs for staff designed up-front with the intent of helping staff perform their tasks without errors?
20. Were all staff trained in the use of relevant barriers and controls?

### **Fatigue/Scheduling**

21. Were the levels of vibration, noise, or other environmental conditions appropriate?
22. Were environmental stressors properly anticipated?
23. Did personnel have adequate sleep?
24. Was fatigue properly anticipated?
25. Was the environment free of distractions?
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.*)
27. Was the level of automation appropriate? (*i.e., Neither too much nor not enough.*)

### **Environment/Equipment**

28. Was the work area/environment designed to support the function it was being used for?
29. Had there been an environmental risk assessment (*i.e., safety audit*) of the area?
30. Were the work environment stress levels (either physical or psychological) appropriate? (*e.g., Temperature, space, noise, intra-facility transfers, construction projects*)
31. Had appropriate safety evaluations and disaster drills been conducted?

32. Did the work area/environment meet current codes, specifications, and regulations?
33. Was the equipment designed to properly accomplish its intended purpose?
34. Did the equipment work smoothly in the context of: staff needs and experience; existing procedures, requirements, and workload; and physical space and location?
35. Did the equipment involved meet current codes, specifications, and regulations?
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?)*
37. Was there a maintenance program in place to maintain the equipment involved?
38. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?
39. If previous inspections pointed to equipment problems, were corrective actions implemented effective?
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?
41. Were adequate time and resources allowed for physical plant and equipment upgrades, if problems were identified?
42. Was there adequate equipment to perform the work processes?
43. Were emergency provisions and back-up systems available in case of equipment failure?
44. Had this type of equipment worked correctly and been used appropriately in the past?
45. Was the equipment designed such that usage mistakes would be unlikely to happen?
46. Was the design specification adhered to?
47. Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy?
48. Were personnel trained appropriately to operate the equipment involved in the adverse event/close call?
49. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?
50. Was the equipment designed so that corrective actions could be accomplished in a manner that minimized/eliminated any undesirable outcome?
51. Were equipment displays and controls working properly and interpreted correctly and were equipment settings including alarms appropriate?
52. Was the medical equipment or device intended to be reused (i.e., not reuse of a single use device)?
53. Was the medical equipment or device used in accordance with its design and manufacturer's instructions?

**Rules/Policies/Procedures**

54. Was there an overall management plan for addressing risk and assigning responsibility for risk?
55. Did management have an audit or quality control system to inform them how key processes related to the adverse event were functioning?
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?

57. Would this problem have gone unidentified or uncorrected after an audit or review of the work process/equipment/area?
58. Was required care for the patient within the scope of the facility's mission, staff expertise and availability, technical and support service resources?
59. Was the staff involved in the adverse event or close call properly qualified and trained to perform their function/duties?
60. Did the equipment involved meet current codes, specifications, and regulations?
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?
62. Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?
63. Were these policies/procedures consistent with relevant state and national guidance, regulatory agency requirements, and/or recommendations from professional societies/organizations?
64. Were relevant policies/procedures clear, understandable, and readily available to all staff?
65. Were the relevant policies and procedures actually used on a day-to-day basis?
66. If the policies and procedures were not used, what got in the way of their usefulness to staff?
67. If policies and procedures were not used, 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.)*

68. What barriers and controls were involved in this adverse event or close call?
69. Were these barriers designed to protect patients, staff, equipment, or the environment?
70. Was patient risk considered when designing these barriers and controls?
71. Were these barriers and controls in place before the adverse event or close call occurred?
72. Had these barriers and controls been evaluated for reliability?
73. Were there other barriers and controls for work processes?
74. 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.)*
75. Were relevant barriers and controls maintained and checked on a routine basis by designated staff?

## APPENDIX 3. INTERVIEWING TIPS FOR RCA<sup>2</sup> REVIEWS

The goal of the interview process is to discover information about what happened and why that will lead to the identification of system issues and ultimately to effective and sustainable corrective actions.

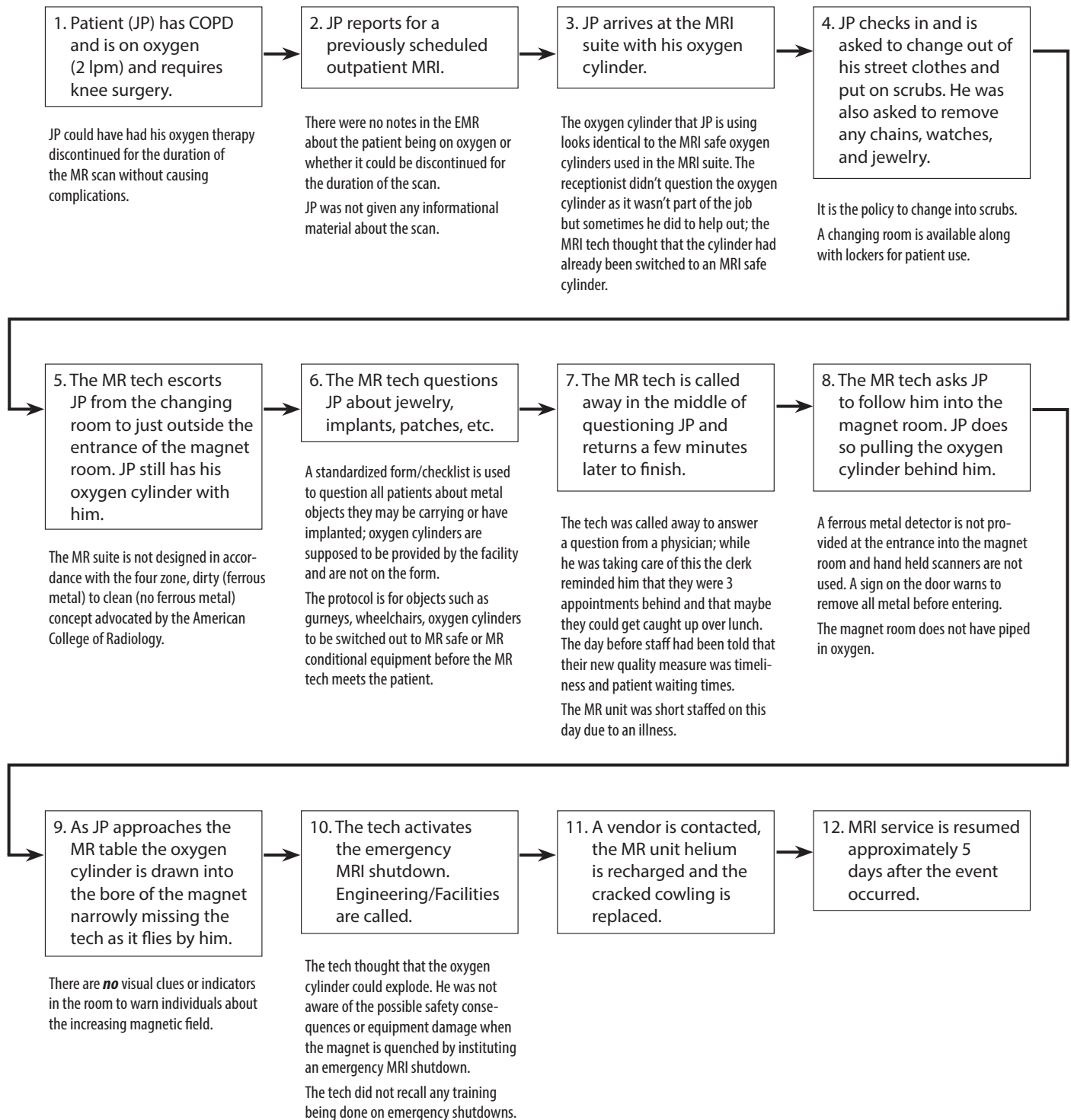
From the writings of Sidney Dekker, we find that a fundamental question of this process is not “where did people go wrong?” but “why did their action make sense to them at the time?”<sup>(26)</sup> To answer questions like these and to achieve the goal of the interview process requires effective interviewing skills and close attention to the tips provided below.

- Interviews should be conducted by the RCA<sup>2</sup> 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 RCA<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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.

## APPENDIX 4. FINAL FLOW DIAGRAM EXAMPLE

All events appearing in this diagram are fictitious. Any resemblance to real events is purely coincidental.

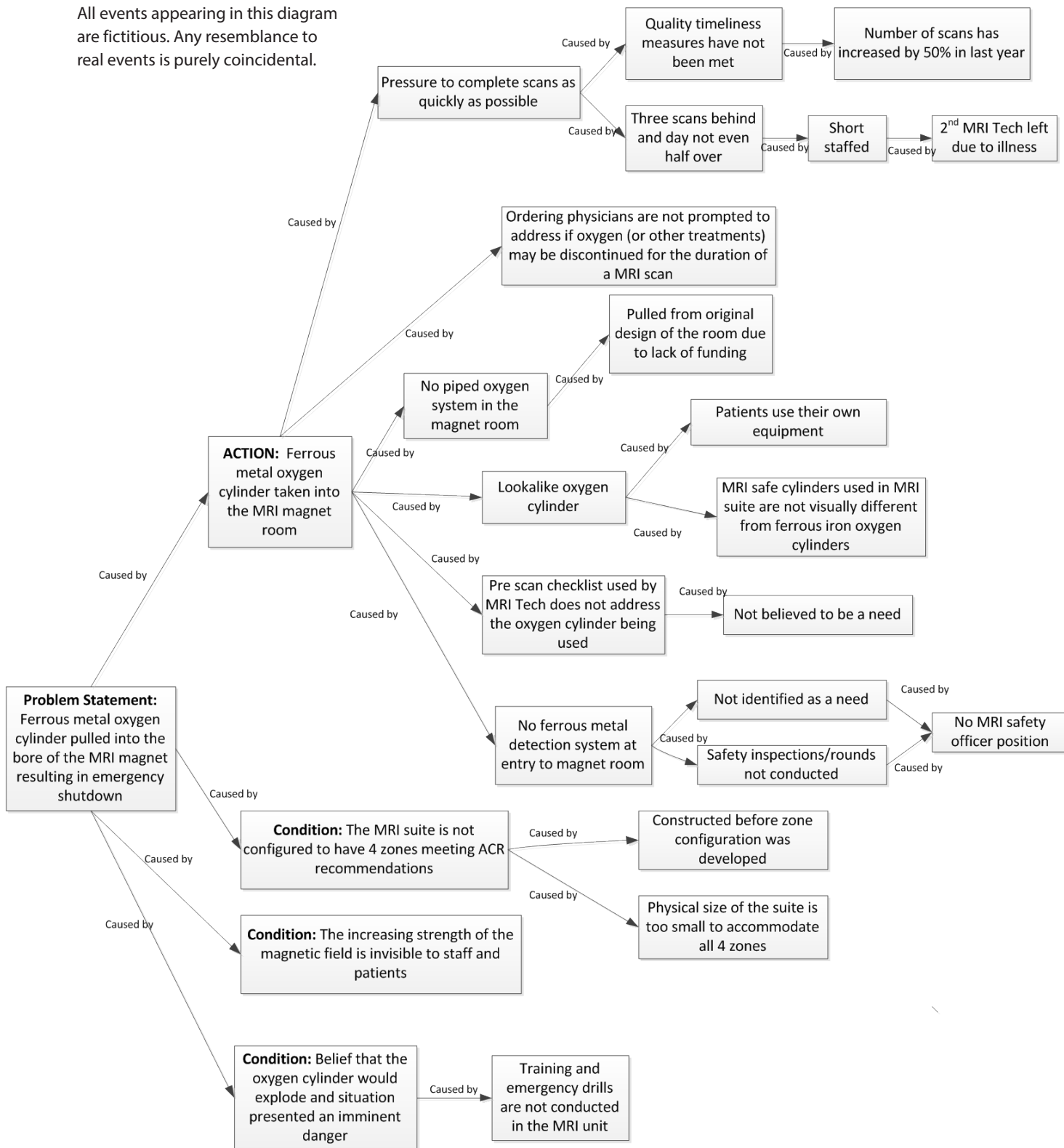




## APPENDIX 5. CAUSE AND EFFECT DIAGRAM EXAMPLE

Based on the Cause and Effect Diagramming Model  
 from *Apollo Root Cause Analysis: A New Way of Thinking*  
 by Dean L. Gano (Apollonian Publications, 1999.)

All events appearing in this diagram  
 are fictitious. Any resemblance to  
 real events is purely coincidental.





## APPENDIX 6. THE FIVE RULES OF CAUSATION

The wording of the rules below is based on The Five Rules of Causation developed by the Department of Veterans Affairs, Veterans Health Administration, and appearing in their *NCPS Triage Cards™ for Root Cause Analysis* (version October 2001, see <http://cheps.engin.umich.edu/wp-content/uploads/sites/118/2015/04/Five-Rules-of-Causation.pdf>) and their document *Root Cause Analysis (RCA)*, [http://nj.gov/health/ps/documents/va\\_triage\\_questions.pdf](http://nj.gov/health/ps/documents/va_triage_questions.pdf). The five rules were adapted from the Federal Aviation Administration technical report “Maintenance Error Causation,” by David A. Marx, June 9, 1999.

After the RCA<sup>2</sup> team has identified system vulnerabilities, these need to be documented and written up to comply with the Five Rules of Causation. Applying the rules is not a grammar exercise. When the rules are met, causal statements will be focused on correcting system issues. Causal statements also have to “sell” why the corrective actions identified by the team are important. Using the format described in this appendix will increase the likelihood that the corrective actions will be supported.

Causal statements are written to describe (1) Cause, (2) Effect, and (3) Event. Something (Cause) leads to something (Effect) which increases the likelihood that the adverse Event will occur.

**Example:** A high volume of activity and noise in the emergency department led to (cause) the resident being distracted when entering medication orders (effect) which increased the likelihood that the wrong dose would be ordered (event).

### Rule 1. Clearly show the “cause and effect” relationship.

**INCORRECT:** A resident was fatigued.

**CORRECT:** Residents are scheduled 80 hours per week, which led to increased levels of fatigue, increasing the likelihood that dosing instructions would be misread.

### Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words. Avoid negative descriptors such as: Poor; Inadequate; Wrong; Bad; Failed; Careless.

**INCORRECT:** The manual is poorly written.

**CORRECT:** The pumps user manual had 8 point font and no illustrations; as a result nursing staff rarely used it, increasing the likelihood that the pump would be programmed incorrectly.

### Rule 3. Human errors must have a preceding cause.

**INCORRECT:** The resident selected the wrong dose, which led to the patient being overdosed.

**CORRECT:** Drugs in the Computerized Physician Order Entry (CPOE) system are presented to the user without sufficient space between the different doses on the screen, increasing the likelihood that the wrong dose could be selected, which led to the patient being overdosed.

### Rule 4. Violations of procedure are not root causes, but must have a preceding cause.

**INCORRECT:** The techs did not follow the procedure for CT scans, which led to the patient receiving an air bolus from an empty syringe, resulting in a fatal air embolism.

**CORRECT:** Noise and confusion in the prep area, coupled with production pressures, increased the likelihood that steps in the CT scan protocol would be missed, resulting in the injection of an air embolism from using an empty syringe.

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

**INCORRECT:** The nurse did not check for STAT orders every half hour, which led to a delay in the start of anticoagulation therapy, increasing the likelihood of a blood clot.

**CORRECT:** The absence of an assignment for designated RNs to check orders at specified times increased the likelihood that STAT orders would be missed or delayed, which led to a delay in therapy.

## APPENDIX 7. CAUSE, ACTION, PROCESS/OUTCOME MEASURE TABLE

Cause/Contributing Factor (CCF) Statement #1:	<i>Each RCA<sup>2</sup> will most likely have multiple CCFs.</i>
---	--

Action 1	<i>Each CCF may have multiple Actions.</i>
Action Due Date	
Date Action Completed	
Responsible Person:	

Process/Outcome Measure 1 ( <i>Each Process/Outcome Measure needs to include: what will be measured; how long it will be measured; and the expected level of compliance.</i> )	<i>Each Action may have multiple Process/Outcome Measures.</i>
Date Measured:	
Responsible Person:	
Was the Compliance Level Met?	Y/N

Management concurs with this Action and Process/Outcome Measure	Y/N
If No, why not? (Answered by Management)	
Is the identification of another action required?	Y/N

### Causal statement example based on the MRI close call scenario in Appendices 1, 4, and 5:

Cause/Contributing Factor (CCF) Statement #1:	<i>The lack of a ferromagnetic detection system at the entrance into the MR magnet 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 MR room being out of service for 5 days.</i>
---	---

Action 1	<i>Install a ferromagnetic detection system at the entrance to all four MRI magnet rooms.</i>
Action Due Date	April 30, 2015
Date Action Completed	Pending
Responsible Person:	Ms. B, Facility Engineer

Process/Outcome Measure 1 ( <i>Each Process/Outcome Measure needs to include: what will be measured; how long it will be measured; and the expected level of compliance.</i> )	<i>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.</i>
Date To Be Measured:	May 10, 2015
Responsible Person:	Dr. A, MRI Safety Officer
Was the Compliance Level Met?	To be determined

Management concurs with this Action and Process/Outcome Measure	Yes
If No, why not? (Answered by Management)	
Is the identification of another action required?	To be determined

## REFERENCES

1. Agency for Healthcare Research and Quality. *Efforts To Improve Patient Safety Results in 1.3 Million Fewer Patient Harms*. AHRQ Publication #15-0011-EF, December 2014. Rockville, MD: Agency for Healthcare Research and Quality. <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html>
2. Nasca T, Weiss KB, Bagian JP. Improving clinical learning environments for tomorrow's physicians. *New England Journal of Medicine* 2014(Mar 13);370(11):991–993.
3. Bagian JP et al. The Veterans Affairs root cause analysis system in action. *Joint Commission Journal on Quality and Patient Safety* 2002;28(10):531–545.
4. Phimister JR, Bier VM, Kunreuther HC. *Accident Precursor Analysis and Management*. Washington, DC: National Academy of Engineering, National Academies Press, 2004.
5. Agency for Healthcare Research and Quality. Patient Safety Organization (PSO) Program. <http://www.pso.ahrq.gov/>
6. Johns Hopkins Medicine, Center for Innovation in Quality Patient Care, The Comprehensive Unit-based Safety Program (CUSP). [http://www.hopkinsmedicine.org/innovation\\_quality\\_patient\\_care/areas\\_expertise/improve\\_patient\\_safety/cusp/](http://www.hopkinsmedicine.org/innovation_quality_patient_care/areas_expertise/improve_patient_safety/cusp/)
7. SAE International. Standard Best Practices for System Safety Program Development and Execution WIP Standard GEIASTD0010, 2014-08-01. <http://standards.sae.org/wip/geiastd0010a/>
8. ISO 9000:2005(en), Quality management systems—Fundamentals and vocabulary, 3: Terms and definitions. <https://www.iso.org/obp/ui/#iso:std:iso:9000:ed-3:v1:en>
9. Department of Veterans Affairs, Veterans Health Administration, *VHA Patient Safety Improvement Handbook 1050.01*, March 4, 2011. [http://www1.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=2389](http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2389)
10. *Aerospace Safety Advisory Panel Annual Report for 2014*. Washington, DC: National Aeronautics and Space Administration, January 2015, 15–16. [http://oior.hq.nasa.gov/asap/documents/2014\\_ASAP\\_Annual\\_Report.pdf](http://oior.hq.nasa.gov/asap/documents/2014_ASAP_Annual_Report.pdf)
11. Department of Veterans Affairs, Veterans Health Administration, *VHA Patient Safety Improvement Handbook 1050.01*, May 23, 2008, <http://cheps.engin.umich.edu/wp-content/uploads/sites/118/2015/04/Triaging-Adverse-Events-and-Close-Calls-SAC.pdf>
12. National Patient Safety Agency, NHS, UK. *Root Cause Analysis Investigation Tools: Guide to Investigation Report Writing Following Root Cause Analysis of Patient Safety Incidents*. <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60180>
13. European Transport Safety Council. *Confidential Incident Reporting and Passenger Safety in Aviation*, May 1996. [http://archive.etsc.eu/documents/bri\\_air3.pdf](http://archive.etsc.eu/documents/bri_air3.pdf)
14. The Joint Commission. *Comprehensive Accreditation Manual for Hospitals. CAMH Update 2, January 2015*. [http://www.jointcommission.org/assets/1/6/CAMH\\_24\\_SE\\_all\\_CURRENT.pdf](http://www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf)
15. Accreditation Council for Graduate Medical Education, Clinical Learning Environment Review (CLER) Program. <http://www.acgme.org/CLER>
16. Bagian JP et al. Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about. *Joint Commission Journal on Quality and Patient Safety* 2001;27(10):522–532.5.
17. Heinrich HW. *Industrial Accident Prevention: A Scientific Approach*. New York: McGraw-Hill, 1931.
18. Health Quality & Safety Commission New Zealand. Severity Assessment Criteria Tables, <http://www.hqsc.govt.nz/our-programmes/reportable-events/publications-and-resources/publication/636/>. And: Guide To Using the Severity Assessment Code (SAC), <http://www.hqsc.govt.nz/assets/Reportable-Events/Resources/guide-to-using-sac-2008.pdf>
19. New South Wales Health Severity Assessment Code (SAC) Matrix, 2005. [http://www0.health.nsw.gov.au/pubs/2005/sac\\_matrix.html](http://www0.health.nsw.gov.au/pubs/2005/sac_matrix.html)
20. Conway J, Federico F, Stewart K, Campbell MJ. *Respectful Management of Serious Clinical Adverse Events*, 2nd ed. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement, 2011.
21. Zimmerman TM and Amori G. Including patients in root cause and system failure analysis: legal and psychological implications. *Journal of Healthcare Risk Management* 2007;27(2):27–34.
22. Bagian JP, King BJ, Mills PD, McKnight SD. Improving RCA performance: the Cornerstone Award and the power of positive reinforcement. *BMJ Quality & Safety* 2011;20(11):974–982.
23. Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. Hierarchy of Controls. <http://www.cdc.gov/niosh/topics/hierarchy/>
24. Mills PD, Neily J, Kinney LM, Bagian J, Weeks WB. Effective interventions and implementation strategies to reduce adverse drug events in the Veterans Affairs (VA) system. *Quality & Safety in Health Care* 2008(Feb);17(1):37–46.
25. Hettinger AZ et al. An evidence-based toolkit for the development of effective and sustainable root cause analysis system safety solutions. *Journal of Healthcare Risk Management* 2013;33(2):11–20.
26. Dekker S. *The Field Guide to Understanding Human Error*. Burlington, VT: Ashgate Publishing, 2006.