



Guide to Performing a Root Cause Analysis

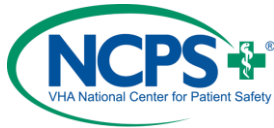
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Introduction

Patient safety events can cause serious harm or death. To address and prevent these threats, health care organizations must unearth the root causes and develop solutions that address the problems from a systems perspective. Despite advances in health care, the occurrence of failures persists. When failures reach the patient, the results may include tragedy for patients and their families, costs to an already overburdened health care system, adverse public perception of an organization, and litigation. They can also deeply affect health care professionals who are dedicated to the well-being of their patients. Most failures are the result of system and process flaws. These flaws are often not immediately apparent and require investigation or systematic analysis.

The most commonly used comprehensive systematic analysis is the Root Cause Analysis (RCA). The RCA is a process for identifying the basic causal factor(s) underlying system failures and is a widely understood methodology used in many industries. Root cause analysis can be used to uncover factors that lead to patient safety events and move organizations to deliver safer care. Its uptake in healthcare has allowed for more accurate and rapid assessment of potential and actual causes of patient harm. The RCA process builds local and national knowledge about system vulnerabilities and helps increase the speed by which patient safety improvements occur throughout the system. Increasingly, health care organizations are using this methodology to investigate close calls (or near misses), no-harm patient safety events, and other signals of risk. Health care organizations no longer have to wait until after a sentinel event occurs to perform a root cause analysis. When an adverse outcome, a sentinel event, or a cluster of less serious incidents or near misses occurs, organizations must develop an understanding of the contributing factors and the interrelationship of those factors. The organization must then implement an action plan to fortify its systems against vulnerabilities with the potential to impact patients.

Purpose of the Guidebook

The purpose of this guidebook is to describe how to complete an RCA according to protocol established by the Veteran Health Administration (VHA) Patient Safety Program and VHA Patient Safety Handbook 1050.01. Intended users of this guidebook include patient safety managers or any persons who may lead, facilitate, or participate in RCAs. Definitions for key terms in the guidebook can be found in the Glossary (Appendix A). Upon review of the guidebook, the user will understand each step associated with the VHA's RCA process, as well as the employment of the RCA Quality Analysis Tool (QAT). A quality RCA example may be found in Appendix B. While the steps outlined below are specific to completing individual RCAs, Appendix C describes the similarities and differences that are important when completing Aggregate Review RCAs. Finally, upon review of the guidebook, users may test their knowledge by answering relevant quiz questions in Appendix D. The answers and supporting rationales are in Appendix E.



Determining when a Root Cause Analysis is Required

RCAs are required for any sentinel event, serious safety event, or for any patient safety event that poses a substantial, direct, and high probability that a serious safety event would have occurred but did not occur due to intervention or chance. These events are given a safety assessment code (SAC) of Actual 3 or Potential 3.

Because of their high frequency, some events receiving a Potential 3 SAC do not require an individual RCA and should either be aggregated and analyzed together, such as in the annual Medication Aggregate Review RCA, or reviewed for inclusion in a patient safety assessment tool (PSAT), such as the annual Falls PSAT or annual Wandering and Missing Patient PSAT. Events falling into these aggregate or PSAT reviews may also receive an individual RCA at the discretion of the facility. SAC 1 or 2 events can be evaluated through the use of an individual or an Aggregate Review RCA, depending on the topic and the needs of the facility. All RCAs must be formally chartered and signed by the facility Director. Appendix D describes steps for completion of Aggregate Review RCAs.

Characteristics of a Root Cause Analysis

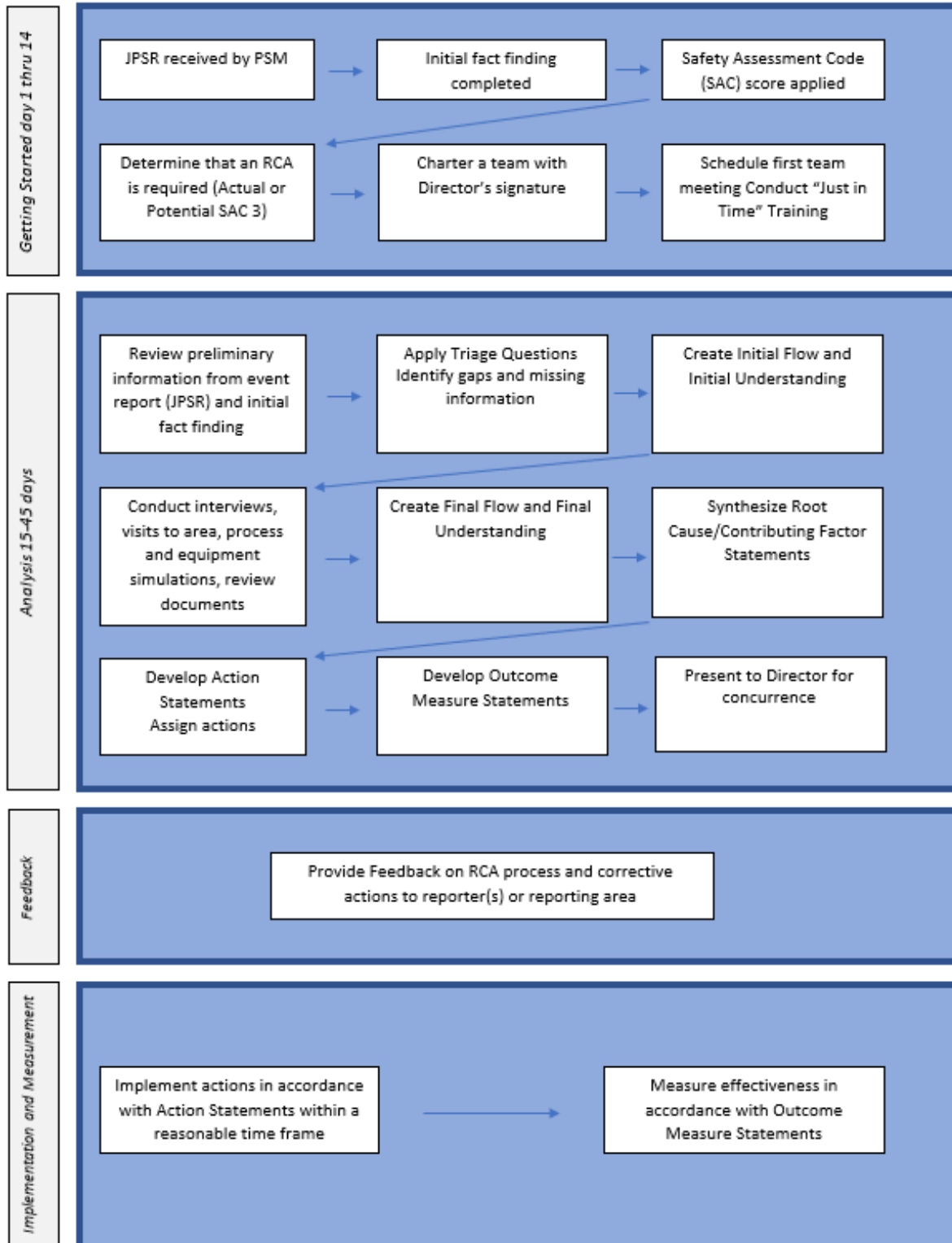
RCAs should adhere to the procedures provided in this document, including the initiation of an RCA with a written charter memorandum. All RCA documents, including the QAT, must have the term “Root Cause Analysis” written on them so that they are protected and deemed confidential under 38 U.S.C. 5705 and the implementing regulations (VHA Directive 2008-077, Quality Management (QM) and Patient Safety Activities that Can Generate Confidential Documents). Email correspondences are not protected. An RCA is not protected unless the RCA charter memorandum is signed by the facility Director or designee. RCAs must be completed, signed by the facility Director, and documented in SPOT within 45 calendar days of the facility becoming aware that an RCA is required.

An RCA is interdisciplinary in nature, identifies system vulnerabilities of risks and their potential contributions to the adverse event or close call, and identifies changes that can be made in systems to improve performance and reduce the risk of event recurrence.

Figure 1 provides a graphic presentation of the process steps for completion of an RCA. Following the Figure, the guidebook will iterate crucial steps in the process to more fully describe key information essential for success.

Root Cause Analysis Flow Diagram

Figure 1. RCA Process Steps



Steps to Completing a Root Cause Analysis

Step 1: Charter a Team

Team composition should be between four and six members. This is founded in the rationale that the team needs to be large enough to allow diverse viewpoints and opinions (avoiding “groupthink”), but small enough so that meetings do not become unwieldy or work deadlines cannot be accomplished.

The membership should include:

- **Leader** – An individual who is well versed in the RCA process and has the requisite knowledge required to keep the team on track and aligned with the required components of adverse event investigations. The leader also organizes meetings, assigns roles and ensures that deadlines are met.
- **Advisor** – An individual with expertise in the RCA process and the various milestone associated with each phase of the team’s work, i.e. flow diagrams, interviewing, simulation, cause and effect diagramming, final understanding, root/cause contributing factor statement development, action planning, outcome measures and communicating findings to leadership for concurrence. The advisor is not normally present for all meetings but is available as needed to assist the team.
- **Subject Matter Expert (SME)** – An individual possessing intimate familiarity with the area, domain, clinical discipline, processes and topic being investigated. The SME is often a front-line staff member who is not directly involved in the event.
- **Non-SME** – An individual unfamiliar with (naïve to) the specific area, processes, or discipline involved in the adverse event or close call.

The charter should, at a minimum, describe the professional title of the individual and their specific role on the RCA team. Individual names can also be provided in the charter memorandum. The following represents an example depiction of team membership.

1. Director of Biomedical Engineering SME
2. Staff Nurse Medicine SME
3. Administrative Clerk Business Office Non-SME
4. Physician Intensivist SME Leader
5. Respiratory Therapist Team Member Recorder
6. Patient Safety Specialist Team Member Advisor

Step 2: Conduct Just in Time Training

Training conducted during the initial RCA team meeting is especially important for new RCA team members and should be completed with every RCA even if there are no members new to the RCA process. NCPS has created a Just in Time training video that may be shown at the beginning of each RCA to ensure all team members have a baseline knowledge of the process: [Just in Time Training Video](#)

Having a senior leader greet the RCA team is recommended. This serves to provide tangible executive leadership support for the RCA team. The senior leader should validate the importance of the work ahead and communicate the executive leadership's team commitment to the process.

Just in Time training should provide an overview of the RCA process that includes the following information:

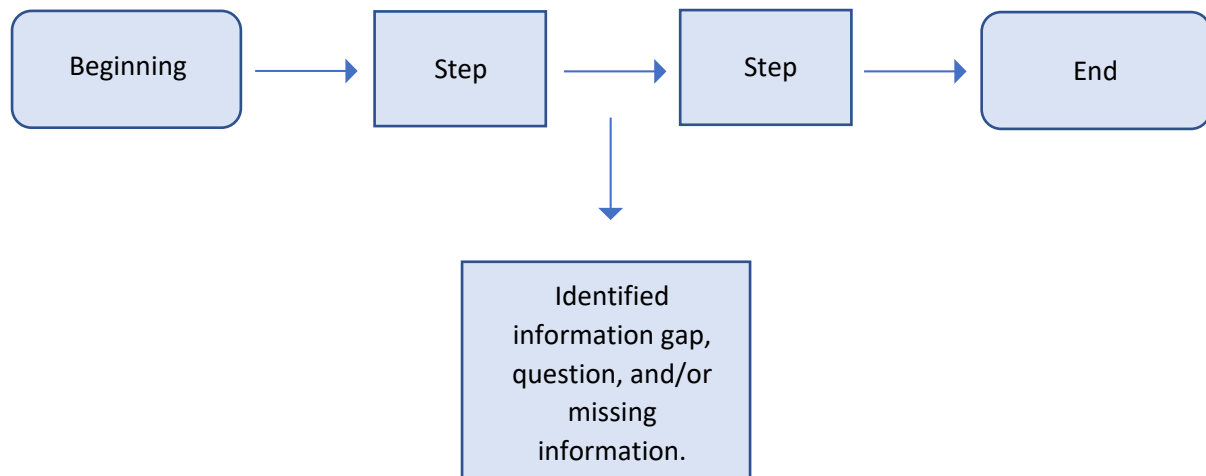
- Confidentiality. “Any documents or records, which result from this RCA, are confidential and privileged under the provisions of U.S. Code Title 38 5705, and its implementing regulations. This material cannot be disclosed to anyone without authorization as provided for by that law or its regulations. *NOTE: The statute provides for fines up to \$20,000 for unauthorized disclosures.*”
- Timeline. Once it is determined that an RCA is required for a reported safety event, the facility has 45 calendar days to complete the RCA.
- Roles and responsibilities. It is recommended that the Patient Safety Manager (PSM) **not** be the leader of the RCA but, be available as the facilitator/advisor to the group. Additionally, there must be a recorder who will document meeting notes and interviews.
- Event briefing. This should be a simple description of what is known about the adverse event at the time of discovery. As the team is briefed, it is likely that they will have questions about the event. The recorder should document questions as they arise to guide the team's next steps.
- Milestones. Milestones and meeting dates/times should be established at the very first meeting, enabling team members to block their schedules in advance. This is particularly helpful to those team members who provide direct patient care, to avoid disruption to clinic schedules or other clinical work.

Step 3: Create the Initial Flow Diagram

The Initial Flow Diagram is a graphic representation of the event using shapes, arrows, and text progressing in stepwise fashion from the first known relevant fact through the final known relevant fact. This depiction represents a general understanding of the event derived from the JPSR report and primary fact finding. It identifies missing information and gaps in knowledge which will direct the team's investigation and analysis.

The Initial Flow Diagram is the visualization of each known process step up to the point in which the system failure occurred. It is an RCA process step that forces the team to lay out known and relevant facts of the event, both graphically and chronologically. While there is no single correct way to illustrate the Initial Flow Diagram, normally, this is accomplished using text within shapes and arrows (see **Figure 2**). Some additional tools include process maps, swim lane diagrams, post-it note boards, mind maps, cause and effect diagrams, fault trees, and event trees.

Figure 2. Sample Initial Flow Diagram



The diagram represents the initial work of the team as they determine each step in the event, where each step is expressed in broad, rather than granular, language. Ultimately, the steps should sequentially flow from one step to the next, to allow a full understanding of what transpired and what elements of the system require improvement. As the team lays out the Initial Flow Diagram and views it in its entirety, it will become apparent that some steps that contribute to understanding systems issues may have been omitted; therefore, additional

information will be required to close gaps in knowledge. The Initial Flow Diagram also enables the team to answer the “where” and “how” to obtain missing information as well as assists the team in identifying the areas of the facility that need to be visited, what processes might be simulated, what documents require review, and who should be interviewed.

The Initial Flow Diagram is different from and complimentary to the Initial Understanding, which is expressed in a more detailed narrative form. The Initial Flow Diagram is constructed **after** the team meets for work, not before, and therefore is not simply a reproduction of the initial event description retrieved from the patient safety reporting system.

Step 4: Craft the Initial Understanding

The Initial Understanding is a written narrative of the event progressing chronologically from the first known relevant fact through the final known relevant fact that represents a general understanding of the event derived from the JPSR report and primary fact finding. It identifies missing information and gaps in knowledge which will direct the team's investigation and analysis. It will include more detailed information not captured in the initial flow diagram.

The Initial Understanding is a narrative expression of the RCA team’s work that produced the Initial Flow Diagram. This means that the Initial Understanding may explain information in greater detail than is possible in the stepwise display in the Initial Flow Diagram. The Initial Understanding should be viewed as separate from, and complimentary to, the Initial Flow Diagram.

The team should first learn about the context of the event, including staffing, environmental and other influencing factors or data points. This critical work involves understanding and defining what factual events took place leading to an adverse event. It is easy to bring in personal biases. However, assumptions can lead to the oversimplification of the process or missing key steps involved in the adverse event. By objectively investigating what happened, the team may find missing information that changes the understanding of the event and in turn, helps the team more accurately connect the dots. Medical records should not be pasted into the Initial Understanding, nor should patient, staff, or facility names be included in the iteration. When necessary, position titles may be used to identify staff roles in the process steps.

Step 5: Identify Information Gaps

While drafting the Initial Understanding, keep the team on task by using a “parking lot” for questions that arise that are not directly associated with the event but may require analysis at a later time. Determine what information is missing or needed for complete understanding of the event by:

- Gathering data to gain understanding of the event, the causal factors, and associated root causes.
- Ensuring consistent use of the Triage Questions, discussed below, to identify system and process vulnerabilities. This allows for continued focus on environmental factors and systems rather than people.
- Continuing to gather data until the team establishes a clear understanding of the event and the existing factors that led up to it.
- Visiting the scene of the event and using the event related equipment, if possible, to safely simulate what happened.

A thorough review of available information will allow the team to determine what is not known about the event and what information still needs to be discovered.

Step 6: Use Triage Questions

Triage Questions are a series of standardized questions designed to assist the team in considering areas of inquiry that might otherwise be missed. Triage questions reveal vulnerabilities in systems and work processes which help RCA teams understand what happened and why. These questions are referenced throughout the RCA process. Link to [Triage Questions](#).

As the definition states, Triage Questions are a standardized set of questions that help to ensure the team is carrying out a comprehensive inquiry. All triage questions should be addressed by the RCA team. Triage Questions are answered either “yes”, “no”, or “not applicable”; each of these answers assumes that the question asked was earnestly considered/addressed by the team and is acceptable. Triage Questions may be applied when the team builds the Initial Flow Diagram; however, they can also be referenced throughout the RCA process.

As the team analyzes the event, they may naturally develop some of their own



questions to augment the standardized Triage Questions. These “team questions” should be combined with the standardized Triage Questions to conduct the investigation and interviews.

Step 7: Collect Resources and Prepare for Interviews

Once the initial sequence of events is mapped out in detail and information gaps have been identified using the Triage Questions, the RCA team must specify what information is required to develop a complete analysis of the event. The RCA team leader should designate individuals responsible for collecting specific information and outline a timeline for collecting the information. Designated individuals will use the Initial Flow Diagram to determine what information is needed such as, policies, procedures, reports, regulations, directives, pertinent medical record components, etc.

When conducting interviews, inform the interviewee of the RCA process and its protections (38 U.S.C. 5705). Be clear that the RCA team hopes to learn about systems issues and solutions from the interview. The team should be aware and sensitive to staff member feelings about the event, including fear of blame and repercussions. The team must account for potential recall or hindsight bias during the interview process. The interviewee should be encouraged to “tell their story”.

Step 8: Conduct the Safety Investigation

Fact-finding involves asking “where, what, how, when, and why” using the Triage Questions as a guide. An RCA team focuses on systems issues and not individual performance. If possible, to do so in a safe manner and without affecting patient care, the team should visit the site of and simulate the event. After fact finding is complete, the team will complete a Final Flow Diagram, incorporating the new information learned.

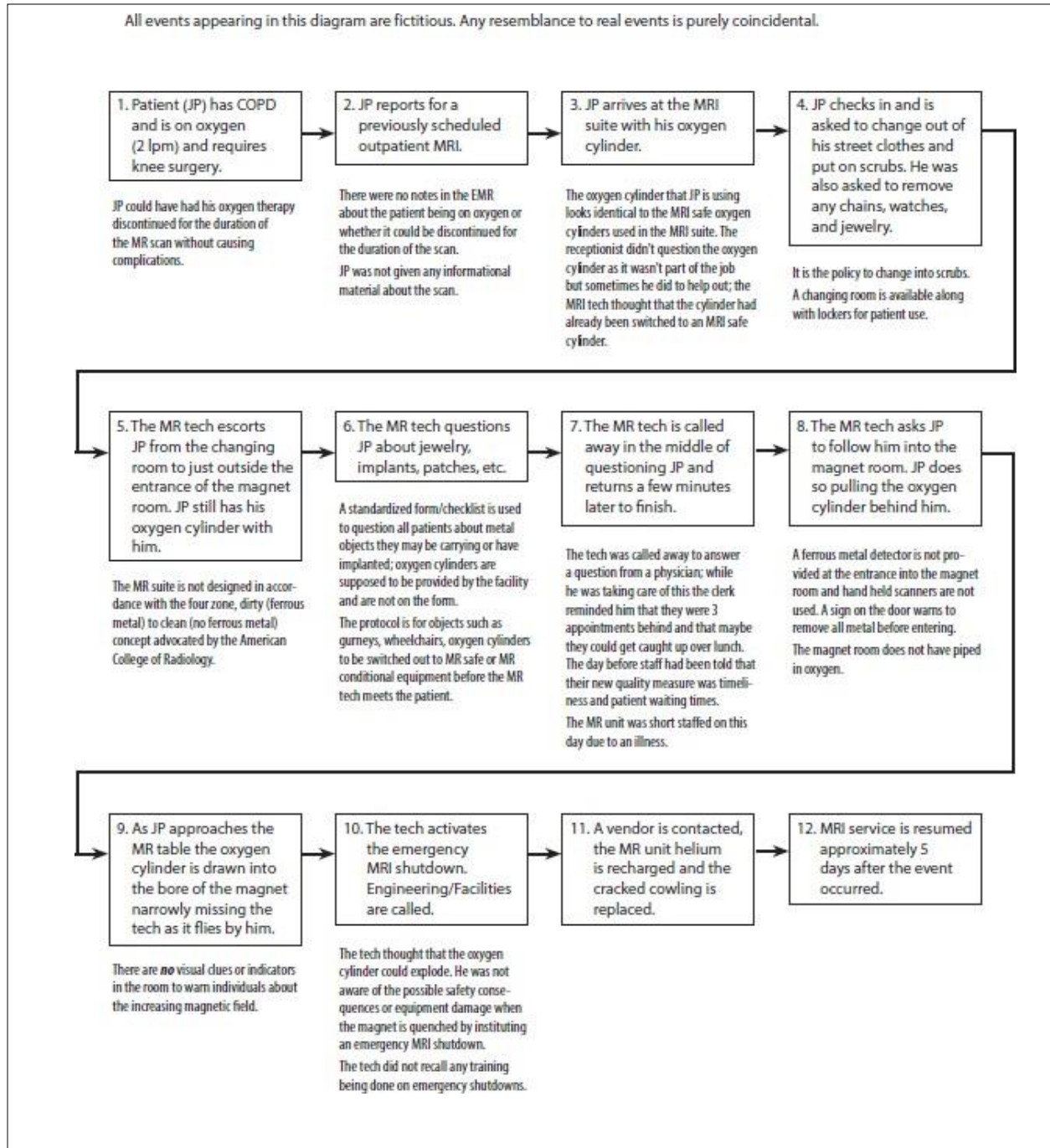
The PSM may request a data search from NCPS to review previous RCAs, aggregate RCAs, and other related information relevant to the event to determine if pertinent actions were implemented and effective. The team will create a record of the documents, websites, and materials used for fact finding to include information received from other organizations (The Joint Commission, NCPS, Falls workgroups, National VHA program offices, etc.).

Step 9: Create the Final Flow Diagram

The Final Flow Diagram is a graphic representation of the event using shapes, arrows, and text progressing in step wise fashion from the first known relevant fact through the final known relevant fact. This depiction represents a complete understanding of the event derived from interviews, simulations, document reviews, literature review, and analysis conducted by the RCA team. It addresses missing information and gaps in knowledge identified in the initial understanding and informs the root cause/contributing factor statements that follow.

The Final Flow Diagram follows the same graphic constructs used for the Initial Flow Diagram – that is shapes, arrows, and text. Because the Final Flow Diagram is constructed from the investigative work completed by the RCA team (interviews, simulations, document reviews, literature review, and analysis), it is markedly different in detail and appearance from the Initial Flow Diagram (see **Figure 3**). Once the final flow diagram is complete, the RCA team will be able to view the event in its entirety and compare what happened to what should have happened. The team is able to visualize the deviations, formulate an understanding, and answer why deviations occurred. If further questions arise, the team may need to do more investigative work, such as follow up interviews or document review for clarification.

Figure 3. Sample Final Flow Diagram



Step 10: Craft the Final Understanding

The Final Understanding is a written narrative of the event progressing chronologically from the first known relevant fact through the final known relevant fact that represents a complete understanding of the event, derived from interviews, simulations, document reviews, literature review, and analysis conducted by the RCA team. It addresses missing information and gaps in knowledge identified in the initial understanding and informs the root cause/contributing factor statements that follow. It will include more detailed information not captured in the final flow diagram.

The Final Understanding is a narrative expression of the RCA team's work that informed the Final Flow Diagram. This means that the Final Understanding will explain information in greater detail than is possible in the stepwise depiction in the Final Flow diagram. While the Final Understanding expresses the same work product, it should be viewed as separate from, and complimentary to, the Final Flow Diagram.

The Final Understanding will provide a comprehensive insight into the story or process resulting in a patient safety event as well as address information gaps, deficiencies, and questions.

When the Final Understanding is complete and includes all analytical work, the team can move to the next step of the RCA process, developing a Cause and Effect Diagram and synthesizing Root Cause and Contributing Statements.

Step 11: Create the Cause and Effect Diagram

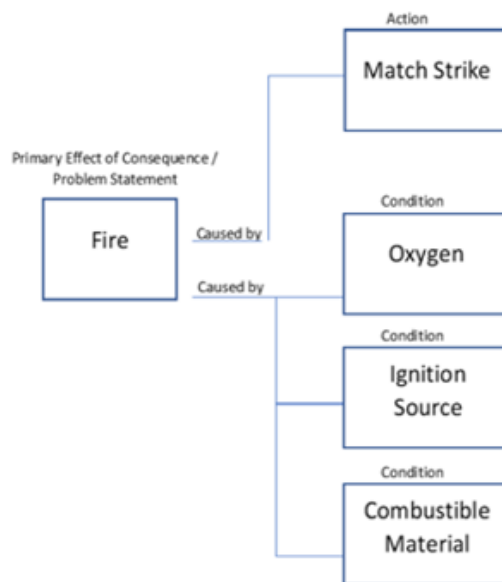
A Cause and Effect Diagram is a systematic method of determining causal links, showing a primary effect of consequence, working backwards with "caused by" statements for specific actions and conditions until a reasonable preceding cause or contributing factor can no longer be identified.

The Cause and Effect Diagram is a required method of determining causation that is applied after the team has constructed the Final Understanding of the event. The diagram begins with a *Primary Effect of Consequence* – this is the problem statement and starting point for the diagram representing that which should be

prevented from occurring/recurring. The diagram works backwards using the term “caused by” or “why”. It is important to identify at least two causes, one an action cause, the other a condition cause for the Primary Effect of Consequence.

Actions relate to causes that are in motion, or in an active state. Action causes are momentary in nature and are easily recognizable. For example, using the simple example of fire, an action cause could be the striking of a match or the placement of a combustible material near an ignition source. Conditions, on the other hand, are those causes that are passive in nature, often unseen or existing quietly in the background that receive little thought or consideration. Condition causes exist over time prior to an action. In the case of fire, conditions would be an oxygen rich environment (air), an existing object made of combustible material (matches), and the presence of an ignition source (tip of match). The action occurring within the condition set in the same relative time and space creates the Primary Effect of Consequence (fire). The Cause and Effect diagram for this example is shown in Figure 4.

Figure 4. Primary Effect of Consequence, Actions, Conditions

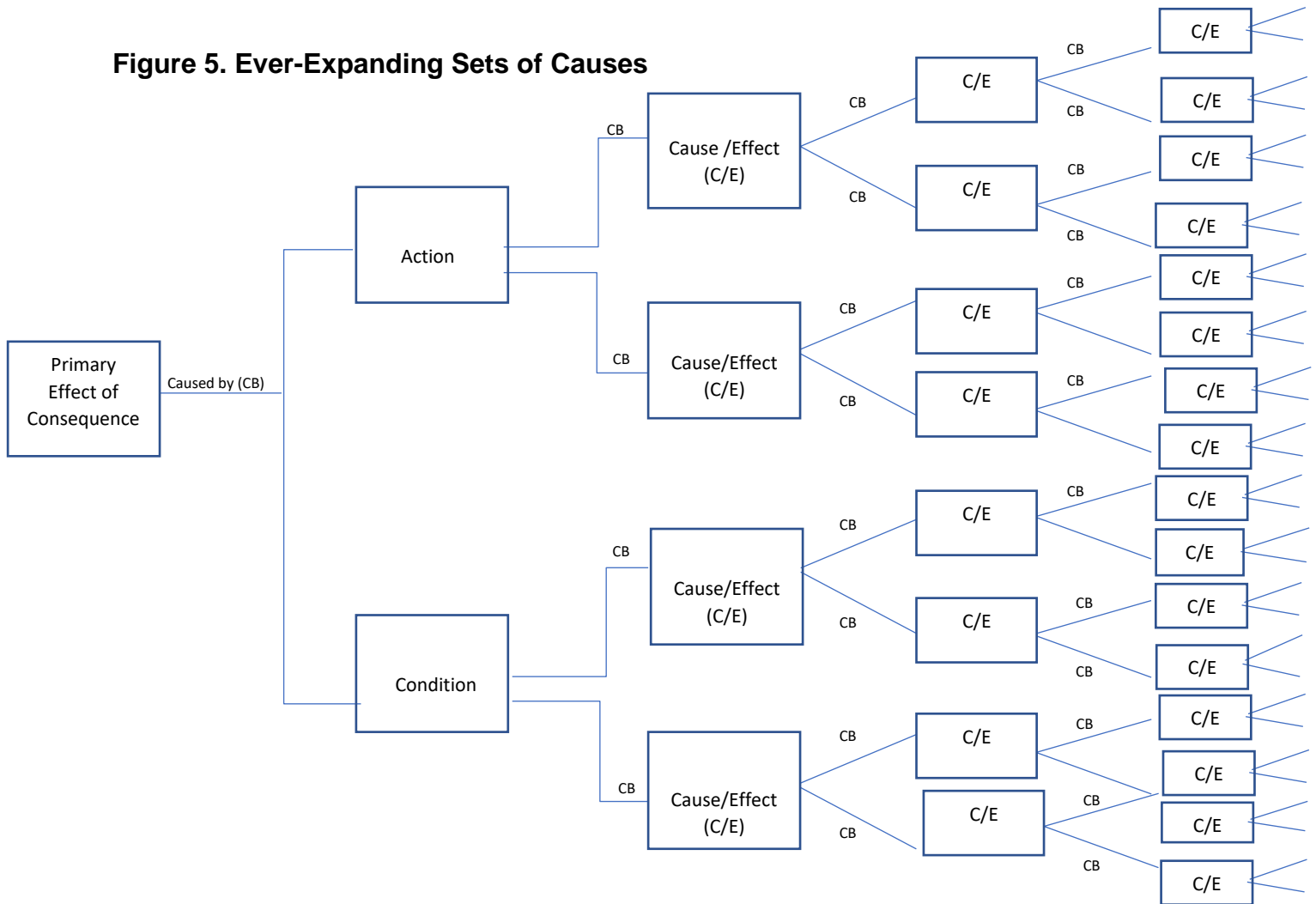


As a Cause and Effect Diagram works backwards from the Primary Effect of Consequence, the causes identified may become effects from which the team continues to work backwards, identifying additional causes. Each time the team asks the question “caused by” or “why”, it identifies more causes in the form of actions and/or conditions. This results in an ever-expanding set of causes (see **Figure 5**). Subsequently, the question becomes where the team should stop

when constructing a Cause and Effect Diagram.

The stopping point occurs when reaching a point of ignorance (*“the team doesn’t know, it just is”*), or when there is neither interest nor a rational reason to continue exploring (*“who cares?”*). For example, if a condition identified is gravity, the team could say a point of ignorance has been reached and it makes no sense to continue asking why. If a condition identified is snowy winter weather, asking why and following through with additional causal inquiries is a fruitless exercise at best. It is important to remember that the more disciplined the RCA team is identifying action and condition causes for each effect, the deeper the team’s understanding of the problem and contributing factors.

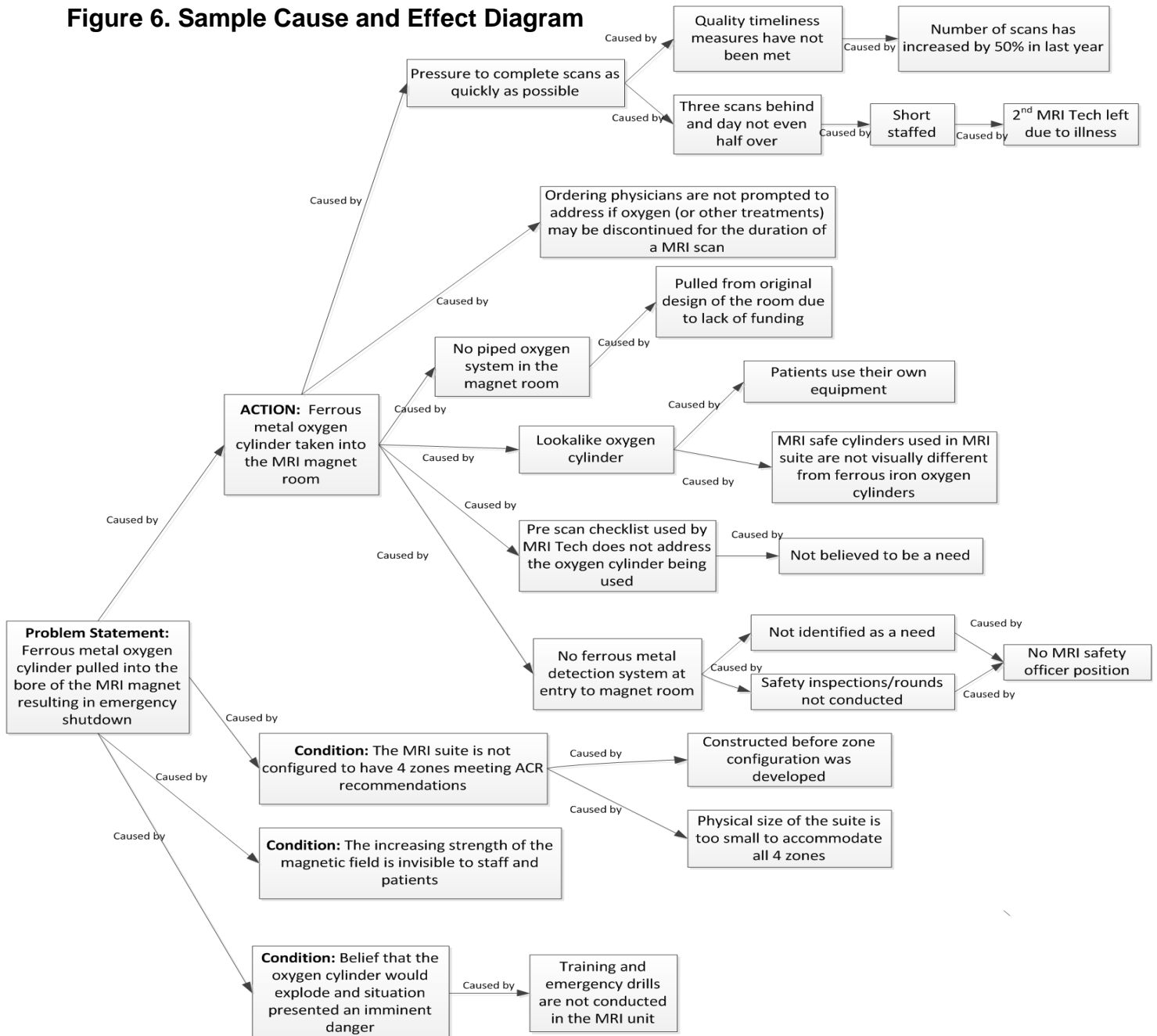
Figure 5. Ever-Expanding Sets of Causes



The methodology described here is a guideline. Not all identified causes and effects fit neatly into a perfectly linear and symmetrical model such as the one presented in **Figure 5**. The team may find as they move deeper into causation,

there may not always be an identifiable action and condition. On the other hand, there may be multiple actions and/or conditions identified. To stay on the right track, the RCA team must identify the Primary Effect of Consequence, then identify at least one action cause and one condition cause. The team can continue asking “why” to develop the diagram. **Figure 6** is an example of a Cause and Effect diagram published by the National Patient Safety Foundation (2016).

Figure 6. Sample Cause and Effect Diagram



Step 12: Identify Root Causes and Craft Contributing Factor Statements

Root Cause and Contributing Factor Statements are formal statements that synthesize the RCA team's findings depicted in the Final Understanding and Cause and Effect Diagram and identify what system elements must be improved.

Root Cause/Contributing Factor Statements (RC/CF) identify what system vulnerabilities contributed to the adverse event or close call. The term “Root Cause” is a misnomer in that events are rarely, if ever, attributed to one causal factor. The team will often identify several factors that influenced the series of events leading to the adverse event or close call. Some factors exert more influence on the event than others. Therefore, the team will select those causal factors (one or more) that rise above others to a point where they require attention and corrective action. It can be thought of as addressing causal factors that contributed the most or whose action plans have the greatest impact on the system and the potential for recurrence.

RC/CF Statements flow naturally from the Final Understanding. It is important that these statements are expressed using a specific cadence that will:

- 1) Lead the team to an appropriate action plan
- 2) Be understood by the cold reader

One methodology to construct a RC/CF Statement that meets these objectives is to use a “*cause, effect, event*” structure. **Example 1** below demonstrates this structure.

Example 1

An RCA team has determined that distractions in the medication preparation area were a major causal factor in an event where a patient received a harmful overdose. A pharmacist was responsible for preparing and dispensing medications while also answering the phone and tending to other administrative duties. The RC/CF Statement may be written as follows:

Cause – The requirement for the pharmacist to simultaneously dispense medication and carry out administrative duties

Effect – **led to** multiple interruptions and distractions during the medication dispensing process

Event – which increased the likelihood that an inappropriate dose would be selected.

Structuring a RC/CF Statement this way, leaves little doubt regarding which and where corrective actions need to be applied. Note that the “*cause, effect, event*” structure is linked by specific words such as “led to” and “increased the likelihood that”. These statements are consistent with the paradigm that identified factors contribute to an event (rather than being expressed as a root cause) and may be thought of as the glue that holds these three elements together. While it is possible to express RC/CF statements in a variety of ways, this method serves to fully express the work of the RCA team up to that point and guides the work of the RCA team moving forward.

It is paramount that RC/CF statements are meaningful, and value added. RC/CF statements should lead the team to answer the questions – “what exactly needs to be fixed and how do we fix it?” To accomplish this, RC/CF statements are written in accordance with the Five Rules of Causation. These five rules are based upon the work of NCPS and the Federal Aviation Administration technical report *Maintenance Error Causation* written by David Marx (1999), explained below:

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

Not in compliance with rule: A resident was fatigued.

In compliance with rule: 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.

Not in compliance with rule: The poorly written manual increased the likelihood that a pump would be programmed incorrectly.

In compliance with rule: The pump 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.

Not in compliance with rule: The resident selected the wrong dose in CPRS which led to the patient being overdosed.

In compliance with rule: Drugs in the CPOE system are presented to the user without sufficient space between different doses on the screen, which led to the wrong dose being selected, increasing the likelihood of an overdose.

Rule 4: Violations of procedure are not root causes and must have a preceding cause.

Not in compliance with rule: 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.

In compliance with rule: Noise and confusion in the prep area, coupled with production pressures, increased the likelihood that steps in the CT scan protocol would be missed, which led to 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.

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

In compliance with rule: The absence of an assignment for designated RNs to check orders at specified times, led to STAT orders being missed or delayed, which increased the likelihood of delays for patients needing immediate therapy.

Step 13: Develop Action Statements

Action Statements identify specific tasks/tools for implementation within a reasonable time frame in order to eliminate or control system hazards or vulnerabilities identified in the Root cause/Contributing Factor statements.

Developing an action plan is a critical point in the RCA process. If the RCA team has adhered to the steps outlined thus far, then selecting an appropriate action plan will be a natural transition. The team will move from knowing what happened, what should have happened, and what system failures occurred, to what should be implemented to prevent recurrence or reduce the severity of harm if the event

should recur.

Having a standardized list of actions will assist the RCA team in the development of action plans that provide effective and sustained system improvement. Using the Action Hierarchy, developed in 2001 and modeled after the National Institute for Occupational Safety and Health Administration’s Hierarchy of Controls, is highly recommended. This tool has been used for decades throughout various industries to improve worker safety (see **Figure 7**).

Figure 7: Action Hierarchy

<p>Stronger (focused on system change)</p>	<ul style="list-style-type: none"> ● Architectural/physical plant changes ● New devices with usability testing before purchasing ● Engineering control or interlock (forcing functions, environment, work area design) ● Leadership/Culture Change ● Simplify the process and remove unnecessary steps ● Standardize equipment, processes, protocols, Clinical Guidelines, order sets, coordination of care ● High Reliability Training
<p>Intermediate</p>	<ul style="list-style-type: none"> ● Eliminate or substitute system/device ● Enhanced documentation/communication ● Redundancy ● Software enhancements/modifications ● Increase in staffing/decrease in workload ● Eliminate/reduce distractions ● Checklist/cognitive aid ● Eliminate look and sound-alikes ● Readback ● Training with simulation
<p>Weaker (reliance on memory/vigilance)</p>	<ul style="list-style-type: none"> ● Double checks ● Warnings and labels ● New procedure/memorandum/policy ● Training ● Additional study/analysis ● Incentives ● Supervision ● Warning Indicators

The Action Hierarchy delineates actions by strength or their ability to be effective and create sustained systems-based improvement. Actions are either Stronger, Intermediate, or Weaker. The general philosophy for the Action Hierarchy is that actions have comparatively more strength the less they depend on human action/attention for effectiveness. For example, implementing a forcing function that physically prohibits the ability to connect an enteral feeding connector to an intravenous line is a Stronger action; whereas having two people review a dosage calculation for a high-risk medication is a Weaker action. It is important to not let the designation “Weaker action” lead the team to believe that such actions are to be avoided. On the contrary, Weaker actions are often necessary to complement actions with higher strength. For example, the Weaker action, Training/Education, is necessary to ensure the appropriate uptake and use of a newly developed standardized checklist, a Stronger action.

An action plan should not consist solely of Weaker actions. Each RCA should consist of at least one action that is designated as Intermediate or Stronger. Actions should be assigned to a specific person to ensure that someone is responsible for implementation. 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. The action plan should clearly specify the title of the individual responsible. The timeline for action implementation should be reasonable, understanding that in most cases, the sooner implementation occurs, the better. Future dates for action implementation should not extend beyond 6 months.

Step 14: Develop Outcome Measure Statements

Outcome Measure Statements are metric statements that determine the effectiveness of an action, are quantifiable (if appropriate), specify a time frame for measurement, and set realistic thresholds.

Each Action Statement must have an associated Outcome Measure Statement. The Outcome Measure should determine both the implementation and effectiveness of the action. Outcome Measure Statements can be further divided into 1) *process* measures, which simply determine if the action or a process associated with an action, i.e. a checklist, use of a communication tool, or training sessions, is implemented; 2) *outcome* measures, which determine the effectiveness of an action. Effectiveness can be measured differently. For example, the rate at which an adverse event occurs may be used, making the adverse event itself the measure – *Falls with injury will be reduced by 15%*. Measuring the actions’ effect on the identified RC/CF Statement can also be used

as an outcome measure. For example, an RCA team has determined the following RC/CF Statement: *Use of hospital beds with an opening greater than 4.75 inches between the mattress and side rail, led to the patient placing his head under the rail, increasing the likelihood of entrapment and suffocation.* The action implemented is to affix a permanent replacement mattress on all beds which decreases the space between the mattress and the side rail to less than 4.75 inches. In this situation, periodic measurement of the side rail and mattress space as mattresses are replaced, would indicate the impact of the action on the RC/CF.

It is also acceptable to *use proxy* measures in some instances. For instance, if alcohol-based hand gel dispensers are placed strategically on a patient care unit to ensure that clinicians are engaging in hand hygiene, the amount of hand gel replaced within a defined period would indicate usage by staff. This may be easier than conducting observations of clinicians in order to witness actual hand hygiene with gel from the dispensers. For example, *Weekly alcohol-based hand gel replacement volume for the unit will increase by 25% from baseline.*

A simple rule for Outcome Measure Statements is to define *what will be measured, how many will be measured, how long the measurements will take place, and what the expected level of compliance will be.* As is the case with actions, identifying a specific individual to conduct the measurement is preferred. For example, using the Outcome Measure discussed above, an appropriate Outcome Measure Statement is constructed as follows:

For a period of 6 months, the Falls Coordinator will measure five new hospital bed-mattress combinations each month. All spaces between the mattress and side rail will be less than 4.75 inches.

Making the Outcome Measure quantifiable is preferable so it is easy to discern whether target thresholds are achieved. In the previous example, Outcome Measure Statement, using the word “all” implies 100 per cent - a quantifiable outcome. For clarity, it is a good practice to spell out the numerator and denominator. The revised statement reads:

For a period of 6 months, the Falls Coordinator will measure five new hospital bed-mattress combinations each month. 100 per cent of spaces between the mattress and side rail will be less than 4.75 inches. The numerator is the number of beds with spaces less than 4.75 inches. The denominator is the number of new beds measured.

Not all Outcome Measure Statements are expressed in this “quantifiable” format. For example, if an action requires a handrail to be installed on steps leading into the whirlpool bath in Physical Therapy, the Outcome Measure may be the simple fact that the handrail has been installed and is in use.



After RCA completion, the team may review the QAT, found in Appendix A, to determine if the RCA has met established quality standards. This tool may guide the team to make revisions to strengthen the RCA.

Step 15: Provide Feedback

Staff who submit a close call or an adverse event report that results in an RCA should receive feedback on the recommended actions being considered or taken. Failure to receive feedback after reporting an event is a commonly cited barrier to reporting adverse events/close calls. Prompt feedback to those reporting adverse events helps establish trust in the system and demonstrates the commitment on the part of the organization to the importance of reporting. It also demonstrates closed loop communication.

Feedback is only provided to individuals who remain on staff when the RCA information becomes available. If the reporter remains anonymous, the feedback process is modified. The PSM will review general information with the staff working in the area where the event occurred. RCA specifics would not be mentioned but proposed improvements can be discussed with the staff and ideas solicited. Keep in mind that the reporter may be in the group getting the feedback, so be sensitive to the potential anxiety of the reporter and the coworkers. The respectful and thankful feedback to the whole group from the PSM will satisfy The Joint Commission requirement for feedback and help to improve patient safety culture. Finally, the confidentiality and protection of the RCA process must be maintained during this discussion between PSM and the reporter.

Step 16: Identify Lessons Learned

Lessons learned are one or two statements that synthesize information gleaned during the RCA process that can be shared with the facility, VISN or VHA. These systems related lessons learned help other facilities avoid the adverse event from occurring.

Lessons Learned are findings that are important to the facility which were discovered during the RCA. These are not to be confused with the actions that are pertinent to addressing the root causes and causal factors of the case. These lessons learned may be system level topics that do not directly influence the outcome of the event under analysis.

The team identifies:

- What was learned?
- Who needs to know?
- How they will be made aware?

It is common to have several lessons learned throughout an investigation of a complex event, but the lessons learned section is *not* the place to put additional actions that address the root causes or contributing factors.

Step 17: Prepare and Present Findings to Leadership

A final RCA presentation to the Director and leadership team facilitates action plan concurrence. Options to consider when creating the final action plan for the Director's Concurrence include:

- Printing out Table 19 from SPOT as a document to be reviewed by the Director and leadership team.
It is important to provide this with "DRAFT" printed across it, along with a "Return to Patient Safety Office." If using this approach, it is recommended that these copies are distributed at the time of the presentation and collected immediately at the completion. No one should leave the room with a copy. The PSM will be sending out the actions to those responsible individuals once the concurrence is complete.
- Another method commonly used is a PowerPoint presentation.

As the team prepares for the final presentation, members should be selected to deliver the information and facilitate discussion. All RCA team members should present sections of the RCA and/or be present to help answer questions that may arise from the Director and leadership team. It is important to remember that not all members of the leadership team must concur on each action. The Director's concurrence is the only one that is required. The Director's signature is mandatory once s/he has provided decisions on all actions.

In the event the Director does not concur, the team should meet again to decide if there is another action that may address the root cause. It is not appropriate for the Director or leadership team to decide the action to replace the one the team generated. In this situation, it is recommended the team reconvene and discuss the options suggested, however, if the team strongly believes the root cause and action/s were appropriately identified, the PSM would check "Mgt Does Not Concur" under that specific RC / Action / Outcome in table 19 in SPOT. In this situation, the Director is required to provide a statement for insertion into SPOT with the reason and rationale to explain why the RCA team's actions are not being supported. That information will be placed in the "Management Comments" section. This non-concur action will not remove the actions and outcomes from the table; however, the actions will not require follow-up. The non-concur action will remain a part of the RCA as non-actionable.



The PSM will ensure the completed RCA concurrence sheet is signed by the RCA Advisor (RCA process expert), all RCA team members, and the facility Director or designee. The date the facility Director signs-off on the RCA is the date the RCA is complete. The Director's signature and date authenticates the completion of the RCA.

Upon Completion of the Root Cause Analysis

Monitor Actions and Outcome Measures

RCA actions and outcomes must be monitored and tracked for completion and sustainment. There should be a system in place for monitoring and tracking RCA actions and outcomes, rather than simply assigning one person to complete this function. It is advisable that the status of RCA actions and outcomes are standing agenda items at patient safety committee or workgroup meetings and that these updates are recorded in the meeting minutes. The committee is then aware of progress of actions and outcomes and committee members may assist in moving items forward. In this way, the facility ensures it is not reliant on one person for this important function, avoiding potential single point vulnerabilities in the system. Examples of tracking systems include shared tools, drives, dashboards, and SharePoint sites that allow for built in redundancy and transparency of the follow-up status of RCA actions and outcome measures.

Communicate Improvements to Staff

Process improvements instituted because of the RCA process should be communicated to facility staff. This is a significant final step so that staff are aware that event reporting makes a difference in the work they do to support Veteran care. Safety Forums are one method used for this communication.

Calculate the Cost

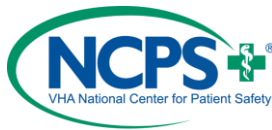
To determine the cost of the RCA, be sure to add all the following:

- Person-hours for all members of the RCA team and any staff consulted during the RCA, multiplied by the hourly cost of each person involved in the RCA.
- Consultation costs for any non-staff time
- Costs of materials used
- Any additional costs incurred during the RCA

RCA Analysis

The following RCA Quality Analysis Tool is used to assess the RCA.

Station ID Number:	RCA Case Number:	Analyst Initials:		
RCA Quality Element	Quality Indicator Measure	Evaluated Points	Total Points	
RCA Team Composition (4 points)	1. Multidisciplinary =1			
	2. Appropriate disciplines / SME for event being investigated =1			
	3. 1 non-SME =1			
	4. Approximately 5 members total =1			
Initial Flow (5 points)	5. Must use shapes, arrows, and text to depict all elements of the event =1			
	6. Must have start and end point in chronological order =1			
	7. Must have more than 1 box depicted =1			
	8. Should be substantive and not simply a reproduction of the "brief description text" in Q1-7 =1			
Initial Understanding (4 points)	9. Must identify questions and/or gaps in the process steps to be used for investigation =1			
	10. Must use narrative form to depict all elements of the event =1			
	11. Must discuss known facts in chronological order =1			
	12. Should be substantive and not simply a reproduction of the "brief description text" in Q1-7 =1			
Triage Questions (1 Point)	13. Must identify questions and/or gaps in the process steps to be used for investigation =1			
	14. All Triage questions addressed =1			
Final Flow (5 points)	15. Must use shapes, arrows, and text to depict all elements of the event =1			
	16. Must have a start and end point in chronological order =1			
	17. Should differ substantially from the initial flow diagram =1			
	18. Must address the questions and/or gaps noted in the initial understanding of the event =1			
Final Understanding (5 points)	19. Must depict a comprehensive understanding of the event reflective of findings derived from interviews, simulations, research, and analysis =1			
	20. Must use narrative form to depict all elements of the event =1			
	21. Must discuss known facts in chronological order =1			
	22. Should differ substantially from initial understanding =1			
Cause and Effect Diagram (4 points)	23. Must address the questions and/or gaps noted in the initial understanding of the event =1			
	24. Must depict a comprehensive understanding of the event reflective of findings derived from interviews, simulations, research, and analysis =1			
	25. Diagram begins with the primary effect of consequence not wanted to recur =1			
	26. Primary effect is connected to a causal action =1			
	27. Primary effect is connected to a causal condition =1			
	28. Causes end at point of ignorance, or where it is no longer value-added or reasonable to continue =1			



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Root Cause / Contributing Factor (RC/CF) Statements (5 points) <i>If more than one RC/CF statement – score should reflect the statement with the lowest score</i>	29. Must have clear connection to the cause(s) expressed in the final flow diagram, the final narrative, and the Cause and Effect diagram =2		
	30. Are written using the “cause”, “effect”, “event” cadence =1		
	31. Must comply with each of the 5 Rules of Causation =1		
	32. Must link to at least one selected triage question =1		
Action Statements (4 points) <i>For criterion 33 through 35 only: If more than one Action Statement – score should reflect the Action Statement with the lowest score</i>	33. Must be specific, concrete, and clear; understood by a cold reader =1		
	34. Must specifically address the system issues identified in the RC/CF Statement =1		
	35. Are assigned to a titled position and given a realistic timeframe for implementation =1		
	36. At least one is in the Intermediate or Stronger category =1		
Outcome Measure (OM) Statements (4 points) <i>If more than one OM Statement – score should reflect the OM Statement with the lowest score</i>	37. Must relate directly to an Action Statement =1		
	38. Must clearly specify what will be measured =1		
	39. Must specify how long or at what interval the measurement will take place =1		
	40. Must state the expected level of compliance i.e. percentage =1		
Total points			
% Score = points/41			

Analyst Comments:

RCA Quality Rubric			
Range	Interval	Percentage	Definition
39 - 41 points Excellent RCA	3	95-100	Addresses all elements. No one element is missing.
34 - 38 points Very Good RCA	5	83-93	Addresses most of the elements but may be missing a few specific criteria.
28 - 33 points Good RCA	6	68-80	Addresses many of the elements, some are missing.
19 - 27 points Fair RCA	9	46-66	Addresses some of the elements, many are missing.
10 - 18 points Poor RCA	9	24-44	Addresses a few of the elements, most are missing.
0 - 9 points Incomplete RCA	10	0-22	Not enough elements addressed, no value.



Appendix A: Glossary

Source: VHA Patient Safety Handbook, 1050.01

Adverse Event. An adverse event is an untoward incident, iatrogenic injury, or other unintended harm directly associated with care or services.

Aggregated Review. The aggregated review process is a method to analyze a group of similar patient safety events to determine common causes and actions to prevent recurrences.

Close Call. A close call is an event or situation that could have resulted in an adverse event but did not, either by chance or through intervention. Such events have also been referred to as near miss events or potential events.

Intentionally Unsafe Act. An intentionally unsafe act is an action that involves reckless behavior done with the knowledge that it poses risk to patient safety. Intentionally unsafe acts in health care include, but are not limited to, criminal acts, acts related to alcohol or substance abuse by an impaired provider or staff member, and acts involving patient abuse.

Joint Patient Safety Reporting System (JPSR). JPSR is a web-based, patient safety event reporting system that can be used by any VHA employee with an active Personal Identity Verification (PIV) card to report patient safety concerns.

Just Culture. Just culture is an atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety related information. Individuals trust they will not be held accountable for system failures; however, the individual is also clear on where the line must be drawn between acceptable and unacceptable behavior.

Patient Safety Assessment Tool (PSAT). PSAT is a Web-based, proactive risk assessment tool used to conduct self-assessments, referred to as “surveys,” on topics related to patient safety. PSAT comprises questions related to patient safety based on regulations, guidelines, evidence in the literature, and accepted best practices.

Root Cause Analysis (RCA). RCA is an event review that focuses on systems and processes to reduce the risk of harm. In order to prevent the problem from reoccurring, the root cause of the problem needs to be eliminated or corrected.

Sentinel Event. A sentinel event is a patient safety occurrence that involves death, serious permanent physical or psychological injury, or severe temporary harm and intervention is required to sustain life.



Serious Safety Event. A serious safety event is a sentinel event or an adverse event that results in permanent lessening of bodily function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient’s illness or underlying condition.

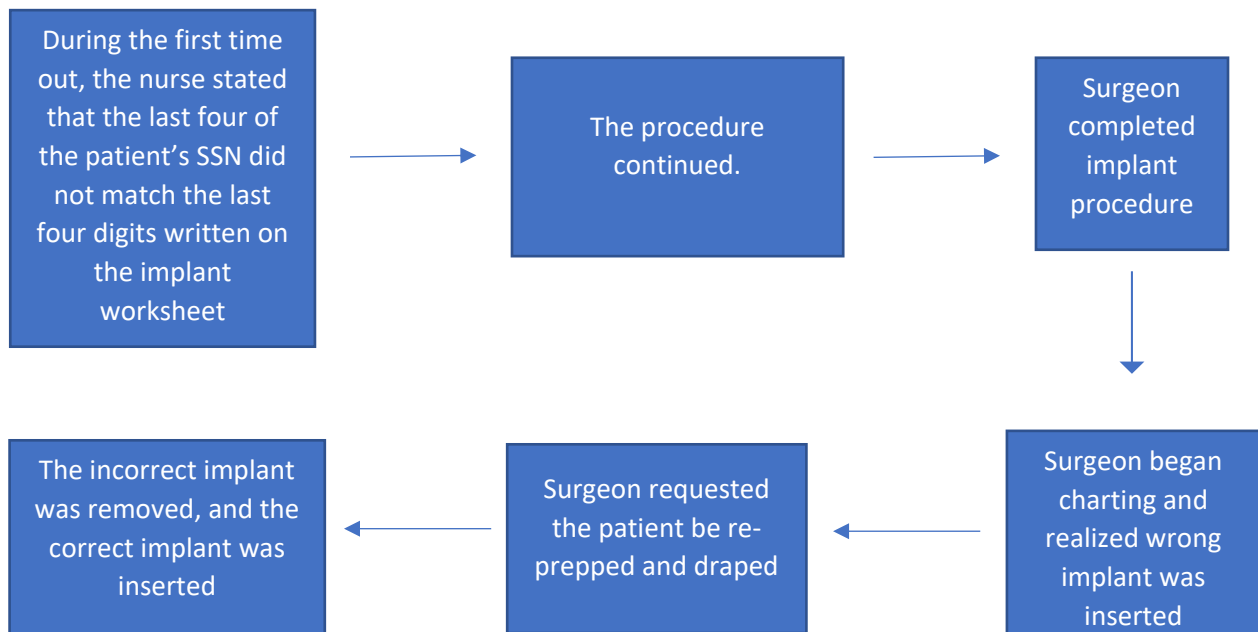
WebSPOT (SPOT). SPOT (not an acronym) is a VHA information system hosted by NCPS and used to capture RCAs and aggregate reviews.

Appendix B: Example Root Cause Analysis

The following RCA is an example of a high-quality RCA, receiving a score of 41/41 on the RCA QAT. Identifiable case details modified to comply with U.S. Code Title 38 5705.

Event Description: wrong implant inserted into patient

Initial Flow Diagram:



Initial Understanding:

When the Dr. was finishing his post-surgical charting, he noted that he had placed the wrong implant into the patient. He requested that the patient be re-prepped and draped. Wrong implant was removed, and correct implant was inserted. During the procedure on the first time out, Dr was informed that on his implant work sheet the last for of this patient's social security number was incorrect. Dr stated "noted" and continued with the case. Implant information on all other documentation matched.

Identify Information Gaps/Resources Needed:

1. Surgery schedule
2. Implant master
3. Implant checklist
4. Timeout note/checklist

Triage Questions: completed

Final Flow Diagram:





Final Understanding:

The patient was evaluated by a physician in specialty clinic. Chart reviewed and medical clearance for implant obtained. The implant surgery was initially scheduled for

April; however, this was cancelled due to the COVID pandemic. Once surgical restrictions for performance of elective procedures were modified, his first implant was scheduled for June, which was uncomplicated. This case, the second implant, was scheduled for July. Practice was for the staff physician to send encrypted email to fee surgeon with the names of prospective patients for implant surgery; also listed was whether or not patient was diabetic, which side and if this case was the second implant (indicating patient already underwent implant surgery on the other side). The surgeon would review the patient's chart via remote access and determine primary and back up implants. The surgeon would then respond on the encrypted email as to the sequence of patients for the next implant surgery day and include the A/O for surgery, staff physician, secretary for surgery, and ambulatory surgery RN and MSA. This information would also be documented by the surgeon, as handwritten on a document which included the implant checklist. In addition, the primary/secondary implant would also be handwritten on a "worksheet". On July 2 the staff physician did send encrypted email to the surgeon containing this patient's last name and last 4, diabetes status and side designation and notation that this was the second implant. The surgeon reviewed the information remotely and determine primary/secondary implants and forwarded the e-mail to the staff physician, AO and secretary of surgery service, and ambulatory surgery MSA including implant specification and sequential order of patients to be scheduled for surgery for that day. The MSA scheduled the patients per the surgeon's sequential order and the nurses checked availability of the implants per the surgeon's e-mail request. This patient was scheduled as the first patient of the day. The day before surgery, the nurse completed the pre-op call. On the day of surgery, the patient arrived at ambulatory surgery and notified staff of arrival via waiting room phone.

The intake nurse took the patient back to the pre-op room, verified identity using two patient identifiers, full name and full SSN, compared these to CPRS and the wristband, and placed wristband on the patient. The staff physician delivered the pre-op medications. The nurse completed the admission process. The surgeon arrived and provided nursing staff with the handwritten papers for the case, to include the form which identified the primary/secondary implants, including the implant checklist which was signed by the surgeon, and the "worksheet" with the primary/secondary implants identified with patient's name and last four. The nurse placed a patient specific, computer generated label, the patient's paperwork, in the patient specific folder. The patient was taken to the exam room by the RN, and the surgeon performed a pre-op exam, with the RN as second verifier documented, the first 3 checks on the implant checklist (review of pre-procedure measurements and calculations and the desired post-operative outcomes). The patient and their folder were taken back to the pre-op room. The intake nurse reviewed the electronic documentation for completed H&P and pre-op templates and verified IMED consent.

Anesthesia arrived and spoke with the patient. The patient was taken back to the OR by the CRNA. Once the patient arrived in the OR, the nurse confirmed the patient's wristband matched full name and SSN in CPRS. The nurse placed the patient in position and the CRNA began anesthetizing the patient. The patient was prepped by the

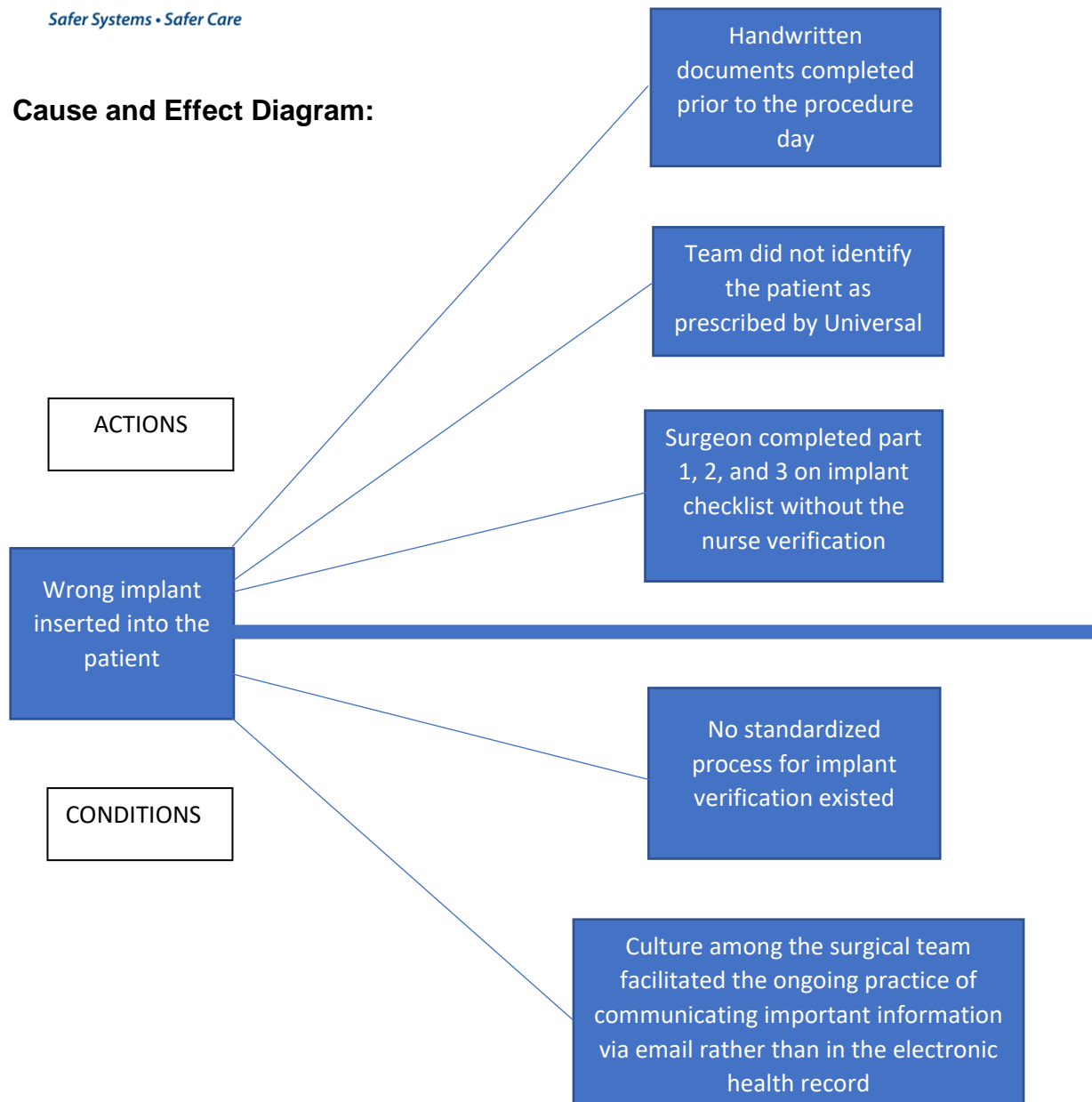
circulating nurse and draped by the implant tech. The surgeon scrubbed and entered the room. The first time out was initiated by the circulating nurse and included participation by the CRNA, surgeon, scrub nurse, second circulating nurse, and implant tech. The 1st time out included the patient's full name, full SSN, allergies, and the procedure to be performed comparing the information in CPRS. All agreed this was correct and the case started. Information on the implant section of the time out was marked as NA for this time out.

The surgeon stated he was ready for the implant. The circulating nurse initiated the 2nd time out, which was for the implant verification. The 2nd time out included the patient's full name, full SSN, procedure to be performed, verification of the primary implant and expiration date comparing this information to the handwritten form "worksheet" which was on the IV pole away from the sterile field for the surgeon reference and the handwritten implant checklist. The nurse stated that the last 4 of the patient's SSN did not match the last 4 digits on the handwritten papers brought in by the surgeon (IV pole paper and the checklist) The procedure continued. The implant was opened and given to the scrub nurse. The implant was loaded. The circulating nurse initiated the 3rd time out. During the 3rd time out, the circulating nurse read the full name and SSN from the printed I-Med consent note with full name and full SSN in CPRS and the procedure to be performed, verification of the primary implant and expiration date, comparing this information to the handwritten form on the IV pole and the handwritten implant checklist.

The implant was inserted. The procedure was complete, and drapes were removed. While documenting in CPRS, the surgeon realized the incorrect implant was inserted into the patient. The surgeon requested that the patient be re prepped and draped. The incorrect implant was removed, and correct implant was inserted. Additional time-outs 2 and 3 are documented as complete. An additional 10 minutes of anesthesia time was required. The patient was taken to recovery and discharged to home without a prolonged recovery time. The surgeon contacted the patient via telephone the evening of the surgery to disclose the event.

The patient had a 1-day post procedure visit where the staff physician noted no adverse findings and the event again was discussed and disclosed to the patient. The one-week post procedure visit was completed, which again showed no adverse findings and patient in full recovery from implant surgery.

Cause and Effect Diagram:



Root Cause and Contributing Factors Statement:

The absence of a formal process for implant selection verification with a primary (original) data source on the DAY of surgery AND during the time-out periods increased the likelihood of mis-selection of the implant, leading to insertion of an incorrect implant.

Action Statements and Outcome Measures:

Action 1: Implement a standard practice to require pre-procedure measurements/calculations be performed on the day of procedure, referencing the original source document and eliminate the use of hand transcribed documents in the



implant verification process. This standard process shall be verified by two individuals and documented.

Measure 1: The utilization of the primary source document will be referenced during the implant verification process for all implant procedures. Monitoring to begin during the month of August for 6 months.

Numerator = number of procedures with documentation/reference made to verification via primary source documents.

Denominator = number of implant procedures completed.

Threshold = 100%

Action 2: Eliminate the use of e-mail communication between parties and require patient information to be documented in the EHR. By implementing this practice, this will force the documentation of the required/preferred primary and back-up implants to be documented in the electronic health record.

Measure 2: 100% of patients referred for implant surgery will have documentation in CPRS between all Parties, to include implant specifications. Monitoring to begin during the month of August for 6 months.

Numerator = number of patients with documentation in CPRS of implant specifications.

Denominator = total number of implant procedures completed.

Threshold = 100%

Lessons Learned:

1. Use of primary source documents as opposed to handwritten documents will assure accurate patient and implant identification.
2. Patient information assessments need to be communicated in the electronic health record versus e-mail.

Appendix C: Aggregate Review RCAs

The Aggregate Review RCA is a method used to identify trends and systems issues by analyzing groupings of similar events to determine common causes, thereby facilitating coordinated actions to prevent recurrences. An Aggregate Review is used to review events that do not require individual RCAs.

The best application of the Aggregate Review RCA includes high-volume cases, such as medication events. Aggregated RCAs, which do not replace individual RCAs, focus on potentially serious close-call events in which significant patient harm has not occurred. It is most helpful to include all events in the chosen category, especially close calls or near misses, to reveal trends in the data. Teams may want to consider including findings from single-case RCAs in their Aggregate Reviews to further enhance their knowledge of system vulnerabilities. Again, when serious patient harm occurs, an individual RCA must be done.

The result of an Aggregate Review RCA is a report that identifies root causes and an action plan, including a detailed measurement plan, that addresses improvements to broad processes that positively affect patient safety. Aggregated Review RCAs are entered into SPOT in the same manner as individual RCAs, with only a few differences in the type and number of questions to be addressed.

Steps in Conducting an Aggregate Review RCA:

1. Determine the theme or category of events to be considered and inclusion criteria (e.g. identify the characteristics of high volume, no or low harm incidents to be analyzed or multi-patient incidents or, identify a theme for multiple completed analyses to be reviewed).
2. Gather and analyze all information about the events being reviewed for a given period, such as the previous 3 months. Think about common elements that may lead to action:
 - Location of events, such as a particular unit
 - Equipment in use at the time
 - Medication ordering issues
 - Patient characteristics
 - Time of day, and staffing at the time of the event
 - Severity and probability of each event (assigned SAC scores)
3. Charter a team with expertise on the subject matter to be analyzed. Like individual RCAs, ensure that the analysis is confidential and protected by having the Director sign an Aggregated Review RCA Charter Memorandum.

4. Include all events for the selected period so there is enough data to determine trends.
5. Create a flow diagram of the general steps involved in the selected process
 - Map the actual process, not the ideal
 - Ask front line staff how the process usually works
 - Focus on linking data (e.g., 60% of falls with toileting) to the process diagram (e.g., no formal assessment of toileting routine done on admission)
6. Use text to describe how the team reviewed the general process.
7. Identify resources/Gather applicable data
 - If applicable, conduct interviews with provider(s), patients, families, and others with knowledge of the incidents and/or care processes involved in the incidents
 - Review literature and obtain expert opinions to collect additional background and contextual information and lend perspective to the analysis
 - Review pertinent resources such as medical records, policies, and committee minutes
8. Use data and the flow diagram to determine the focus of the Aggregate Review RCA
 - The goal is to identify a part of the process where patients are at most risk. For example, if 60 % of the falls were related to toileting, the team may focus on toileting.
 - Other considerations for determining the Aggregate Review focus may include asking, what is causing the highest percentage of falls? What is creating the greatest risk? What focus will yield the most benefit? Establish priorities based on the data and findings.
 - Write a description of your focus and why you chose it.
 - Highlight on your flow diagram the area of the process your team will focus on for this Aggregate Review.
9. Determine root cause/contributing factors, as with individual RCAs, utilizing Triage Questions, Cause and Effect Diagramming, and the Five Rules of Causation.
10. Determine actions to address the root causes, as with individual RCAs.
11. Establish outcome measures, as with individual RCAs.
12. Present to leadership and obtain concurrence.
13. Implement actions and determine if outcome measures were met.



14. The findings, recommended actions and their outcomes should flow into and be coordinated with the organization's improvement processes, including processes for communicating and sharing learning.

Appendix D: Quiz Questions

- Q1:** TRUE or FALSE -- Root Cause Analysis (RCA) is utilized by VHA to identify human error responsible for an adverse event or close call.
- Q2:** An RCA must be initiated with a Charter Memorandum. WHY?
- A. It grants and provides RCA team members with the necessary time to work on the RCA
 - B. It officially notifies the facility Director of the event
 - C. It establishes protection and confidentiality of the RCA
 - D. It establishes the date that the facility is aware of the event
- Q3:** TRUE or FALSE – To be timely, an RCA must be completed, signed by the facility Director within 45 days of the facility becoming aware that an RCA is required and submitted to NCPS through the Patient Safety Information System.
- Q4:** TRUE or FALSE -- An RCA must be done for any reported adverse event or close call where the severity is determined to be catastrophic.
- Q5:** TRUE or FALSE – Individuals involved in an adverse event are encouraged to be members of the RCA team investigating the event.
- Q6:** The following Information is required to be included in the RCA Charter Memo, except:
- A. Brief description of the event
 - B. Date the memo was chartered
 - C. Name of the person who reported the event
 - D. Names of the RCA team members
- Q7:** The RCA team must understand the meaning of confidentiality of the RCA. Which One of these is not an aspect of confidentiality?
- A. U.S. Code Title 38 5705 is the statute that provides protection of the RCA
 - B. Protection applies to all documents, records, and interviews that result from the RCA
 - C. Statute provides for fines up to \$20,000 for unauthorized disclosures
 - D. The Facility Director may grant a waiver to the protection of an RCA if he/she deems it necessary
- Q8:** TRUE or FALSE – Just in Time training does not need to be done for every RCA team, especially if the team has previously worked together.

- Q9:** TRUE or FALSE -- Preventing hindsight bias is crucial to developing an understanding of what happened during an adverse event or close call.
- Q10:** The most critical task to accomplish as the RCA team begins its work is:
- A. Brainstorming possible actions
 - B. Mapping out the sequence of events
 - C. Developing understanding of the motives of individuals involved in the event
 - D. Polling team members what they believe caused the event
- Q11:** TRUE or FALSE – Triage Questions only need to be used if or when the team has difficulty identifying information gaps.
- Q12:** TRUE or FALSE – Visiting the location of the event and simulating what happened is recommended
- Q13:** What are some resources available to the RCA team to fill in the gaps of the event? Check all that apply:
- A. Police Report
 - B. Interviews
 - C. Literature Review
 - D. Medical Record Review
 - E. Interrogation of those involved
 - F. Policy and Regulation Reviews
- Q14:** TRUE or FALSE – When conducting interviews, interviewees should be informed of the RCA process and its protections.
- Q15:** TRUE or FALSE – Questions for interviews are not recommended to be developed before the interview.
- Q16:** What does fact finding entail?
- A. Taking fingerprints of the scene to determine who was involved in the incident.
 - B. Looking at the performance of the individual involved in the incident.
 - C. Asking the “where, how, why, when and what” questions using Triage Questions as a guide, focusing on systems issues and not individual performance.
 - D. Visiting the site of the event and talk to other patients about their care in that area.

Q17: TRUE or FALSE – It is not recommended that an RCA team creates a final understanding flow diagram.

Q18. What is the purpose of an initial understanding?

- A. To tell you what you know
- B. To tell you what you don't know
- C. To tell you what happened
- D. To tell you how it happened
- E. All the above
- F. A and B
- G. C and D
- H. None of the above

Q19. What names can be included in the narrative of the event?

- A. Patient's name
- B. Doctor's name
- C. Names of staff interviewed
- D. All the above
- E. None of the above

Q20: Using the 5 rules of causation when writing root causes and contributing factors, which of the following is not correct:

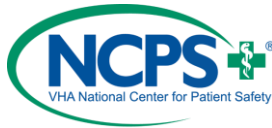
- A. There should be a cause and effect relationship
- B. Using specific and accurate descriptors is preferred rather than vague and negative words
- C. There is always a preceding cause to human errors
- D. Violation of procedures are root causes
- E. Failure to act is only causal when there is a pre-existing duty to act

Q21: TRUE or FALSE -- It is important for the team to identify who was responsible for the error and address the situation with the individual/s involved.

Q22: Which actions below are considered stronger actions?

- A. Architectural/physical plant changes
- B. Training and education
- C. New devices with usability testing prior to purchase.
- D. Creating a very specific policy
- E. A and C

Q23: RCA Teams should consider the following actions when appropriate to the root cause except:



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- A. Avoiding architectural/physical plant changes
- B. Human factors engineering consultation (e.g., to analyze, troubleshoot and streamline work areas and processes, to evaluate equipment use and conduct usability testing)
- C. Forcing functions that design processes or equipment so that it is only possible to do the correct thing the first
- D. Tangible involvement and action by leaders in support of patient safety (e.g., greeting and closing out with RCA teams; patient safety related individual or team rewards; constructive feedback; town meetings; newsletters)
- E. All of the above

Q24: RCA Actions should be all of the following except:

- A. Have reasonable completion dates, the majority being completed within one years' time
- B. Contain concrete and clear directions
- C. Vetted with the process owners
- D. Should be written in vague terms so that the responsible person can shape the RCA Action plan and outcome measures however they want

Q25: TRUE or FALSE -- When an action and outcome has been determined with a process owner as reasonable, the choice is the process owner's on whether to complete the action.

Q26: TRUE or FALSE -- Prompt feedback to those reporting adverse events helps establish trust in the system and demonstrates the commitment on the part of the organization to the importance of reporting.

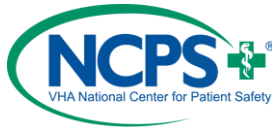
Q27: TRUE or FALSE – The most common perceived barrier to reporting is not getting feedback on what action is taken.

Q28: TRUE or FALSE -- Lessons learned from an RCA should only be shared with facility leadership and anyone involved in implementing identified actions.

Q29: TRUE or FALSE -- All team members do not need to agree on the action plan.

Q30: TRUE or FALSE -- The Director's signature is the only signature required on the concurrence sheet.

Q31: TRUE or FALSE -- If the Chief of Staff does not concur with one of the final actions, the team must accept the suggested action made by the COS.

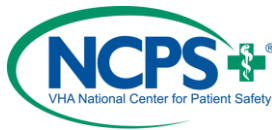


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- Q32:** TRUE or FALSE -- Tracking actions and outcomes is very important to mitigate future events.
- Q33:** TRUE or FALSE -- The RCA is a confidential document and process. There should never be transparency of actions, outcomes and lessons learned from the RCA.
- Q34:** TRUE or FALSE -- The PSM is totally responsible for completing, tracking and monitoring the actions and outcomes from an RCA.
- Q35:** TRUE or FALSE -- Communication of process improvements from the RCA should be communicated to all facility staff.

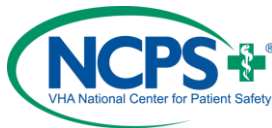
Appendix E: Quiz Answers

	Answer	Explanation
Q1	FALSE	An RCA is a focused review that is used to learn from and respond to safety-related issues primarily focusing on systems and processes rather than individual performance.
Q2	C	The Director's signature is the invoking power of U.S. Code Title 38 5705 protection. Without the signature, the work of the RCA could be discoverable.
Q3	TRUE	The 45 days is calendar days, which begins when the facility becomes aware that an RCA is required.
Q4	TRUE	Catastrophic events will always require an RCA, and on occasion, a Major may as well. For this reason, is it important for the PSM to understand the process of SACing each and every event.
Q5	FALSE	Individuals involved in an adverse event are Not to be a member of the RCA team, however, those individuals may provide an insight to understand "why" something occurred. They can and should be interviewed in a non-judgmental way.
Q6	C	There is no need to know the reporting individual on the Charter of the RCA. The PSM may know and use that information for initial investigation of the event, but many times the reporter is anonymous.
Q7	D	The Director cannot grant a waiver to a congressional statute such as U.S. Code Title 38 5705. It would take an act of Congress to change the statute.
Q8	FALSE	Just in Time training is required for all RCA members, even if they have been on an RCA team previously. This ensures all members start out on the same page.
Q9	TRUE	Team members come with their own biases and may attempt to immediately oversimplify the process and jump to conclusion prior to the full understanding of the process.
Q10	B	It is through the mapping of the steps that provide the critical understanding of the event and what happened.
Q11	FALSE	The Triage Questions can be used to help frame questions that need to be answered to assist in closing the information gaps.
Q12	TRUE	Visiting the location of the event and attempting to recreate what happened provides the team with an additional layer of understanding the event and what happened.



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	Answer	Explanation
Q13	B, C, D, F	Several resources should be used to help fill in the gaps of the what happened of the event. These include literature reviews, interviews, review of the medical record(s) and review of current policy, regulations and SOPs. Since RCAs are non-punitive information from peer reviews, police reports, etc. are not to be used.
Q14	TRUE	All individuals interviewed for RCAs should be informed of the RCA process, the goal of their interview and told that their interview and the RCA process are protected, that RCAs are protected and privileged under U.S. Code Title 38 5705 protection and no punitive action can result.
Q15	FALSE	It is recommended that the RCA team prepare interview questions ahead of time to ensure that the RCA team gets the information that they need, and to make the interview more comfortable for the interviewee.
Q16	C	Fact Finding entails asking the question of where, when, how, why and what to fill in all the holes in the event picture in order to understand the root causes of the event. Fact finding should focus on systems issues and not on individual blame or performance.
Q17	FALSE	After fact finding is completed, it is recommended that RCA teams complete a final understanding flow diagram, filling in the gaps from the initial flow diagram to complete the picture of the event.
Q18	F	What you know and what you don't know. The team does not know exactly what happened or how it happened until after further investigation has been completed and this is not included in the initial understanding. Therefore answers C. and D. would not apply.
Q19	E	None of the above. RCAs require that names of individuals not be included in the narrative to protect identities. Remember we are focusing on systems not people.
Q20	D	Procedure and Policy violations are not root causes understanding the premise that people do not come to work to intentionally or blatantly disregard them.
Q21	FALSE	When the RCA team uses the 5 rules of causation, it helps avoid the "blame and train" reaction.
Q22	E	Training/education and policies are considered weaker actions but may also be vitally necessary to any action plan.
Q23	E	All the answers provided are considered strong actions to any RCA action plan.
Q24	D	It is important to clearly define the action, to ensure proper completion and avoid misinterpretation of what is understood.



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	Answer	Explanation
Q25	FALSE	Actions and Outcomes are not choices for the process owner. They are required to be completed.
Q26	TRUE	Reporting patient safety events is never held against the reporter, and all staff are responsible for reporting.
Q27	TRUE	Providing feedback to both the reporter and facility staff is an effective action that can be taken by the PSM to improve patient safety culture.
Q28	FALSE	As part of a Learning Organization, sharing lessons learned includes the facility but also the VISN and entire VA.
Q29	FALSE	It is important for the team to come to a consensus on the action plan.
Q30	FALSE	All team members are required to sign the concurrence sheet prior to be presented to the Director for signature.
Q31	FALSE	The Director is the only executive team member that must concur. However, if the Director's thinks the Chief of Staff has a valid point, the team may reconvene to discuss the option presented. The team is not expected to change its course in the action plan. Either the Director agrees or does not agree.
Q32	TRUE	Actions and outcomes are very important to identify and correct but tracking and monitoring for sustainment will increase the changes of mitigating future events of the same nature.
Q33	FALSE	The RCA is confidential and protected by U.S. Code Title 38 5705, and the discussions from the team should never be discussed outside the RCA team. But the Lessons Learned, Actions and Outcomes should always be shared to promote transparency and a learning environment.
Q34	FALSE	While it is true the PSM typically does make sure the tracking of actions / outcomes is accomplished, it is recommended multiple systems are used to track and monitor actions to avoid single point vulnerabilities by engaging others such as the patient safety committee, shared tools, drives and dashboards for information dissemination.
Q35	TRUE	Communicating process improvements is essential to a patient safety culture. There are several ways to communicate this such as safety forums, patient safety committees, patient safety newsletters, etc.

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