Implementing Root Cause Analysis and Action: Integrating Human Factors to Create Strong Interventions and Reduce Risk of Patient Harm

Laurie Wolf, PhD,* Kristen Gorman, MHA, PMP,* Joshua Clark, RN, MHA, CPPS, CPHQ,† Jonathan Gleason, MD,‡ and Sarah Henrickson Parker, PhD*§

Objectives: The goal of this study was to develop a systems approach for root cause analysis and action to achieve strong, sustainable interventions. The team integrated human factors principles into the design of interventions to ensure solutions maintain compatibility with human capabilities and limitations resulting in stronger solutions to prevent reoccurrence.

Methods: This study was conducted at a 7-hospital health system located in southwestern Virginia. Including human factors in a new root cause analysis and action process allowed the team to design strong interventions. To assess the results of this process, a team evaluated all interventions over a 4-year period (2.75-y preimplementation and 1.4-y postimplementation). Interventions were initially blind coded and then consensus coding was executed to finalize the strength of each intervention according to the VA National Center for Patient Safety evaluation tool.

Results: The new process resulted in an efficient method to address adverse events with increased staff satisfaction and interventions more resilient to human error. The number of events with strong interventions increased from 43% to 69% after implementation of the new process.

Conclusions: Tailoring an event investigation process to an organizational culture is critical to implementation success. Adding human factors into the design of interventions helped facilitate intervention implementation and sustainability. Blinded ratings showed that with the integration of human factors, there was improved strength of interventions. This indicates that a focus on strong system improvement (rather than weaker individual human-based solutions) will lead to improved staff satisfaction and patient safety.

Key Words: RCA², root cause analysis, patient safety, proactive, implementation, human factors engineering, human factors

(J Patient Saf 2022;00: 00–00)

Up to 400,000 patients die each year because of medical error, making medical error the third leading cause of death in the United States⁴ and costing the nation roughly $1 trillion annually.⁵ To better understand serious safety issues, the Joint Commission requires that all serious patient harm events undergo a thorough investigation and review process.¹ One of the most common methods used to perform these reviews is root cause analysis (RCA).

Despite significant resource investment and training, applications of RCA have been ineffective at reducing the recurrence of harm.⁶⁷ Root cause analysis is an engineering method, grounded in the physical sciences, designed to uncover the causes of equipment failures and manufacturing defects.⁸ As such, traditional RCA methods assume that failures are linearly linked and traceable to a single root cause through a process of asking a series of 5 “why” questions, with the answer to each question being the basis for the next. Unfortunately, these assumptions are not valid when applied to human error.⁹ Experts in human error have repeatedly suggested that errors are caused by a breakdown in nonlinear interactions among multiple, tightly coupled system variables (e.g., human, environment, task, technology, and organizational factors).⁹¹⁰ Thus, traditional RCA methods are inherently unable to reliably identify causes of errors or generate effective corrective actions.

This article contributes to current literature by illustrating that RCA² methods can be successfully implemented in healthcare. Modifications can be made to traditional RCA process to contribute to success in healthcare. For example, clarification of roles and contribution to each step in the RCA process, acknowledging the complexities in health care of multifactorial contribution to understanding human error, and attention to working toward the strongest intervention possible (do not stop with interventions of education that are susceptible to human fallibility).

To address these issues, the National Patient Safety Foundation (NPSF) disseminated a set of guidelines called Root Cause Analysis and Action or RCA² (pronounced “RCA squared”), to help healthcare organizations translate traditional RCA into a process for investigating and preventing errors that cause harm.¹⁰ Numerous recommendations to the traditional RCA were contained in these guidelines. Of interest for this work are the recommendations that RCA teams include a member with a working knowledge of human factors, and facilitation by a leader specially trained to conduct an RCA². Traditional RCA guidelines stop short of providing a foundational systems perspective with implementation recommendations that would enable adopters to fully leverage sustainable improvements. Consequently, there is a significant gap in the RCA² process that currently limits its utility in supporting a thorough human factors analysis of patient harm event.

In this case study, we will articulate our team’s effort to implement a human factors informed RCA² process and specifically the application to the design of strong solutions. While some error researchers have focused on improving the data collected in the RCA² process,¹¹¹² this article is focused on integrating human factors into implementation of an RCA² process to achieve stronger (systems/engineering based) solutions.

METHOD

This report has been written to be in adherence to the SQUIRE guidelines.¹³

This quality improvement project took place in a not-for-profit healthcare organization based in Roanoke, Virginia, with 7 hospitals and 273 practice sites serving a 20-county region in central southwestern Virginia and southern West Virginia. A multidisciplinary team worked to apply the NPSF version of the RCA² process recommendations. A customized guidebook was written to implement the new process into the hospital system. This guidebook

From the *Carilion Clinic, Roanoke, Virginia; †Jefferson Health, Philadelphia, Pennsylvania; ‡Prisma Health, Greenville, South Carolina; and §Virginia Tech Carilion School of Medicine, Roanoke, Virginia.

Correspondence: Laurie Wolf, PhD, 15 Old Woods Ave, Roanoke, VA 24016 (e-mail: ldwolf@carilionclinic.org).

The authors disclose no conflict of interest.

Copyright © 2022 Wolters Kluwer Health, Inc. All rights reserved.
was augmented with an easy-to-use template to serve as a reminder of the process and critical elements for documentation. The NPSF’s recommendations were customized by combining key elements from staff input with other evidence-based approaches to serious safety event (SSE) response such as CANDOR.\textsuperscript{14} causal factor identification tools (such as fishbone diagram and 5 why technique), and intervention strength spectrum. To ensure appropriate implementation, the team identified the following process goals:

- Faster event response time with clear team roles and responsibilities.
- Immediate senior leadership debrief communication.
- Leadership engagement throughout the review process.
- Integration of human factors engineers in partnership with the multidisciplinary team to review and improve how humans interact with processes and systems.

The iterative timeline of activities and milestones are shown in Figure 1. This process was not linear in execution, but for the sake of clarity, we have articulated it in phases and steps. The work was accomplished in three phases:

Phase 1: Customized RCA\textsuperscript{2} process (discusses customization of the RCA\textsuperscript{2} guidebook and internal procedures)

Phase 2: Training and implementation (training for individuals responsible for RCA\textsuperscript{2} reviews and the entire quality improvement team)

Phase 3: Assess strength of interventions (discusses the development of action items and interventions and how they were evaluated from a human factors standpoint.)

In line with the NPSF RCA\textsuperscript{2} recommendations, human factors principles were integrated throughout the process, rather than added as a separate session or additional focus.

**Phase 1: Customized RCA\textsuperscript{2} Process**

**Step 1: Kaizen Event**

A 3-day, multidisciplinary Kaizen event was held to clarify roles and responsibilities of those involved in the RCA\textsuperscript{2} process. The goal was to develop a consistent process to trigger and execute RCA\textsuperscript{2} resulting in strong interventions. A current state process map was developed, and barriers were identified. Fifteen team members included: IT experts (2), patient advocacy (1), patient safety (1), quality improvement (4), performance improvement (3), human factors (2), and risk management (2). The team brainstormed improvements that could be made for each of the following categories: patient safety (1), quality improvement (4), performance improvement (3), human factors (2), and risk management (2).

Roles and responsibilities were clarified for each team member that responds to an RCA\textsuperscript{2}. To augment the existing event review process, the SSE reporting software, accessible to all team members, was customized for each role. This platform became the repository where all roles could communicate information about the event in one place. This reduced duplicate documentation and created a system of information transparency between the multidisciplinary RCA\textsuperscript{2} team roles. To ensure sustainability, standard work was established and agreed upon for all roles.

**Presurveys/Postsurveys**

Staff satisfaction with the RCA\textsuperscript{2} process was measured with a qualitative survey. A Likert scale survey was collected from each participant before (before Kaizen), after (2 weeks after Kaizen), and again 10 months after the Kaizen to evaluate sustainment of success.

**Step 2: Identify RCA\textsuperscript{2} Events**

It is important to objectively identify events that meet criteria for an RCA\textsuperscript{2} review. The RCA\textsuperscript{2} process is time and resource intensive, so it is important to identify the most appropriate events to review. In addition to severity and probability of an adverse event, a method was developed to include proactive considerations (e.g., trends in events without harm) to be included in the decision to perform an RCA\textsuperscript{2}. This method involves discussion among patient safety and quality leaders to consider safety initiatives and hospital system trends. Based on these discussions, a final disposition is determined by leadership and the RCA\textsuperscript{2} is triggered. This method is an attempt to be more proactive by being inclusive for trending future events as well as reacting to current adverse events regardless of severity of outcome.

**Step 3: Leadership Communication**

Executive communication was built into the protocol for awareness early in the RCA\textsuperscript{2} process. These leaders are critical to address barriers during intervention development as well as final approval and support of interventions at RCA\textsuperscript{2} closure. Leaders can help overcome barriers of time and resources to ensure interventions are robust enough to prevent reoccurrence of the event.

**Phase 2: Training and Implementation**

**Step 1: Customize Guidebook and Documentation Template**

While the above work was progressing, the team also customized the NPSF RCA\textsuperscript{2} guidebook. This was a collaborative effort from all system hospitals and ambulatory practices. The content (and resources required for each step) had to be applicable to small rural hospitals, outpatient clinics, as well as a large academic medical center. A customized RCA\textsuperscript{2} guidebook was developed using a cross-functional team of nurses, physicians, human

---

**FIGURE 1.** Timeline of activities to customize RCA\textsuperscript{2} process, develop and implement guidebook, and assess strength of interventions.
factors engineers, experts in process improvement, and project managers. A template was adapted from the guidebook for ease of documentation and included investigation tools that were germane to local practices and culture.

**Step 2: RCA² Process Training**

All patient safety staff from the hospital enterprise were trained and mentored using hands-on scenarios allowing participants to practice the RCA² process in a safe environment. They attended interactive training sessions led by a human factors expert to review the tools and templates for all stages of the review. Support was provided as needed for mentorship during initial events and the development of implementation plans.

**Phase 3: Assess Strength of Interventions**

A comparison of the strength of interventions from before RCA² implementation and postimplementation was needed to evaluate success of the new process. Although the VA guide was primarily used as a scoring guide, consideration was given in the final consensus score if the action item would prevent recurrence. Prevention of recurrence is not part of the VA scoring guide.

To provide examples of various strengths of interventions, Table 1 represents interventions that were developed because of a single incident. Interventions that are rated as strong are system based where risk is reduced by less reliance on human behaviors. Teaching staff about hazards is not as sustainable as the solution to permanently mount the ventilator onto the wall. For an intervention to be strong, it had to be implemented and resilient to human behavior and/or error.

**Assessment**

We conducted a blinded comparison of 44 RCA events (with a combined total of 230 interventions) before RCA² implementation and 13 RCA² events (79 interventions) after implementation. Four raters (3 human factors experts, one quality and safety expert) rated each intervention for strength and assigned a rating of strong, intermediate, or weak, using the hierarchy levels and categories based on VA National Center for Patient Safety scoring methodology. These initial ratings were done independently, blinded to whether the intervention was before or after implementation. Initial ratings were collated by a third party. No interrater reliability was calculated for the initial ratings. A consensus meeting was held to discuss the strength of each intervention and achieve consensus where scores were not in agreement. The consensus score was documented for all interventions on the RCA² event action plan.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Description of Intervention</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Education for ancillary staff</td>
<td>Weak</td>
</tr>
<tr>
<td>2</td>
<td>Report event to FDA</td>
<td>Weak</td>
</tr>
<tr>
<td>3</td>
<td>Workflow evaluation and changes</td>
<td>Intermediate</td>
</tr>
<tr>
<td>4</td>
<td>Remove 2/3 of ventilator batteries</td>
<td>Intermediate</td>
</tr>
<tr>
<td>5</td>
<td>Staffing competency evaluation</td>
<td>Intermediate</td>
</tr>
<tr>
<td>6</td>
<td>Place gauss alarms on all portable equipment</td>
<td>Strong</td>
</tr>
<tr>
<td>7</td>
<td>Permanently mount ventilator onto the wall (no more wheels)</td>
<td>Strong</td>
</tr>
</tbody>
</table>

| FDA, Food and Drug Administration. |

**RESULTS**

This quality improvement project resulted in the implementation of a customized RCA² process. The individuals currently investigating adverse events were more satisfied with the new RCA² process. Survey results showed that satisfaction was improved over baseline measures and was sustained over a 10-month period. After implementation, we found that action items of RCA² events included more interventions rated as strong than before the improvement process.

**Results Phase 1: Customized RCA² Process**

Operational improvements were integrated to ensure that the updated process was “hardwired” into daily work. For example, a daily conference call was established as an opportunity to improve communication and escalate awareness of adverse events. This call includes patient safety and risk departments discussing events occurring in the last 24 hours and trends that may identify serious safety concerns to be escalated to the system-wide level huddle that occurs later in the morning. The system-wide huddle includes senior leadership that can immediately help eliminate barriers for quick resolution.

As a result of the IT participation in the Kaizen event, a work catalog was developed that identified all software changes required and reasons to justify these changes. There were approximately 200 action items for IT completion before the implementation of the new RCA² process could begin. For example, the team built and integrated shared awareness software, called “Collaboration Station” to enhance communication during an event review (Fig. 2). This redesigned software supports shared and trackable communication between quality, risk, and other teams pertinent to the patient safety process.

**Results Phase 2: Training and Implementation**

Improvements were seen on all staff satisfaction survey questions, from post Kaizen through the 10-month follow-up (Fig. 3). The biggest improvement from baseline to 10-month post Kaizen was related to the efficiency of the process from the time an event is entered in the SSE software until a disposition decision is made. This rating improved from 3 (before) to 7.3 (after) to 8.6 (follow-up) as shown in Figure 3. Because of the small sample size, no inferential statistics were performed on these responses.

**Phase 3: Rating Strength of Action Items**

Before implementation of RCA², we found that RCAs included at least one strong intervention 43% of the time (19/44) as shown in Figure 4. After implementation, this improved to 69% (9/13). Root cause analyses that included 2 or more strong interventions improved from 7% (3/44) before to 54% (7/13) after the new RCA² process was implemented. During this timeframe, there were no additional reported or observed errors resulting from similar event conditions once strong action items have been in place.

A Pearson $\chi^2$ test was calculated, with significant results ($P = 0.000$). Given the small sample size, we also calculated a Fisher’s exact test and it was not significant ($P = 0.123$). Although the results show that the number of strong interventions recommended after the improvement in the RCA² process was greater than expected, it cannot be declared statically significant because adverse events did not occur frequently enough to reach an absolute conclusion.

**DISCUSSION**

Serious safety events remain an ongoing risk to patients and providers. Action plans that prevent recurrence of events are
challenging to develop and even more challenging to implement. To that end, the Institute of Healthcare Improvement and NPSF developed RCA\textsuperscript{2}, with emphasis on “action.” Like many other institutions, our team implemented the RCA\textsuperscript{2} process across 7 unique hospitals. In this quality improvement project, we customized a multidisciplinary RCA\textsuperscript{2} process for our health system. Finally, we conducted a blinded evaluation process to determine whether interventions were weak, intermediate, or strong and compared frequency of strong interventions before and after implementation of the new RCA\textsuperscript{2} process. (The NPSF scoring framework was used to rate the strength of interventions.)

To ensure interventions were as strong as possible, human factors perspectives were integrated into brainstorming solutions, encouraging strong, independent, system-oriented interventions. The goal was to avoid or at least supplement weaker solutions such as staff training or policy change that are vulnerable to human fallibility.

Achieving the strongest level of intervention for every RCA\textsuperscript{2} event may not be possible. For example, an event occurred where a new employee failed to recognize a patient with a deteriorating condition. The team struggled to achieve a strong intervention to ensure the event would never occur again. Action items included education and improvements in orientation and the preceptor/mentoring program; however, these interventions are scored, at best, as intermediate strength when incorporating training with simulation activities.

It is critical to include systems thinking into the RCA\textsuperscript{2} process to achieve strong action items that do not rely on an individual to prevent recurrence. A systems approach will consider environmental and organizational issues, equipment, physical layout, tasks, and human capabilities and limitations. One way to do this is to integrate human factors into the process at all stages. The scientific discipline of human factors is concerned with understanding human capabilities and limitations, whether they be

FIGURE 2. Screen shot of “collaboration station” (shared repository for information about an adverse event) where example data is in bold font. (This is a fake case and any alignment with an actual event is purely coincidental.)
cognitive, interpersonal, or physical, and using that knowledge to inform the design of work, environment, or technology, so that the work is designed to fit the human. In short, it is a systems approach to comprehensively understand a problem and develop a solution.

Customization of the RCA² process is recommended for each healthcare system to achieve sustainment and fit to individual hospital culture. For example, scenarios for the hands-on training have the most impact if they come from actual situations experienced by each hospital.

Lessons Learned

The lessons learned were generated by the authorship team in an iterative fashion using debriefs after each training, and updates to the guidebook, which served as a “living document” for our process changes. An important lesson as that implementing the RCA² process must address the entire event reporting process. Initially, the intention was to implement the RCA² guidebook without addressing the event processing roles and responsibilities. There was a process in place but there was confusion and inconsistency that needed to be improved before the RCA² process could be implemented successfully. Roles and responsibilities need to be clarified to ensure that every event is triaged appropriately. This is especially important in recognizing trends of events that may not result in a negative outcome, to reach toward proactive prevention.

Making an RCA² process scalable to an entire healthcare system requires collaboration from many disciplines. The initial process owners were the centralized patient safety, quality, and risk team at the level one trauma center and academic medical center.
This team built a proposed framework for the new RCA\(^2\) process. This was then taken to individual department’s patient safety leadership so that all personnel involved were given a forum for feedback and changes to align processes. Acceptance of the new process was most successful when training scenarios were customized. For example, case studies for ambulatory clinics would include events like vaccine dosage while intensive care unit training involved examples with medication administered with intravenous pumps or through G tubes. In addition, the RCA\(^2\) framework was reviewed by community hospitals and ambulatory patient safety leadership. This collaborative approach created a standardized and streamlined process for all patient safety experts.

This project resulted in some scalable processes with hospitals across our system as well as applicability to hospitals nationwide. Communication strategies such as leadership debrief calls after an adverse event and brief, daily conference calls to communicate events can be replicated at other health care facilities.

Study Limitations
This quality improvement study was limited in that we did not systematically vary the implementation of the new RCA\(^2\) process, nor control for the implementation. As commonly accepted with quality improvement projects, the new process was needed as quickly as possible and was not perceived to be equitable to adopt in one hospital and not another, as all were members of the same healthcare system. In addition, the sample sizes were small, so we were not able to conduct inferential statistics. For staff satisfaction surveys, there were between 8 and 10 surveys for each phase because of the limited number of people in the department.

For the strength of intervention assessment, there is an uneven number of RCA events for comparison. During the pre–RCA\(^2\) period from January 1, 2016, to September 15, 2018, there were 44 RCA events. The strength of intervention post–RCA\(^2\) evaluation period began the day the new process was implemented on September 16, 2018, and ended on February 24, 2020, with 13 RCA\(^2\) events. Consequently, this project represents an applied project, in which the sample sizes were uneven. Our team attempted to explore the proportion of strong, intermediate, and weak interventions for SSEs before and after implementation of a robust RCA\(^2\) process and integration of human factors into the solutions. We do not believe that the change in the number of SSEs was related to the implementation of RCA\(^2\). However, the perspective of human factors is on better system design; therefore, the integration of human factors at multiple organizational levels could possibly influence the number of events. We did not explore this relationship in this study. Although we did conduct a statistical comparison, our sample size is (thankfully) small. Therefore, any interpretation of the results of the test is spurious at best. Future studies should consider using a multisite sample, in which appropriate statistical tests can be run on larger sample sizes.

For each of our strong interventions, our team was able to document their implementation, even if it was not immediately after event. However, we did not go back to the source and determine the specific impact for every intervention (e.g., have any further events occurred, is the intervention still in place). Others have shown that weak interventions quickly diminish in both sustainability and effectiveness.\(^7\)

Attempts were made to enhance cross culture validity by implementing a common methodology in a hospital system with small rural hospitals, outpatient clinics, as well as a large academic medical center. This demonstrates some generalizability in modifying a common process, such as RCA\(^2\), to be germane to local practice and may produce similar results in various types of healthcare settings. Again, because of the small number of RCA\(^2\) events, separating results by hospital type was not possible.

Another opportunity for improvement is to develop a more robust process to rate the strength of interventions. The action hierarchy based on the root cause analysis tools developed by the VA National Center for Patient Safety can be limiting, generic, and difficult to interpret.

CONCLUSIONS
Customizing the RCA\(^2\) process to align with hospital culture and structure achieved a clear understanding of roles and responsibilities, resulting in staff satisfaction. This satisfaction and alignment to culture lead to sustained usability and success of the new RCA\(^2\) process. While this was scaled across a 7-hospital system, further study is needed to understand if this customization process can be scalable to other healthcare organizations.

The healthcare industry should focus on the strength of interventions in RCA\(^2\) to improve patient safety and attempt to reduce future hazards and reoccurrence. This case study is useful because precomparison to postcomparison showed the number of RCA\(^2\) events with strong interventions was greater than RCA events before the process change. The number of strong interventions was increased by implementing best practice, system thinking, and incorporating human factors experts into the entire review process. Any event that had human error as a contributing factor required deeper investigation and development of interventions stronger than education or policy change. The implication for healthcare practice is that strong interventions may take more resources and time, but the reward will be long-term sustainment and reduced risk of reoccurrence.

Implementing a robust RCA\(^2\) process is possible if the process is customized for the healthcare system. Involving front-line staff in customization of the process ensures the guidelines not only will apply to the actual work process but also will simultaneously build awareness of the need for change and support for sustaining the process. A system approach to developing a comprehensive RCA\(^2\) process results in strong interventions that will sustain and improve safety for staff and patients.

ACKNOWLEDGMENTS
The authors thank Clinical Advancement and Patient Safety Department at Carilion Clinic for the operational contributions and execution of this work.

REFERENCES
1. Makary MA, Daniel M. Medical error—the third leading cause of death in the US. BMJ. 2016;353:i.2139.


