

# Patient Safety Tip of the Week

## July 14, 2015 NPSF's RCA<sup>2</sup> Guidelines

We've always had a strong conviction that the RCA (root cause analysis) is probably the most important learning tool that an organization with a good culture of safety has at its disposal. We encourage organizations to do RCA's not just on events with bad patient outcomes but on any event that had the potential to induce harm (near-misses).

In our March 27, 2012 Patient Safety Tip of the Week "[Action Plan Strength in RCA's](#)" we emphasized the importance of tracking whether recommended action steps were implemented following an RCA, whether they were effective, and whether there were any unintended consequences. All too often action steps never get implemented at all or consist solely of "weak" action steps and organizations are then surprised when a similar adverse event occurs in the future. Moreover, even the most well intentioned and well planned action steps sometimes lead to consequences that were never anticipated.

The National Patient Safety Foundation (NPSF) has recently released a very valuable resource to help guide organizations (or even smaller units) in doing root cause analyses ([NPSF 2015](#)). NPSF has recognized the above problem with ineffective action steps and has actually coined a new term – the **Root Cause Analysis and Actions** or **RCA<sup>2</sup>** to emphasize the importance of the action steps.

The RCA<sup>2</sup> appropriately acknowledges that the goal of the RCA<sup>2</sup> is to prevent the same or similar type of adverse event from occurring in the future. Its goal is to recognize system-related issues and vulnerabilities that place an organization at risk for such occurrences and then to take appropriate action steps to eliminate or mitigate those system-related issues and vulnerabilities.

One key tenet of the RCA<sup>2</sup> is that it only addresses system issues. It should not address or focus on individual performance. In fact, NPSF recommends that all organizations should define "blameworthy" events and actions that fall outside the purview of the safety system and define how and under what circumstances they will be handled separately. Of course, we would emphasize that system issues that lead to or facilitate improper individual performance must be addressed under the RCA<sup>2</sup> process. For example, workarounds are (often) improper individual actions that almost always have a system issue that led to their use. Another example is "normalization of deviance" where the culture of the system led to acceptance of a certain deviation from proper practice as being "normal" and allowed that deviation to be performed by many individuals.

NPSF cites important revelations from NASA when it looked at its mishap reports. NASA noted that reports on mishaps that are subject to public view typically have two

significant shortcomings that compromise the more important intent of mishap investigations. First is that all important information often does not get reported or gets “spun”. Second is that investigations focusing on individual blame tend to be shortened and fail to focus on all the relevant contributing system problems that need to be fixed. Moreover, those focusing on blame tend to generate a false sense of security that the underlying “cause” of an incident has been dealt with. These same caveats often apply to the investigations done in healthcare.

Keeping individual performance out of RCA’s or RCA<sup>2</sup>’s is important in developing trust in the organization and development of a non-punitive safety culture. Equally important in fostering a good safety culture is providing feedback from the RCA<sup>2</sup>’s in a timely fashion to those who brought the event to attention, those who may have been involved in the event (directly or indirectly), and all relevant stakeholders in the organization. Identification of system vulnerabilities requires reporting by all (staff, administration, patients, public). To develop trust in the process requires that such reporting be easy and that reporters know that action will be taken and used to improve the safety of the system. **Feedback** is therefore **crucial**.

NPSF recognizes that resources are not limitless and that an organization cannot possibly investigate in detail all potential vulnerabilities. Therefore, they recommend every organization develop a **risk-based prioritization system** for determining which hazards should be addressed first. This emphasizes the need to address issues that are likely to lead to harm before they actually cause harm. The risk-based prioritization system should address both the potential outcome severity and the probability of occurrence. The RCA<sup>2</sup> document includes a very useful tool, the Safety Assessment Code (SAC) Matrix, to help in such prioritization. Near-misses (aka “close calls”) also need to be prioritized. The NPSF document notes that close calls occur 10 to 300 times more frequently than actual harm events.

One of the questions we are most often asked about RCA’s is “**who should be on the RCA team?**”. NPSF does a good job in the RCA<sup>2</sup> document of advising regarding this question. They recommend the core team have 4-6 members. This facilitates scheduling meetings and optimizing resource utilization. Of course, many other people will be involved from time to time as interviewees or providers of expertise. NPSF notes that many organizations set aside a specific time slot every week for RCA<sup>2</sup> teams that can be cancelled if there are no events or issues that need to be reviewed that week. Our own experience is that even hospitals with as few as 50-100 beds can average 2-4 RCA’s per month so we agree with establishing a regular weekly time slot for RCA<sup>2</sup>’s. The NPSF document nicely describes who should be on the teams and what qualities they should bring to the team. They emphasize that staff directly involved in an event or supervisors of staff involved in an event should not participate in the RCA<sup>2</sup>. Using patients (who have not been involved in the event under review) as team members may be helpful and has pros and cons discussed in the NPSF document. Likewise, teaching institutions should consider having a housestaff member participate.

**Timing of the initial RCA<sup>2</sup> meeting** is important. NPSF recommends it be held within 72 hours of the event. That helps ensure that events are accurately recalled by witnesses and should allow enough time for scheduling interviews and other activities. In our July 24, 2007 Patient Safety Tip of the Week “[Serious Incident Response Checklist](#)” we discussed the many other things that need to be done immediately after serious events. That column included a link to our [Serious Event Response Checklist](#), which includes things like sequestering involved equipment, identification of witnesses, disclosure to patient or family, notification of regulatory bodies and Board if necessary, and others.

The NPSF document goes on to provide a graphical representation of the RCA<sup>2</sup> process. It includes fact finding, flow diagramming, development of causal statements, identification of potential solutions and corrective actions, implementation of action steps, monitoring/measurement and feedback.

In addition to development of the timeline or chronological flow diagram of the event the RCA<sup>2</sup> team identifies gaps in knowledge about the event and develops team-generated questions that need to be answered in further interviews, review of documents or policies, consulting experts or best practices, and site visits.

The NPSF document strongly recommends the team visit the location of the event to get a better knowledge of the workspace and environment. In one of our earliest columns (see our April 2, 2007 Patient Safety Tip of the Week “[More Alarm Issues](#)”) we noted how multiple visits to the site of an event demonstrated that, rather than a single individual being blameworthy, a fundamental design flaw in the environment consistently led to staff reducing the volumes of critical alarms.

The RCA<sup>2</sup> document discusses **triggering questions** in a very useful appendix. This groups questions into logical categories such as communication, training, fatigue/scheduling, equipment/environment, rules/policies/procedures, and barriers.

The RCA<sup>2</sup> document also has an excellent appendix providing **interviewing tips**. These include recommendations such as having only 1 or 2 team members interview witnesses so as not to intimidate them with a large group. They also stress the importance of steps to ensure the recall of witnesses does not get contaminated (eg. interview as soon as possible, interview only one witness at a time, tell them not to discuss with others, etc.). Perhaps the most important consideration is letting the interviewee understand that the RCA<sup>2</sup> is looking for system issues that need to be fixed and the team is not looking for someone to blame. Interviews should be held in a comfortable environment and avoid making it look like a legal deposition or trial. That is especially true when interviewing patients or their families. We used to see meetings with families held in Board rooms. That was probably the worst possible environment. It was intimidating for families and also gave the impression they were “up against a faceless corporate enemy”.

The NPSF RCA<sup>2</sup> document provides several other useful **tools** in appendices, including **Cause and Effect Diagramming** and the **Five Rules of Causation**.

Perhaps the most important section of the entire document is that regarding **actions**. One tool provided in the RCA<sup>2</sup> document is the **Action Hierarchy**. We previously discussed strength of actions in our March 27, 2012 Patient Safety Tip of the Week “[Action Plan Strength in RCA’s](#)”. In that column we included an analogy to the effectiveness of signs and tools used to try to get drivers to slow down in construction zones on highways. We put them together in pictures with RCA action items and now incorporate them in our webinar presentations on doing good RCA’s. [Click here](#) to see them. Remember: images are more likely to be remembered than words!

Our March 27, 2012 Patient Safety Tip of the Week “[Action Plan Strength in RCA’s](#)” discussed the importance of **making sure recommended actions are carried out**. The NPSF document recommends that responsibility for implementing an action be assigned to one individual, not a committee, and that a date be set for implementation. It notes that at least one measure (process or outcome measure) be set for each action and monitored over time. It provides a table with example measures in an appendix.

It is amazing at how often an RCA on a new event uncovers that the action items recommended to prevent recurrence after a previous similar event were never carried out. Our March 30, 2010 Patient Safety Tip of the Week “[Publicly Released RCA’s: Everyone Learns from Them](#)” discussed an RCA done on a case where enteral feedings were inadvertently given intravenously. At that hospital there had been a similar incident several years earlier. After the first incident an extensive root cause analysis was done and multiple recommendations were made, including key recommendations that should have prevented the current incident. But all those recommendations had not yet been fully implemented. More importantly, the recommendations were communicated back to those individuals deemed to be in the “need to know” but not widely disseminated to middle or front line management nor to front line staff.

We recommend you keep a list or table of such identified action items from all your RCA’s to discuss at your monthly patient safety committee or performance improvement committee meetings. Action items should remain on that list until they have been implemented or completed. Only that sort of rigorous discipline will ensure that you did what you said you were going to do, i.e. that you “**closed the loop**”.

One important consideration not specifically noted in the NPSF RCA<sup>2</sup> document is monitoring for **unintended consequences**. As we noted in the introduction of today’s column, even the most well intentioned and well planned action steps sometimes lead to consequences that were never anticipated. The NPSF document does note that staff and/or patients and families should be allowed to make comments during the feedback process and those could possibly identify some potential glitches. But sometimes the unintended consequence does not appear for some time after the action is implemented. For example, one ‘strong’ action resulting from an RCA<sup>2</sup> might be removal of a certain medication or piece of equipment from a certain clinical setting. Several months later you might find that there was actually an unanticipated need for that medication or equipment.

The RCA<sup>2</sup> document emphasizes the importance of **leadership**. That includes both the CEO and senior administration but also the Board. Those parties must understand and support the RCA<sup>2</sup> process and make sure that adequate resources are provided. When a recommended action is not approved by the CEO or Board there should be an explanation as to why such action was not approved. The CEO and Board probably should also have a role in the initial risk-based prioritization system. One study ([Morse 2012](#)) noted a variety of reasons for that failure of implementation of action plans but most involved lack of leadership support, usually because the resources needed did not seem commensurate with the proposed value of the action item (see our September 15, 2009 Patient Safety Tip of the Week “[ETTO’s: Efficiency-Thoroughness Trade-Offs](#)”).

The RCA<sup>2</sup> process should also be **completed in a timely fashion**. The NPSF document notes that organizations like the VA, Joint Commission, and state health departments recommend or require RCA’s to be completed within 30-45 days. That is a pretty long time frame and may be necessary for some of the actions to get approval from various committees, medical executive committees, Boards, etc. But your major action items identified should start being implemented sooner in most cases. Delays in implementation of some action steps may leave other patients at risk. It might also put the institution at risk for some bad press as one hospital recently learned ([Dobbs 2015](#), [True 2015](#)). At that facility a patient died after a 5-fold dosing error of ketamine. The dose ordered was 100 mg but the nurse drew up 500 mg from a multidose vial because he/she anticipated the physician would order more during a procedure and inadvertently gave the patient the full 500 mg dose. Though it contradicted policy, the practice of drawing up extra doses in anticipation that “it might be needed” had become commonplace in the ICU where the event occurred (“normalization of deviance”). An RCA was apparently done promptly and identified several action steps with a few days of the adverse event. However, when the [state regulatory agency](#) showed up about 45 days later to survey the facility several of the most important action steps had not yet been completed. One was removal of the 500 mg vials of ketamine from the clinical sites (a strong action) and replacing them with 200 mg vials and this had not yet been accomplished. The other, inservicing of all relevant nursing staff (ordinarily “education” is a weak action but in this particular instance was important since the abnormal practice had become widespread amongst staff in those units) also had not been completed.

There are two additional action steps we feel need to be included in most RCA’s. One is **ensuring that the loop is closed regarding disclosure and apology** where appropriate (see our numerous columns on disclosure and apology listed at the end of today’s column). After a serious event in which there has been patient harm one individual (often the medical director or the attending physician) should be assigned to be the liaison with the family and keep them updated regarding the status of the findings of the RCA and lessons learned and how they will be used in a constructive manner.

And the other action step has to do with the “**second victim**” (see our December 17, 2013 Patient Safety Tip of the Week “[The Second Victim](#)”). Even though the RCA<sup>2</sup> document stresses that issues regarding individual responsibility should not be part of the RCA<sup>2</sup> process, sometimes the “second victims” are simply caregivers who did nothing wrong

but were deeply impacted by the events. So one action step is making sure your “second victim” program is involved where appropriate. It is also most important that the second victim receive **feedback in a prompt fashion** after the RCA and investigation have taken place. One study ([Ullstrom 2013](#)) found that many second victims needed to understand and learn from the event. But many of the second victims reported lack of followup after conclusion of the investigation.

Your RCA<sup>2</sup> program should also be reviewed annually. The NPSF RCA<sup>2</sup> document provides examples of measures that should be considered in that annual review.

You’ll find the NPSF’s RCA<sup>2</sup> document to be very useful in helping your organization improve its RCA process and ensure that appropriate attention is given to the actions, hence truly doing **Root Cause Analysis and Actions** or **RCA<sup>2</sup>**.

**Update:** See our July 12, 2016 Patient Safety Tip of the Week “[Forget Brexit – Brits Bash the RCA!](#)”

**Some of our prior columns on RCA’s, FMEA’s, response to serious incidents, etc:**

July 24, 2007	“ <a href="#">Serious Incident Response Checklist</a> ”
March 30, 2010	“ <a href="#">Publicly Released RCA’s: Everyone Learns from Them</a> ”
March 27, 2012	“ <a href="#">Action Plan Strength in RCA’s</a> ”
March 2014	“ <a href="#">FMEA to Avoid Breastmilk Mixups</a> ”

**Some of our prior columns on Disclosure & Apology:**

July 24, 2007	“ <a href="#">Serious Incident Response Checklist</a> ”
June 16, 2009	“ <a href="#">Disclosing Errors That Affect Multiple Patients</a> ”
June 22, 2010	“ <a href="#">Disclosure and Apology: How to Do It</a> ”
September 2010	“ <a href="#">Followup to Our Disclosure and Apology Tip of the Week</a> ”
November 2010	“ <a href="#">IHI: Respectful Management of Serious Clinical Adverse Events</a> ”
April 2012	“ <a href="#">Error Disclosure by Surgeons</a> ”
June 2012	“ <a href="#">Oregon Adverse Event Disclosure Guide</a> ”

**Other very valuable resources on disclosure and apology:**

- IHI’s “Respectful Management of Serious Clinical Adverse Events” ([Conway 2010](#))
- The Canadian Disclosure Guidelines ([Canadian Patient Safety Institute 2008](#))
- The Harvard Disclosure Guidelines ([Massachusetts Coalition for the Prevention of Medical Errors 2006](#))
- The ACPE Toolkit ([American College of Physician Executives](#))
- Oregon Patient Safety Commission [Oregon Adverse Event Disclosure Guide](#).

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