Wake Up Safe and Root Cause Analysis: Quality Improvement in Pediatric Anesthesia

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In 2006, the Quality and Safety Committee of the Society for Pediatric Anesthesia initiated a quality improvement project for the specialty of pediatric anesthesiology that ultimately resulted in the development of Wake Up Safe (WUS), a patient safety organization that maintains a registry of de-identified, serious adverse events. The ultimate goal of WUS is to implement change in processes of care that improve the quality and safety of anesthetic care provided to pediatric patients nationwide. Member institutions of WUS submit data regarding the types and numbers of anesthetics performed and information pertaining to serious adverse events. Before a member institution submits data for any serious adverse event, 3 anesthesiologists who were not involved in the event must analyze the event with a root cause analysis (RCA) to identify the causal factor(s). Because institutions across the country use many different RCA methods, WUS educated its members on RCA methods in an effort to standardize the analysis and evaluate each serious adverse event that is submitted. In this review, we summarize the background and development of this patient safety initiative, describe the standardized RCA method used by its members, demonstrate the use of this RCA method to analyze a serious event that was reported, and discuss the ways WUS plans to use the data to promote safer anesthetic practices for children. (Anest Analg 2014;119:122–36)

Registries of adverse events associated with anesthetic care for the pediatric population have influenced pediatric anesthetic practices through the years. For example, “the Pediatric Perioperative Cardiac Arrest registry was formed in 1994 to study the causes and outcomes of perioperative cardiac arrests in anesthetized children.”7 Subsequently, several publications have reported on perioperative cardiac arrests in children related to medications and congenital heart disease.2–4 Retrospective databases are valuable because they provide insight into trends, but they may not provide an accurate interpretation of the causes.5 In 2006, members of the Society for Pediatric Anesthesia Quality and Safety Committee stated that using process and outcome measures that reflect quality in anesthesia and identifying institutions that performed well on those measures would help other institutions improve the quality of their pediatric anesthetic care delivery. A few years later, in 2008, the Society for Pediatric Anesthesia developed the quality improvement (QI) initiative, Wake Up Safe (WUS). Unfortunately, there are few meaningful outcomes that reflect quality in anesthesia separate and apart from surgical outcomes. Consequently, the founding members of WUS decided to concentrate on serious adverse events in pediatric anesthesia.

Reports on these serious adverse events by member institutions include a thorough internal analysis by anesthesiologists at that particular institution to identify the cause(s) that led to the event. In the long-term, results of these analyses may reveal trends and causation of events. Understanding the causes of adverse events can promote changes to processes of anesthesia care and thereby lead to improved quality and safety of anesthesia for children. In addition, member institutions report demographic data of every anesthetic delivered at that institution. With this added information, the incidence of adverse events can be more clearly defined.

This review describes the structure of WUS; discusses one technique of safety analytics, root cause analysis (RCA); demonstrates the RCA for a reported serious adverse event; and reviews how this information might be used to prevent future occurrences of that event or similar events. As an organization, WUS uses QI methodology to imbed safety analytic (specifically RCA) and QI techniques in the member institutions to enable them to drive safer clinical practices in pediatric anesthesia. This article is an introduction to RCA and to a future series of articles based on cases reported to WUS.
Wake Up Safe and Root Cause Analysis

SERIOUS ADVERSE EVENTS SUBMITTED TO WUS

An important step of the WUS initiative was to develop a registry for reporting serious adverse events (Table 1). Events are occurrences, and adverse events are untoward or unfavorable medical occurrences. WUS captures serious adverse events that occur during anesthesia or within 24 hours of the end of anesthesia care and result in death, are life threatening, or result in prolonged hospitalization or disability. Events known as “never events” are also captured by WUS; these include events or medical errors that should never occur, such as wrong-side procedures, fire, and patient awareness.

Currently, WUS consists of 22 institutions (Table 2). Each institution has a committee of at least 3 anesthesiologists who were not involved in the serious adverse event that conducts an internal RCA on any event that is submitted to WUS. This committee determines the root cause(s) and develops actions for improvement. The institution’s representative member then submits the findings to WUS.

In addition to self-reported adverse events, institutions receive information from hospital-wide incident reporting systems. Other methods that might be useful for identifying serious adverse events include postoperative follow-up, review of intensive care unit admissions, internal safety/incident reporting system, family complaints, surgeon complaints, and reports of codes or “rapid response team” calls.

ROOT CAUSE ANALYSIS

Health care practitioners are taught first and foremost to “do no harm.” According to a 2010 report from the Office of Inspector General, an estimated 13.5% of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays. An additional 13.5% of Medicare beneficiaries experienced events during their hospital stays that resulted in temporary harm, and 44% of those events were clearly and likely preventable. In the Institute of Medicine report, To Err is Human, Building a Safer Health System, it was concluded that errors were caused by faulty systems. Systems should be designed such that it is difficult for people to do the wrong thing and easy for people to do the right thing.

Since 1997, the Joint Commission (JC) has required health care institutions to perform a RCA when a serious adverse event occurs. An important component of a RCA is a step-by-step approach to review the chain of events and contributing factors until the root cause is identified. By looking for the root cause, inadequacies or flaws in the system will be discovered. Reason described system failures when he proposed the “Swiss Cheese Model.” Each slice of cheese serves as a protective layer. When all the holes line up in the layers, the system is set up for a serious adverse event. The system must be designed with multiple defenses: smaller and fewer holes.

Traditionally, focus was placed on specific practices and errors committed by an individual. Adverse events

Table 1. Wake Up Safe Categories of Serious Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Death</td>
<td>Deaths are reportable if they occur during anesthesia or within 24 hours of the operation</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>Cardiac arrest is defined as the use of cardiac compressions during an anesthetic or during the first 24 hours after the end of the operation</td>
</tr>
<tr>
<td>Acute lung injury</td>
<td>New onset of impaired gas exchange associated with parenchymal lung injury</td>
</tr>
<tr>
<td>Acute cardiovascular deterioration</td>
<td>Unanticipated need for postoperative cardiovascular support, such as vasopressors or ECMO</td>
</tr>
<tr>
<td>Musculoskeletal injury</td>
<td>Soft tissue or muscle injury that requires ongoing treatment or surgical intervention (includes IV infiltration)</td>
</tr>
<tr>
<td>Skin injury</td>
<td>Burns or other skin injury</td>
</tr>
<tr>
<td>Bone or joint injury</td>
<td>Injury to bones or joints related to anesthesia or patient positioning</td>
</tr>
<tr>
<td>Brain injury</td>
<td>Injury to brain related to anesthesia resulting in neurologic signs or symptoms</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>Injury to spinal cord related to anesthesia resulting in neurologic signs or symptoms</td>
</tr>
<tr>
<td>Nerve injury</td>
<td>Peripheral nerve injury resulting in ongoing numbness, pain, or other symptoms related to general or regional anesthesia or patient positioning</td>
</tr>
<tr>
<td>Eye injury</td>
<td>Injury to eye or visual system (other than corneal abrasion that resolves in 24 hours)</td>
</tr>
<tr>
<td>Surgery or anesthesia on the wrong body part</td>
<td>Start of surgery or anesthesia (such as regional nerve block) on the wrong body part or wrong side of patient</td>
</tr>
<tr>
<td>Surgery or anesthesia on the wrong patient</td>
<td>Start of surgery or induction of anesthesia on the wrong patient</td>
</tr>
<tr>
<td>Fire</td>
<td>Spark or flame in the OR that results in patient injury or damage to surgical supplies or equipment, including surgical drapes</td>
</tr>
<tr>
<td>Awareness under anesthesia</td>
<td>Patient memory of events that occurred in the OR while under general anesthesia</td>
</tr>
<tr>
<td>Medication error</td>
<td>Medication error: wrong drug, wrong patient, infusion error, or administration of drug that patient is known to be allergic to, resulting in the need for ongoing care not a result of underlying disease</td>
</tr>
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</table>

ECMO = extracorporeal membrane oxygenation; IV = intravenous; OR = operating room.


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Table 2. Participants in Wake Up Safe

<table>
<thead>
<tr>
<th>Institution</th>
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<tbody>
<tr>
<td>Cincinnati Children’s Hospital Medical Center</td>
</tr>
<tr>
<td>Monroe Carell Jr Children’s Hospital at Vanderbilt</td>
</tr>
<tr>
<td>Seattle Children’s Hospital</td>
</tr>
<tr>
<td>Children’s Hospital Boston</td>
</tr>
<tr>
<td>Emory Children’s Center</td>
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<tr>
<td>Texas Children’s Hospital</td>
</tr>
<tr>
<td>Johns Hopkins Children’s Center</td>
</tr>
<tr>
<td>Children’s Hospital Los Angeles</td>
</tr>
<tr>
<td>Morgan Stanley Children’s Hospital of Columbia University</td>
</tr>
<tr>
<td>The Children’s Hospital of Philadelphia</td>
</tr>
<tr>
<td>Children’s Memorial Hospital Chicago</td>
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<tr>
<td>Children’s Hospital of Pittsburgh</td>
</tr>
<tr>
<td>Phoenix Children’s Hospital</td>
</tr>
<tr>
<td>CS Mott Children’s Hospital</td>
</tr>
<tr>
<td>Children’s National Medical Center, Washington, DC</td>
</tr>
<tr>
<td>Arkansas Children’s Hospital</td>
</tr>
<tr>
<td>Nationwide Children’s Hospital</td>
</tr>
<tr>
<td>Colorado Children’s Hospital</td>
</tr>
<tr>
<td>St Jude Children’s Research Hospital</td>
</tr>
<tr>
<td>Cook Children’s Hospital</td>
</tr>
<tr>
<td>Montefiore Children’s Hospital</td>
</tr>
<tr>
<td>Cardinal Glennon Children’s Hospital</td>
</tr>
</tbody>
</table>

were believed to be the result of an individual’s forgetfulness, inattention, negligence, or carelessness. Quality assurance describes a retrospective approach to analyze serious adverse events by trying to determine who was at fault after an adverse event. In contrast, QI describes the approach of analyzing serious adverse events and determining system or process flaws that led to the event. QI is both retrospective and prospective; it focuses on improving the system to improve the end result. Unlike quality assurance, which “involves a systematic measurement and comparison against a standard,” QI raises the standard. QI develops a system that provides adequate barriers or conditions to prevent errors that lead to complications. Errors are viewed as consequences rather than causes. Most adverse events are believed to result from a system fault that may involve breakdowns in communication, training, organizational transfer of knowledge, staffing patterns, patient-specific issues, workflow, technical failures, or inadequate policies and procedures. When one or more of these components in the system breaks down, adverse events will ensue. The QI process uses various tools and methods to improve clinical care, patient safety, and overall patient experience. QI methods can be used to produce safer health care practices in busy hospital environments. The focus of WUS is QI.

Rather than concentrating on an individual, the RCA identifies changes that should be made in the system to reduce the risk of a similar event occurring in the future. The goal was to identify active errors (those between humans and a complex system) and latent errors (hidden problems within the health care system) that contribute to adverse events. Practitioners investigate the basic factor(s), the root cause that led to a situation in which performance did not meet expectations. One must determine whether the outcome is an expected or unexpected complication of therapy and whether an error occurred. Error is defined as failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim. RCA begins with a multidisciplinary meeting to identify key factors that contributed to the event or error. Data collection, reconstruction of the event, review of the records, and interviews with participants are important components in this process. The multidisciplinary team then analyzes the event to identify how the event occurred (active error) and why the event occurred (latent error). Analysis delves deep to find answers based on hidden causes and their effects rather than on the most apparent or superficial factors that contributed to the event. RCA will reveal the faulty system processes, thereby enabling remedies to be created and implemented.

The RCA process should answer 3 important questions: What happened? Why did it happen? What can be done to prevent it from happening again? A fourth and equally important question should be included in the long-term follow-up (or monitoring) of the solutions put in place: Has the risk of recurrence been reduced? Monitoring for recurrence of the adverse event is one method of measuring the effectiveness of the RCA. If the risk for recurrence has not been reduced, another action plan may need to be formulated.

ROOT CAUSE ANALYSIS METHODOLOGIES

RCA has several methodologies that have many similarities and common elements. The Healthcare Performance Improvement (HPI), Veterans Affairs (VA), and JC have developed 3 methodologies commonly used in hospitals in the United States. Member institutions of WUS have recently undergone an intense study of the HPI method. A comparison of these 3 methodologies is presented in Table 3. There are many other tools and methods that provide structure to the analysis. All RCA methods include questions to analyze and identify system flaws. The simplest form involves asking the “5 Whys.” In this basic RCA form, the question “why” is asked multiple times until the root cause of the problem is determined. Each time the question “why” is asked, other causes can be excluded:

Problem: A medication error has occurred when a muscle relaxant has been administered instead of neostigmine.

Why? The provider reaches for the wrong vial.
Why? Vials of muscle relaxant and reversal are in close proximity in the anesthesia cart.
Why? The trays/drawers are organized with similar medications grouped together, rather than using a system where certain medications are “isolated” so they are not easily picked up in error.
Why? The trays/drawers are organized and stocked by pharmacy, not by anesthesia providers.
Why? It’s always been that way. No one asked the anesthesia providers for their input on optimal medication layout.

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Table 3. Comparison of Root Cause Analysis Methods

<table>
<thead>
<tr>
<th>Identification of events</th>
<th>The Joint Commission</th>
<th>Veterans affairs</th>
<th>HPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sentinel events</td>
<td>Safety assessment code assigned to events</td>
<td>• SSE</td>
<td></td>
</tr>
<tr>
<td>• Organizational leaders decide to do RCA</td>
<td>• PSE</td>
<td>• Near miss</td>
<td></td>
</tr>
<tr>
<td>RCA team members</td>
<td>• RCA coordinator</td>
<td>• PSM</td>
<td>“Known Complications” test</td>
</tr>
<tr>
<td>• Service managers</td>
<td>• Service managers</td>
<td>• RCA coordinator</td>
<td>Executive sponsor</td>
</tr>
<tr>
<td>• People involved</td>
<td>• People involved</td>
<td>• RCA analysts</td>
<td></td>
</tr>
<tr>
<td>Recommendations</td>
<td>• Action plan</td>
<td>• Corrective actions</td>
<td>Subject matter experts</td>
</tr>
<tr>
<td>• Measurement strategy</td>
<td>• Plan to verify the action has intended effect</td>
<td>• People involved</td>
<td></td>
</tr>
<tr>
<td>Monitoring of action plan follow-up</td>
<td>• Individual facilities</td>
<td>• Individual facilities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NCPS</td>
<td>• TJC</td>
<td></td>
</tr>
</tbody>
</table>


One common element of RCA methods is an interdisciplinary group of experts and those familiar with the event. This group performs incident analysis and fact-finding, formulates action plans, and monitors resulting action plans. Finding the root cause may be challenging. Factors that contribute to adverse events and failures can be found everywhere. Even if a particular factor may be seen as necessary for the mishap to occur or is considered “sufficient” to lead to the adverse event, it may not be the root cause. The root cause must have a proven cause-and-effect relationship, whereby if it is corrected, recurrence of the event and other similar events is prevented.

THE JOINT COMMISSION ROOT CAUSE ANALYSIS AND ACTION PLAN

The JC RCA and Action Plan tool has a list of 24 questions that help to identify the root causes for an adverse event. The JC guides hospitals with events that are considered sentinel and for which an immediate RCA should be conducted. However, organizational leaders ultimately determine which events should have an RCA.1 As in all the methodologies, the question “why” must be asked to determine the reasons a process failed.

Using the JC’s methodology, the intended workflow is analyzed. Relevant process steps are listed and defined by policy, procedure, protocol, or guidelines. Next, steps that did not occur as intended will be examined. Did deviations from the intended processes occur? The JC’s method examines human factors that were relevant to the outcome: Did the ordering physician fail to follow procedures/protocol when writing orders? Did he experience fatigue, cognitive bias, or other personal problems? In addition to analyzing human factors, the JC’s questions look at equipment issues, staffing limitations, communication, and environmental factors. Was the staff competent and qualified to perform the tasks? Were the staffing ratios adequate? Could the system breakdown be related to communication: verbal, written, or electronic? These questions should also encourage the team to identify other areas where the event could occur. With each question, the team should record the findings of the investigation, the root causes, and plan of action. For each planned action, an implementation date and associated measure of effectiveness should be decided. Improvements should be made not only in the area where the event took place, but be expanded to include all areas where the event could occur. The JC follows-up on outcomes, but there is little routine follow-up on these plans. Requirements vary widely within individual institutions.13

VETERANS AFFAIRS

The VA RCA method first determines whether the event was the result of a criminal act or related to alcohol/substance abuse. If the answer is yes, those events do not undergo an RCA. The VA RCA aims to design a system that is “fault tolerant.” It is not possible to eliminate human errors; therefore, a system must be designed such that when an individual error occurs, it does not result in harm to the patient. The VA method asks “why” questions to reveal the root cause. However, with the VA method, events are reviewed and assigned a safety assessment code to prioritize the actual and potential severity and frequency of the event.

The RCA questions are grouped by categories, similar to the JC method, to examine problems that may involve human factors (i.e., communication, training, fatigue/scheduling, environment/equipment, policies/procedures, or barriers. As in the JC method, questions assess communication-related issues: patient information and the availability of information for equipment, policies, and procedures. The method evaluates for faulty documentation and communication of orders within the involved health team. Questions explore whether the facility encouraged suggestions from the staff about risky situations and risk reduction. The VA RCA method also analyzes whether staff have adequate job training, whether they have continuing education opportunities, and whether the results of the training are monitored over time. The effects of scheduling/staffing issues, sleep


The “Known Complications” Test

Four questions:

1. Was the procedure, treatment, or test appropriate and warranted based on nationally recognized standards of care?
2. Was the complication a known risk, was it anticipated, and did the care team plan ahead to take steps to prevent it?
3. Was the complication identified in a timely manner (i.e., at the time of occurrence)?
4. Was the complication treated according to the standard of care and in a timely manner?

If the answer to ALL four questions is YES, the event is considered a known complication and not a Safety Event.
If the answer to ANY question is NO, the event is a Safety Event.

deprivation, or environmental conditions and stressors are key system factors to analyze. The role and involvement of the management team are also evaluated.

Equipment issues that may have had a role in the serious adverse event are also assessed. If an infusion pump was involved, did it meet current codes? Was it maintained properly? Were personnel trained properly to operate the pump? Questions about the use and location of the equipment, fire protection and disaster drills, regulations, and codes are also considered when evaluating equipment or environmental issues. These questions help practitioners determine whether equipment failure relates to human factors issues, policy and procedure, or training needs.

If there was a policy that was not followed, it is important to determine why not. No one in health care comes to work intending to cause harm. If a policy or procedure is not followed, it is important to discover the barriers that prevented it from being followed. Was the provider not educated about the policy or was he unaware that it existed? Is the policy too cumbersome to follow? Does the policy not fit with current practice? If there was a policy and it was followed, but harm still occurred, then the policy may need to be revised.

The institution’s rules, policies, and procedures must be up to date, address work processes related to the adverse event, and be consistent with federal and VA policies and standards. Moreover, previous events and resulting effective interventions from past events are examined. This process assesses whether the policies and procedures were easily accessible to the staff or were used on a day-to-day basis. If any area is found to be deficient, the RCA will help to uncover positive and negative incentives that were absent.

Barriers and controls are also evaluated, whether or not they were in place before the event. These questions examine whether the protection of patients, staff, equipment, and environment, as well as patient risk, were considered in the design of the barriers and controls.

The patient safety manager creates the RCA team and reports the event to the National Center for Patient Safety (NCPS). Patient safety managers are responsible for cataloging adverse events into the database and alerting the NCPS to inform other facilities of unsafe situations and appropriate corrective actions. Similar to the JC method, the VA requires that each RCA contain recommended corrective actions and a plan to verify that the action has the intended effect. Follow-up of the action plan is left to individual facilities. However, the VA has the NCPS review the individual reports and enforce the recommendations. The NCPS also disseminates advisories and alerts. Every event, human error, or procedural deviation must have a preceding cause. It is discovering the cause of the error, not the error itself, that will help determine productive prevention strategies.

Healthcare Performance Improvement

One goal of WUS is to standardize the RCA method commonly used by most member institutions. All the current WUS organizations are participants in the Solutions for Patient Safety Collaborative, which uses HPI methodology. Although HPI is a commercial entity, many institutions that participate in WUS use the RCA methodology developed by HPI to discover the root cause of adverse events.

Users of the RCA method from HPI start by determining whether the event was a safety event or a known complication with the “Known Complications” test (composed of 4 questions; Fig. 1). If the event was a known complication, an adverse event may have occurred, but it is not a safety event that warrants an RCA. The next question is whether actions deviated from generally accepted practice standards (GAPS). If the standard of care was observed, the care team anticipated and prepared for a possible event, the complication identified in a timely manner, and the event managed appropriately, then no deviation from GAPS occurred and it is not considered a safety event (see safety decision tree, Fig. 2).

Regardless of whether the event is considered a safety event according to HPI, whether the adverse event results in death, is life threatening, or results in prolonged hospitalization or disability and occurs during anesthesia or within 24 hours of the end of anesthesia care, the event is reported to WUS.

If the event is determined to be a safety event, it is further classified as a serious safety event, precursor safety event, or near-miss safety event (Figs. 2 and 3). An error that is a deviation from GAPS but is recognized and corrected before it reaches the patient is a near-miss safety event. A precursor safety event is an event that reached the patient but caused minimal or no temporary harm. A serious safety event reaches the patient and results in serious harm.

RCA can be applied to any version of a safety event, including the near miss, because serious harm could have resulted and the weaknesses in the system that allowed the unsafe situation must be rectified. An organization that has a robust safety culture will have a high volume of near-miss reports, with RCAs completed for each. It is difficult initially to convince people to report a near-miss event. The overwhelming sentiment is often, “Well, no one got hurt,” or “I don’t want to cause any trouble.” In a highly developed safety culture, everyone is vigilant in his effort to identify what could go wrong in their daily work and proactively seeks to remedy such potential failures. Performing an RCA for a near-miss event is part of that safety work.

**THE HPI RCA TEAM**

The HPI RCA team consists of many members with special roles. The QI facilitator conducts interviews of the personnel...
involved in the event before the first meeting of the RCA team. The actual RCA team may or may not consist of the individuals who were involved in the incident. Including these individuals in the RCA would help recreate the involved human factors (e.g., time pressures, fatigue, and unfamiliarity with policies or procedures) that led to the event. However, involved individuals may be concerned that their competence is being judged and be reluctant to speak up. RCA teams also include representatives who can speak for the individuals involved. These individuals are stakeholders who are usually managers and directors of the areas involved in the event. These individuals can “benchmark” or speak to how the work is usually done or the manner in which it should be done.

Other members of the RCA team are the RCA analysts. These individuals are experienced RCA facilitators who perform the RCA process. The final member of the team, unique to the HPI method, is the RCA executive or physician sponsor. This individual is the senior leader who “owns the quality of the overall RCA outcome.” It is important to include “owners” because their seniority may be needed to ensure that changes are implemented. Having this member on the team emphasizes the importance of the process. The executive sponsor has the resources (financial, influence, power) to implement changes that are recommended by the RCA.

IMPLEMENTATION OF AN HPI RCA
The HPI RCA method can be performed in 3 steps: identify, analyze, and resolve. After the event is identified, data are gathered and personnel are interviewed. During this phase, various factors (documentation, policy/protocol, staffing, equipment, procedures) will be considered. The QI facilitator interviews the involved personnel and collects data from the clinical record. It is vital to the integrity of the RCA process that interviews with the personnel occur soon after the event so as not to confuse the memory of the interviewees. The goal of an RCA is to develop an unbiased version of events. Names are removed, and instead, one refers to the role of the individuals involved. For example, “the resident ordered an excessive dose of heparin,” not “Dr. Jones ordered an excessive dose of heparin.”

After the event has undergone the identification process, the second step of the RCA process involves analyzing for proximate causes, contributing factors, and root causes. Proximate causes are actions that trigger the adverse events or deviations from the standard or best practice. The inappropriate act, or proximate cause, is the action that deviated from the expected or best practice. Contributing factors should also be identified. Contributing factors are the conditions that contributed to the proximate cause. Such factors may be important, but elimination of these alone would not prevent a recurrence of the inappropriate act. Contributing factors may include fatigue (working a long shift to cover for a sick colleague) or an unbalanced assignment of patients (too many patients or patients who were too complex). These are very important factors to recognize and rectify, but alone they would not have prevented this particular error from reaching this patient on this day. The root cause is defined as the most prominent contributing factor that if eliminated, would have prevented the adverse event.

In the quest to identify the root cause and repeatedly ask “why,” QI tools such as the fishbone diagram (Fig. 4) can be helpful. Multiple proximate causes may be identified, and the root cause should be determined for each proximate cause. Diagramming the steps in the process can help identify the root cause(s).

In task analysis, the usual steps in a process are evaluated by mapping the expected process and comparing it to the process that was followed in the case being investigated. These steps are determined by an existing policy or protocol, but sometimes it is discovered that no one follows the policy or that there is no policy. In such cases, one must ask those who perform the task what the usual steps are. Process mapping identifies steps in the process that might have failed.

Planning corrective or preventative actions is the final step of an HPI RCA. These actions must be targeted directly to address the root cause and must be designed to reduce the likelihood of recurrence. HPI does recognize the failure

Figure 4. Fishbone diagram. A quality improvement tool used to map out contributing factors that lead to an event.
on the part of the individual that caused the inappropriate action and seeks to categorize such events into the following failure mode groups: competency, consciousness, communication, critical thinking, and compliance (Fig. 5). For example, an inappropriate action caused by inattention or distraction would be considered a consciousness failure.

However, in designing the corrective methods, HPI also focuses on the system failure mode that underlies the individual failure. The 5 categories of system failure are policy and procedure, technology and environment, structure, culture, and process (Fig. 6). With the occurrence of a system failure, individual failure could ensue. A combination of these failures could result in an inappropriate act.

Corrective actions should be designed to reduce the likelihood of recurrence. In this step, trends should also be identified. Corrective actions developed from an RCA must be SMART (specific, measurable, achievable, relevant, and timely).

- Specific
- Measurable
- Achievable
- Realistic
- Timely

An action plan should clearly address the following questions: who will do what, by when, and how will we know that a change was made? (How will we measure success?) Corrective actions should be remedial actions for all adverse conditions. Corrective actions to prevent recurrence should be developed for all identified root causes. After root causes have been confirmed, the corrective action plan is finalized. Corrective actions are planned for the root cause and for other causal factors. The report is given at organizational meetings. It is incumbent upon the analyzing team (patient safety specialist, managers, and educators) to monitor for effectiveness. The individual facilities should follow outcomes and monitor for recurrence of the events.

**HPI RCA METHOD FOR A REPORTED SERIOUS ADVERSE EVENT: CASE DESCRIPTION**

The following case is a composite of several events reported to WUS that we are using to demonstrate the RCA method. We have changed the case details to comply with Patient Safety Organization (PSO) regulations that the information be de-identified. Whereas the HPI RCA method calls for a multidisciplinary team, 3 anesthesiologists who are not involved in the event must scrutinize cases for the WUS database using a series of questions created about each event. These questions standardize the approach to analyze the event and the causative factors. The HPI method framework (identify, analyze, and resolve) has been used for the RCA of the following case. Details of the event, including the patient’s comorbidities, health care personnel involved in the event, human factors, environmental factors, and other details (Tables 4 and 5) and its analysis were submitted to WUS. The questions are worded specifically to conform to the common formats published by the PSO office of the Agency for Healthcare Research and Quality (AHRQ). Common Formats refers to common definitions and reporting formats that allow health care providers to collect and submit standardized information regarding patient safety events.

**Case Scenario**

A 20-kg, 6-year-old girl with renal failure presented to the operating room (OR) late on a Friday afternoon for placement of a tunneled dialysis catheter and a percutaneous liver biopsy. Almost all the tunneled catheters at this institution are placed by the interventional radiology (IR) service. However, the IR service was overloaded, and the pediatric surgeon on call agreed to place the catheter in the OR. He had not placed a dialysis catheter in quite a while, and the procedure was delayed because of his unfamiliarity with the appropriate type and size of catheter required for this child.

The procedure was uneventful. The surgeon had been instructed to “pack” the lumens with heparin, although no specific information was given regarding the concentration or volume of heparin to be used. Nursing staff gave the surgeon 10 mL heparin at a concentration of 5000 U/mL instead of 1000 U/mL. The surgeon was unaware that there were specific volumes for each lumen and injected 5 mL heparin into each lumen. The total volume should have been 4 mL (2 mL in each lumen).

In the postanesthesia care unit (PACU), the nurses noted excessive bleeding from the line insertion site and that the blood pressure was decreasing. The patient was administered fluid boluses but was still hypotensive. A decision was made to transfer the patient to the pediatric intensive care unit (PICU). In the PICU, she had increasing transfusion requirements and had a cardiac arrest secondary to hyperkalemia. The coagulation studies were markedly elevated, prompting an investigation of the heparin.

**DISCUSSION OF MEDICAL ISSUES**

To maintain patency of the dialysis catheter, the lumens are filled with heparin (1000 U/mL). The amount of heparin given in this case was erroneous in 2 ways: the concentration was too high and the volume was too large. This patient received 10 mL heparin at a concentration of 5000 U/mL instead of 4 mL heparin at a concentration of 1000 U/mL. Assuming that the excess volume entered her circulation, the patient received 6 mL heparin at a concentration of 5000 U/mL or 1500 U/kg of body weight. Heparin exerts its anticoagulant effect by enhancing antithrombin III, and it is effective after 1 circulation. The usual dose for anticoagulation before initiating cardiopulmonary bypass is 300 to 400 U/kg of body weight. Although it is unclear whether this patient’s transfusion requirements qualified as massive transfusion, the cardiac arrest was secondary to hyperkalemia that was temporally associated with increasing transfusion requirements. In this case, the patient had several risk factors for transfusion-related hyperkalemic cardiac arrest, including renal failure and a low cardiac output state as manifested by her ongoing blood loss and persistent hypotension. Furthermore, because she was in renal failure, preexisting metabolic and electrolyte abnormalities, although not reported, were likely present and would have contributed to her cardiac arrest.

Massive transfusion of stored packed red blood cells can result in hyperkalemia. Because this patient was in...
renal failure, any pretransfusion hyperkalemia and acidemia would have made her less tolerant of any significant exogenous potassium load from a red blood cell transfusion. Mildly increased levels of serum potassium (6–7 mEq/L) will yield electrocardiogram changes such as peaked T waves and a prolonged PR interval, progressing to a widened QRS wave. As hyperkalemia becomes more pronounced at 10 to 12 mEq/L, ventricular fibrillation and asystole ensue.16

**LEVEL OF HARM TO THE PATIENT**
The patient required resuscitation for cardiac arrest. The levels of harm defined by the AHRQ include death, severe permanent harm, permanent harm, temporary harm, additional treatment, emotional distress, and no harm (Table 6). At the minimum, according to AHRQ Common Formats terminology (version 1.1), this event led to temporary harm associated with postsurgical bleeding that required transfusion, and later, hyperkalemic
cardiac arrest. Temporary harm is defined as bodily or psychological injury, that is likely not permanent. The adverse event in our case scenario had the potential to cause permanent harm or severe permanent harm with lifelong injury if the resuscitation from the arrest was associated with neurologic or other end-organ deficits. In addition, hyperkalemic cardiac arrest could possibly cause death.

Because this error reached the patient, resulted in serious harm, and was associated with a deviation from GAPS, it is classified as a serious safety event. If the surgeon or nurse had double checked the concentration and the intended volume of heparin before administering the injection and had realized that the concentration was 5 times higher than it should be and that only 4 mL should be injected, the correct concentration of heparin would have been administered.

Figure 6. Healthcare Performance Improvement (HPI) algorithm for the 5 categories of system failure that contribute to the occurrence of a safety event. (Reproduced with permission from HPI).
RCA PHASE: IDENTIFY THE SERIOUS ADVERSE EVENT

To gather data for the RCA, a QI facilitator interviews the people directly involved in the event (surgeon, anesthesiologist, circulating nurse, and surgical technician). These interviews are necessary to understand human factors (e.g., pressures, thought processes, environmental conditions) that may have had a role in the decisions made by the individuals. Moreover, individuals at the periphery of the event may be interviewed, such as the interventional radiologist, the nephrologist, and the charge nurse. Was the placement of a tunneled dialysis catheter and percutaneous liver biopsy a medical emergency that needed to be performed that Friday afternoon? Was it feasible to perform the procedure that evening or a time that the IR service was available? Was the nurse assigned to a room that had procedures with which he/she was unfamiliar?

A QI facilitator interviews personnel and collects data. The content experts on the RCA team, such as the nursing director, the anesthesiologist (schedule runner), another interventional radiologist, and a surgeon (not involved in the event) establish the standard practice for these cases: How often does the surgical service assist in placement of tunneled dialysis catheters because the IR service is busy? Is it a common practice for the 2 services to communicate if technical questions arise? The results of the interviews should be compared to any existing policies or procedures. The final member of the team is the RCA executive sponsor or organizational leader. He will help implement the changes that are decided by the RCA team to prevent the recurrence of the serious adverse event. The RCA is conducted on a strict timeline; when the corrective actions are determined, the action plan should be implemented within 90 days.

RCA PHASE: ANALYZE THE SERIOUS ADVERSE EVENT

Data gathered from interviews, medical records, and policies or protocols should then be used to establish the sequence of events. In an RCA, it is helpful to diagram the sequence of events to identify the root cause (Fig. 7). Policies regarding heparin should be reviewed. Is there a policy about the availability of highly concentrated heparin? In other words, are both 1000 and 5000 U/mL
concentrations stocked in the OR? Is there a protocol in place when medications are drawn by the circulating nurse and ultimately administered sterilely by the surgeon? Is there any verification of dose? Is it common practice to label the syringes that will be used in the surgical field? Are the policies and information about catheters that are used primarily in the radiology suite readily available to the general OR? Were current policies being followed? If not, why were they not followed?

Task analysis examines the physical and mental tasks routinely performed by all the people involved in a process. It objectively looks at each step to help identify areas that should be changed to avoid subsequent errors. Comparing a map of the expected process to a map of the process that led to the investigated event can help identify the steps that are flawed (Fig. 8).

After performing the task analysis, proximate and contributing causes are determined. The proximate cause triggers the adverse events or deviation from the standard or best practice; the event most likely would not have occurred if the proximate cause had not occurred. In this event, the proximate cause was a heparin overdose. If the patient had not received the dramatic overdose of heparin, she would not have required massive blood transfusions that resulted in a hyperkalemic cardiac arrest. In this case, many contributing factors led to the error. Contributing factors are the conditions that contribute to the proximate cause; however, the elimination of these factors alone would not prevent a recurrence of the inappropriate act. If these events had not occurred, it is possible that the event severity would have been lessened or may not have occurred at all.

- Radiology was too busy to do the procedure.
- General surgeon did not consult with radiology.
- Concentrated heparin at 5000 U/mL was readily available.
- Surgeon did not determine the dead space of catheter lumen before placing or “packing” the lumen.
- Nursing staff, anesthesiologist, and surgeon did not discuss dose and dose per kilogram.
- Overdose was not recognized.
- Patient was transferred from PACU to PICU with insufficient workup of the unexpected hypotension and intravascular volume requirements.
- Heparin dose was not communicated to PICU.

### Table 6. Agency of Healthcare Research and Quality (AHRQ) Harm Scale

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Death at the time of assessment</td>
</tr>
<tr>
<td>Severe permanent harm</td>
<td>Severe lifelong bodily or psychological injury or disfigurement</td>
</tr>
<tr>
<td>Permanent harm</td>
<td>Lifelong bodily or psychological injury or increased susceptibility to disease</td>
</tr>
<tr>
<td>Temporary harm</td>
<td>Bodily or psychological injury but likely not permanent</td>
</tr>
<tr>
<td>Additional treatment</td>
<td>Injury limited to additional intervention during admission but no other injury</td>
</tr>
<tr>
<td>Emotional distress or inconvenience</td>
<td>Mild and transient anxiety or pain or physical discomfort</td>
</tr>
<tr>
<td>No harm</td>
<td>Reached patient, but no harm was evident</td>
</tr>
</tbody>
</table>


**RCA PHASE: RESOLVE DEVELOPMENT OF PREVENTABLE ACTIONS**

The development of an action plan is the last and most crucial part of the RCA process. After examining the task analysis and each proximate or contributing cause, the RCA team develops interventions that will minimize recurrence. In this step, process and/or policy changes may be implemented to improve the system. For this scenario, the interventions or actions that might prevent a future occurrence of heparin overdose include:

- When a catheter placement is requested by a medical service, the catheter size should be specified in the patient’s chart and/or by verbal communication between the 2 providers.
• Concentrated heparin should be limited to the pharmacy.
• Information concerning dialysis catheter sizing and dead space for the catheter according to patient size should be readily available.
• A time out should be performed before administering concentrated heparin or other drugs in the field.
• The nursing staff, anesthesiologist, and surgeon should all verify the heparin volume and concentration.
• Any complication after a surgical procedure that involves an unexpected level of bleeding or intravascular volume requirements should trigger a response (a coagulation study) in the PACU.

The determined interventions should be SMART to increase the odds of successful implementation. An example of a SMART corrective action for this proximate cause would be:

Starting April 1, 2014, concentrated heparin at 5000 units/mL will not be stocked in the OR PYXIS, but will have to be ordered from pharmacy. Heparin at a concentration of 1000 units/mL will continue to be stocked in the OR PYXIS. Whenever IV heparin is being given to maintain the patency of a line, the nurse, anesthesiologist, and surgeon must verify the volume of the heparin flush to be administered through a catheter and concentration of the heparin. The syringe containing heparin will be labeled with the correct concentration. This volume will be the maximum amount of concentrated heparin allowed on the field. We will achieve 100% compliance with this policy by November 1, 2014.

ADVISORIES FROM WUS
After each reporting institution has conducted its own internal RCA of a serious adverse event and entered the data into the WUS database, WUS members can review the database, look for trends, and query the database if there is an area of interest. This process has led to the dissemination of advisories relating to wrong-side procedures, medication errors, and cardiac arrest associated with blood transfusion in young children. It is still premature to make any inferences regarding the effect of these advisories on the incidence and nature of events at participating hospitals. These advisories can be found at http://www.wakeupsafe.org/findings.iphtml.

CONTINUING EDUCATION IN WUS
Collecting information about adverse events does not improve care by itself, rather it is necessary to use the information to implement change in processes of care. Although reporting events and publishing advisories are useful steps, members of WUS believe that to make a significant improvement in patient care, an active QI initiative is needed. WUS members have widely different experience with QI. As a result, WUS has developed a program to improve members’ knowledge in safety analytics and QI science and to help members implement change in their own institutions.

In the Autumn of 2011, founding members were offered a 13-hour, on-line QI course produced by the Institute for Healthcare Improvement (www.ihi.org). New members are now encouraged to take the course as well. Special meetings...
devoted to education of QI methods (e.g., Plan Do Study Act, Lean) are organized for members. In November 2011, WUS members met to consolidate learning and to decide on a QI initiative. The topic chosen was medication errors because these are the most common type of events reported to WUS. The spread of this QI initiative to new members is currently under discussion. WUS members believed it was important to understand and achieve proficiency with RCA. In March 2013, WUS conducted a meeting to understand 1 method of RCA.

**CHALLENGES AND OPPORTUNITIES WITH RCA AND WUS**

RCA is helpful for identifying system flaws and planning corrective actions. However, following up and verifying that the corrective actions actually decrease risk are difficult. Some institutions, especially smaller hospitals, may have very limited QI resources to implement the changes needed to reduce risk. Time, money, and manpower are needed to collect data, make corrective actions, and verify that those actions reduce risk for adverse events. Budget reductions have forced WUS member institutions to face challenges in their attempts to mobilize resources for gathering data and instituting change. WUS is identifying ways to encourage hospitals to commit necessary resources and remain active in the PSO. Each institution must commit the time and manpower necessary to learn QI methods and tools, perform RCAs for each serious adverse event, and enter the information into the database. All involved member institutions understand the importance of maintaining the integrity of the submitted data that will lead to the improvement of anesthetic care quality and are committed to devoting the necessary time and energy.

The success of an RCA and subsequent corrective actions will be evident by a decrease in reported recurrence of events at each institution. However, RCAs may be performed incorrectly or incompletely, or may not produce usable results. Repeat adverse events may indicate that recommendations were not fully adopted or that the RCA failed to identify the true causative factors.13 In addition, health care organizations may evaluate each RCA independently rather than draw conclusions across investigations. Although this practice may improve a process around a particular event, it fails to identify larger system problems within organizations that may be the cause of a multitude of events. Improved methods are needed to evaluate RCAs and measure the effectiveness of the proposed interventions. Currently, the peer-reviewed literature contains no method of RCA. In March 2013, WUS conducted a meeting to understand 1 method of RCA.

**DISCLOSURES**

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