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Systematic approaches to adverse events in obstetrics, Part II: Event analysis and response

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ABSTRACT

The critical arm of improvement and change comes after events are identified and classified. Getting and making things right when things go wrong defines a successful safety program. This article reviews the important tasks that should be familiar to any team approaching a serious event on an obstetrics unit. Root cause analysis is a critical, but often misunderstood, tool for dissecting the contributing factors leading to an adverse event. Successful root cause analyses have a standardized approach that result in meaningful action plans. Disclosure to the patient of the event and error, if applicable, is a new concept that is gaining traction in medicine. The review of a structured disclosure program can help programs adopt a method that has successfully gained the trust of patients and families with very few complications. Second victim support through coordinated debriefing of the individuals and teams who worked during the event is a final important measure that is important to prevent burnout or identification and classification is just the beginning to having a systematic approach to adverse events. The critical arm to improvement and change comes in the analysis and response to these events, which includes root cause analysis, corrective action plans, error disclosure, and second victim support.

Systematic investigation: Root cause analysis

After a serious safety event, sentinel event, or state reportable event is detected, an investigation should begin immediately. Root cause analysis (RCA) is the retrospective investigation of a serious adverse event, often mandated by regulatory or accrediting agencies, to determine the direct and indirect factors that led to it.[1] The term "root cause" refers to the fundamental or initiating factor beginning the chain of events leading to harm. Root cause analysis should not be confused with failure modes and effects analysis, which is a *prospective* investigation into a process to proactively identify possible failure points and targets for change.[2] The primary goals of RCA are to identify the system factors that led to the error and to suggest solutions that can prevent similar errors in the future. The emphasis on system error does not avoid an investigation of human error. Rather, human error is often investigated with the question "How did the system fail to allow the human error to happen?" Blame of individuals should be avoided. Cases that involve an individual's behavior that is risky or reckless are often referred away from the root cause analysis into a clinical peer review setting, as this is most often the investigative venue that is most prudent for professional review of practice standards.

Performing a good root cause analysis depends on knowing at the start why these projects fail to conclude anything

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valuable or, even more importantly, fail to make change that will prevent the event from happening again. The National Patient Safety Foundation has identified the following 5 common characteristics of unsuccessful RCAs[1]:

1. Lack of a standardized approach.
2. Failure to identify systems level causes.
3. Superficial solutions/countermeasures.
4. Poor implementation of solutions.
5. Lack of follow-up.

This list indicates that failure in root cause analysis comes as much from breakdowns in the actions or plans as it does from improper analysis. In fact, it is argued that the term root cause analysis fails to place enough emphasis on the actions that need to come of it. As a result, a new standard for root cause analysis has been proposed by the National Patient Safety Foundation as follows: root cause analysis and action (RCA^2 or RCA-squared).[1] The goal of the new recommendations is to standardize the process, focus on systems, emphasize action and improvement, and promote traction and sustainability of the changes.

The new RCA^2 recommendations suggest that analysis should begin within 72 h of an event and a timeline for completion (generally 30–45 days) should be kept. Meetings to review findings and planning should be scheduled regularly. Scheduling a final meeting to discuss the results and recommendations of the report to service-line leadership or to the hospital medical or safety leadership can help keep adherence to the time deadline. An interdisciplinary team should be assembled of 4–6 people with appropriate expertise (physicians, midwives, nurses, pharmacists, IT specialists, etc.) who are free of conflicts of interest. For instance, if one of the providers involved is in a group practice, a member of that group practice should not be on the core team. The team lead should be someone who has experience and training in RCA. Sometimes, to develop a cadre of staff to be capable of leading an RCA, this leadership can be shared. The work to complete the RCA should not be additional work added to their job; appropriate time should be allotted and this should be considered an important part of their daily role.

The process of interviewing should be well thought out and planned and should be done by only one or two members of the RCA team. Typically, administrative or clinical leaders should not perform interviews, as this can compromise the openness of the interviewees. Interviews should be scheduled with individuals involved in the event including the staff and clinicians, the patient, and the patient's family. Interviews with front line staff who were not involved but who work in the involved area can assist in investigating routines or standard practices. Group interviews should be avoided, as the perspective of an individual without the bias of others is critical. It is important in these interviews to separate the emotional and psychological debriefing from a traumatic event from the "fact-finding" questioning in an RCA. An RCA should stick to the story and the facts and focus on objectivity, while providing minimal degrees of emotional support, which should come from formal second victim support techniques, as discussed later. The interviewer should use a technique of active listening and should refrain from judgment or blame.[1]

The Joint Commission's "root cause analysis and action plan framework template" can be used to ensure complete adherence to process in an RCA and that all appropriate questions and investigations have been performed.[3] The 24 analysis questions (ranging from "Were there any steps in the process that did not occur as intended?" to "Was the available technology used as intended?") help the RCA team cover all of the typical failures that occur in a health care setting. However, the RCA^2 guide has an even more comprehensive set of triggering questions that cover virtually every possibility for failure.[1]

From the interviews, process mapping and flow diagraming can be helpful for looking at the event. "Fishbone" diagrams can be helpful in separating the processes leading to the adverse event into categories (patient, provider, process, organization, or equipment) but typically process flow diagrams that start at the patient's entry to care are reliable enough.[2] Each point of failure should be identified and singled out. Forming causal statements to describe the cause, effect, and event for each point of failure is helpful for framing the problem and is probably the hardest part of the RCA. We ask use the question "WHO did WHAT, because HOW and WHY?" to create effective causal statements. A theoretical example of this statement might come from a case of harm to a neonate related to birth attributable to tachysystole and inadequate fetal monitoring: "The nurse and obstetrician did not recognize and respond to the presence of tachysystole during oxytocin administration because there was a mindset of inadequate labor progress and there was no protocol to help define tachysystole when contractions are seen on tocodynometer but not felt by the patient and to outline appropriate actions."

A causal statement like this, however, does not always get at the core of the problem. The National Patient Safety Foundation outlines "five rules of causation" to give causal statements "teeth"[1]:

1. Clearly show the "cause and effect" relationship.
2. Use specific and accurate descriptors for what occurred, rather than negative and vague words.
3. Human errors must have a preceding cause.
4. Violations of procedure are not root causes, but must have a preceding cause.
5. Failure to act is only causal when there is a preexisting duty to act.

Vincent and colleagues summarized a systematic approach of this type in 2000, incidentally prior to publication of formalized approaches by professional bodies, and specifically use a case of a difficult delivery that leads to the death of a baby.[5] Providing a very simple protocol, this review is a good starting place for those wishing to formalize their event analysis process.

While root cause analysis focuses on sentinel events and serious safety events, they can be useful for investigating less severe adverse events as well. The time involved can be a barrier to using the formal processes of RCA, but a