

Medication Safety Alerts

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ROOT CAUSE ANALYSIS: LEARNING FROM ADVERSE EVENTS AND NEAR MISSES

Imagine that you are the pharmacist for a medical unit in a community hospital. A critical medication incident has occurred. Staff involved in the event, as well as the rest of the staff on the unit, have been counselled to “be more careful” in future. You have been reading about patient safety and the need to approach problems from a systems perspective. You suggest that a more thorough review of the event might be warranted. Root cause analysis, the subject of this article, might be the right approach.

When a critical incident occurs in a health care environment, practitioners, patients, and families share a common desire to determine 3 things:

- What happened
- Why it happened
- What can be done to reduce the likelihood of a recurrence

These 3 goals form the basis of root cause analysis, an analytic tool for performing a system-based review of incidents, including but not limited to medication incidents. Root cause analysis is relatively new to health care, but it is well established in other industries as a way to determine the root causes and contributing factors that led to an event and to identify needed system improvements. To provide a standardized approach to the retrospective analysis of critical incidents and near-miss events in health care, the Institute for Safe Medication Practices Canada (ISMP Canada), Saskatchewan Health, and the Canadian Patient Safety Institute worked together to develop the Canadian Root Cause Analysis Framework,¹ intended for use in a quality improvement context.

At first glance, the concept of root cause analysis may not seem new. When critical incidents occur in health care organizations, there is generally a review of the event, and recommendations are made to prevent recurrence. However, current review processes may be cursory and may focus too heavily on the actions of individuals at the “sharp end”, the point where care is delivered. Root cause analysis delves more deeply into the underlying causes and contributing factors of an event, including consideration of organizational, environmental, and regulatory factors. These “blunt end” factors influence how work is configured and accomplished but are often beyond the control of individual practitioners and may not be immediately recognized as causal factors. True root causes are the earliest points where action could have been taken to enhance the support system and thus to prevent the event or mitigate harm from the event.

A Multidisciplinary Process

It is recommended that root cause analysis be undertaken by a multidisciplinary team to ensure that all perspectives are represented. The typical team has 4 to 6 core members, including a facilitator, a team leader, a senior leadership representative, and front-line staff with relevant knowledge about the processes related to the event. Staff who were directly involved in the event are interviewed to ensure a complete understanding of what happened and the nature of the circumstances; in some cases they may participate as team members. A chronology of the sequence of events is developed by gathering information from interviews, an assessment of the physical environment, and a review of the medications and devices involved.



Once the team has a clear understanding of the event itself, a series of “why” questions is asked, until the underlying or “root” causes have been identified. Diagramming should be used in this process. Diagramming is useful for directing attention toward systemic issues and away from the actions of individuals. Visualization of process issues helps to avoid hindsight bias and helps the team to see where gaps exist. Root cause analysis often reveals underlying system deficiencies that are not immediately obvious, as well as issues that have become so familiar to those working in a particular environment that they are not identified as hazards.

Focus on Outcomes

Root cause analysis is outcome directed, with an emphasis on concrete, high-leverage actions based on human factors engineering principles, to ensure that any changes made are sustainable. Human factors engineering is concerned with the design of systems, tools, processes, and machines and takes into account human capabilities, limitations, and characteristics. Error is an inevitable consequence of being human; however, proactive consideration of the potential for human error reduces the likelihood that error will be translated into injury.

System improvements developed through a root cause analysis are targeted to eliminate individual root causes or contributing factors or, where elimination of these factors is not possible, to provide control measures. Often, when an incident occurs, practitioners are given information through memos and newsletters, or new “policies” are created with the expectation that staff will follow them. Although these are necessary components for implementing changes in health care environments, they do not change underlying conditions or physically direct practitioners to perform in a different way. In-service “training” that fails to include an assessment or certification component does not ensure that practitioners can actually perform processes and use devices. Effective actions must ensure long-term behavioural change.

Physical changes, such as “forcing functions” or “constraints” will be the most successful in the long term. A forcing function is a design feature that makes it impossible to perform a specific erroneous act.² For example, oral syringes cannot be physically connected to IV catheters. A constraint function is a withholding step in a process that makes it improbable that a specific erroneous act will be performed.¹ For example, if concentrated potassium chloride is absolutely required on a patient care unit, sequestering the compound makes it improbable that it will be selected and administered in error. Additional effective

strategies that have been well established in other industries include automation of repetitive processes, computerization of the storage and retrieval of data and information, simplification and standardization of processes, and the use of reminders, checklists, and double checks. This “hierarchy of effectiveness” is summarized in Box 1.

Box 1: Hierarchy of Effectiveness^{3,4}

1. Forcing functions
2. Automation and computerization
3. Simplification and standardization
4. Reminders, checklists, double checks
5. Rules and policies
6. Education and provision of information

Impact on Organizational Culture

Canadian health care organizations must develop and nurture an organizational culture that encourages open discussion of risks and opportunities for learning. One feature of this type of culture is the understanding by organizational leadership that adverse events occur when the unintended actions of individual caregivers are translated into undesired effects on patients, i.e., when error coincides with opportunity. Even highly competent and dedicated practitioners can be involved in preventable adverse events. Injury-free performance can be accomplished only by building systems that anticipate human error, not by expecting individuals to perform perfectly. Other industries, such as aviation and nuclear power, have worked diligently to develop such cultures. These industries are known as high-reliability organizations, and they share a collective preoccupation with the possibility of failure. As organizations begin to analyze critical incidents and near misses systematically, front-line staff develop a better understanding of the relationship between process and outcome, which helps them to see how underlying system factors contribute to conditions that allow errors to occur. Root cause analysis helps to develop a positive organizational culture by providing a mechanism for analyzing events that does not assign blame and that results in tangible, system-directed actions to reduce the likelihood of event recurrence. An effective root cause analysis demonstrates trust and respect for staff and patients, as well as commitment to ensuring safe patient care.

Opportunity for Shared Learning

One area where health care lags behind high-reliability industries is shared learning. Sir Liam Donaldson has been quoted as describing a scenario wherein a standard inspection revealed that an orange wire essential for the safe operation of an airplane had become frayed; an industry-wide alert was issued immediately. Donaldson then asked the question “When will health-care pass the orange wire test?”⁵ High-profile examples of medication error such as repeated deaths from incorrect administration of vincristine and concentrated potassium chloride demonstrate the recurrent nature of error in health care. The system failures that underlie error remain unrecognized in many settings; thus, when organizations undertake root cause analysis of critical incidents, sharing the learning and prevention strategies beyond the walls of an individual institution has great value for reducing the likelihood of the incident recurring in other organizations. Even if an organization has been unable to “solve” the problems identified in a root cause analysis, the sharing of experiences can be of benefit to others, who may not otherwise become aware of the underlying problem.

ISMP Canada provides training and workshops on root cause analysis and can also be contracted to assist with analysis of sentinel events. For more information, contact ISMP Canada at rca@ismp-canada.org.

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