ImproveDx

The Newsletter of the
Society to Improve Diagnosis in Medicine
Volume 3 · Number 1
January/February 2016

Root Cause Analysis for Diagnostic Error Assessment

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Patient safety problems are characterized by complexity—dynamic factors interacting and creating hazards that are often challenging to understand and prevent. Those factors, such as faulty communication, awkward computer interfaces, and poorly coordinated care, are usually attributed to the healthcare system. By fostering a culture of patient safety and Just Culture,[1] organizations encourage clinicians and others not to blame themselves and each other when things go wrong. Instead they should work together to discover and solve hazards caused by the systems in which they work.

Diagnostic errors fit the model of hazards caused by system factors but often include an additional dimension. Individuals' cognitive processes—how clinicians think—also contribute to diagnostic errors and interact with system-based problems. Although recognizing cognition as a potential contributing cause may complicate efforts to understand diagnostic errors, organizations must not avoid acknowledging and fully analyzing these problems.

Although recognizing cognition as a potential contributing cause may complicate efforts to understand diagnostic errors, organizations must not avoid acknowledging and fully analyzing these problems.

In addition to accepting the fact of human imperfection in cognition, as well as other human factors, organizations need to adapt the tools and processes used to analyze patient safety incidents to include those caused by diagnostic errors.

Root cause analysis (RCA) has been used successfully in other industries for decades.[2] It is commonly used, sometimes mandated,[3] in healthcare to analyze events of patient harm. As awareness of diagnostic error has grown, some organizations have begun to use RCA to analyze these events and offer examples for others to follow.[4,5]

Begin With a Definition

Organizations will find that deciding how to define and identify diagnostic errors is the first challenge in the RCA process. There are currently at least four accepted definitions of diagnostic error,[6] all of which have merit and should be considered. During a webcast on the topic of diagnostic errors and RCA,[7] Bob Trowbridge, MD, division director of general internal medicine at Maine Medical Center in Portland, offered a way of defining errors that alludes to the potential contribution of physicians' cognitive errors:

> *A diagnosis that was delayed or wrong that occurs when all the clinician needed to make the diagnosis was potentially there, but because either the clinician or the system or both wasn't functioning at the level of which they're capable, the diagnosis wasn't made.*

Although the Institute of Medicine (IOM) has attempted to settle on a definition of diagnostic error,[8] organizations still face the next challenge of identifying possible incidents for analysis and learning. While there should be no shortage of errors to analyze—the IOM estimates that most people will experience "at least one diagnostic error in their lifetime"[8(p1)]—most organizations will need to develop new approaches to find them. Current approaches to detecting adverse safety events aren't effective

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for diagnostic error. The Global Trigger Tool,[9] for example, is considered a gold standard for monitoring safety, but was designed exclusively to monitor treatment and the provision of care, not diagnosis. Mark L. Graber, MD, president and founder of the Society to Improve Diagnosis in Medicine, suggests organizations start by asking patients and physicians directly to report problems with diagnosis.[7] Patients are acutely aware of delays and mistakes in their care, but few organizations engage them effectively to obtain feedback. New automated approaches that use algorithms to search electronic records are another promising approach to identify patients at risk for harm from diagnostic error.[10]

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Lay the Groundwork for RCA

The National Patient Safety Foundation (NPSF) convened a panel of experts in late 2014 to evaluate the use of RCA throughout healthcare and recommend improvements. Believing that the ultimate purpose of RCA is to take action to prevent recurrence, the panel renamed the process "root cause analysis and action" or RCA^2.

The panel's report, *RCA^2: Improving Root Cause Analyses and Actions to Prevent Harm,*[11] offers direction and tools to help prioritize events, including near misses, for RCA. Because preventing future harm is the ultimate goal, first priority should go to analyzing events involving issues that pose the most risk, not necessarily those that have already resulted in the most harm.

To manage this process effectively, the report recommends using a standardized system, such as a risk matrix, and asking one person (not a committee) to manage the process. Needless to say, to include diagnosis among the adverse events considered for RCA, the individual prioritizing events must understand the problem and factors that typically contribute to these errors.

Determining if a diagnostic error has occurred and whether it was preventable or not can be difficult and may itself be subject to the cognitive biases—hindsight bias, for example— that cause diagnostic errors in the first place.

In 2005, a team of researchers analyzed cases of diagnostic error to gain a detailed understanding of how they happen in order to help guide future improvement efforts.[12] Along the way, they learned why diagnostic error is so challenging to analyze. They developed a list of 12 questions to "provide insights into recurring themes and challenges we faced, and perhaps even serve as a checklist for others to structure their own patient care reviews."[12(p263)] The 12 questions reflect the complexity of factors that must be considered when analyzing possible diagnostic errors, including:

> *What is the correct diagnosis? How much certainty do we have, even now, about what the correct diagnosis is?*
>
> *What was the physician's diagnostic assessment? How much consideration was given to the correct diagnosis? (This is usually difficult to reconstruct because differential diagnosis is not well documented.)*[12(p265)]

Assemble the Team

For diagnostic error, Trowbridge thinks the RCA team should include nurses and physicians who were directly involved in the incident being analyzed—a departure from the NPSF RCA^2 recommendations. In RCA^2, direct participants are interviewed but do not serve on the team. For diagnostic error, knowing exactly what happened during clinical encounters and what the clinicians' thought processes were is crucial and known only to those involved. While that information may be uncovered with interviews, some experts report that physicians are more likely to be actively engaged in RCA when the process is focused on diagnosis[4] than on other events, which provides an opportunity.

The RCA team should also include members with expertise in diagnosis and training in cognitive errors. Trowbridge suggests looking for a cognitive specialist among clinicians involved in medical education. With their expertise in managing clinical knowledge, medical librarians are also valuable RCA team members.[13]

Organizations should also consider including patients and family members or their representatives on the RCA team.[14] While there are examples of patient and family involvement in RCA, this remains a future goal for most organizations. Tanya Lord, PhD, is developing a program for New Hampshire hospitals that will train community members to represent patients and family members in the RCA process. They will receive training in patient safety, interview patients and families to become familiar with the event, and then play a neutral role as a member of the RCA team.[15]

Patients, community members, and other non-clinician team members, as well as frontline staff, can benefit from training focused on diagnosis, cognitive factors, and clinical reasoning. Medical trainees should also be included, to introduce them to the importance and process of quality improvement work in clinical care.

The RCA team should make sure the tools it uses in conducting the analysis allow it to fully

explore the factors that contributed to the event. Fishbone diagrams, for example, are often used by RCA teams to isolate and organize contributing factors into categories such as environment, equipment, staff members, and policies and procedures.[16] These diagrams are easy to modify by including appropriate categories for analyzing diagnostic errors. Maine Medical Center uses a fishbone framework for diagnostic errors that includes categories such as affective factors, cognitive process/faulty reasoning, and clinician support, in addition to clinical data gathering, communication, and context of care.[4(p168)]

Outpatient Settings

RCA is often performed in hospitals but rarely in outpatient medicine, where most diagnostic errors occur. The Department of Veterans Affairs (VA) health system, however, has conducted RCAs in outpatient settings since at least 2005. The VA National Center for Patient Safety conducted a study in 2013 of reports from 111 RCAs conducted between 2005 and 2012, focused on delayed diagnosis and treatment of outpatients.[5] The study findings offer important lessons for other systems but, as a traditional RCA, it focused on system factors such as electronic record systems and care coordination, not individual cognitive processes. Organizations should work on training and supporting outpatient facilities to begin using root cause analysis for all patient safety events, including diagnostic error.

Recent attention to diagnostic improvement is the impetus for these modifications in RCA, but the additional categories of contributing factors do not apply solely to diagnosis. During the NPSF webcast, Graber pointed out, "Cognitive and human factors elements arise in almost every adverse medical event. We should get in the habit of considering these things in all of our RCAs, not just the ones on diagnostic error."[7]

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'Citizen Jury' Recommends Ways to Improve Diagnosis

The Society to Improve Diagnosis in Medicine (SIDM), the Jefferson Center, and the Maxwell School of Citizenship and Public Affairs at Syracuse University are working with healthcare consumers to develop a list of the ways patients can reduce diagnostic error. The project is using a process developed by Jefferson Center's founder, Ned Crosby, PhD, to provide informed deliberation and recommendations for action on specific social issues. The centerpiece of the process is referred to as citizen juries.

The project on diagnostic error is part of a two-year study funded by the Agency for Healthcare Research and Quality.

Citizen juries are groups of between 20 and 100 people recruited randomly and selected to reflect demographics of the local area. A daily stipend and support for child care and other expenses helps remove financial hardship as a barrier to participation. The juries meet in person for a few days to learn and deliberate about a specific topic. At the end of the meeting, they issue recommendations.

The Jefferson Center has facilitated citizen juries on topics including the global implications of climate change, citizen participation in ballot initiatives, and priorities for arts programs in public schools. Among other projects, the Jefferson Center is currently working with researchers from the University of Massachusetts Medical School's Eunice Kennedy Shriver Center to develop priorities for a system to collect data about autism in Massachusetts.

The project on diagnostic error is part of a two-year study funded by the Agency for Healthcare Research and Quality with two research interests: assessing the quality of he deliberative process and discovering practical methods for reducing diagnostic error through patient engagement.

To develop a citizen jury for diagnostic error, Kyle Bozentko, executive director, and Larry Pennings, associate director of the Jefferson Center, worked with Tina Nabatchi, associate professor at the Maxwell School, and mailed recruitment materials to nearly 15,000 households in Onondaga County in central New York state. With additional digital outreach and advertising, they were able to select enough individuals for citizen jury meetings held over two three-day periods.

The first panel, numbering approximately 50 people, met at Syracuse University in August 2015. The initial session included a half-day of presentations by SIDM representatives Paul Epner and Kathy McDonald. Half of the panel had been enlisted for this education-only part of the program and were finished after completing pre- and post- surveys. The remaining participants—the citizen jury—stayed for two and a half days of further presentations, which included Helen Haskell and Peggy Zuckerman, both members of SIDM's Patient Engagement Committee. Following facilitated discussion, the jury made preliminary identification of improvement actions. In November, the same 25 people came together again for a similar three-day program. At the end of that session, they issued recommendations for actions patients can take to reduce diagnostic error, as well as barriers they may encounter in the current healthcare system. The recommendations are available on the Jefferson Center's website.

In early February 2016, a new group of 100 citizens met in Syracuse for a one-day event. They received some background information about diagnostic error and the earlier deliberations and assessed the citizen jury's recommendations for relevance and usability. In coming months, the three organizations will issue a final report on the project and the patient recommendations.

ImproveDx is a bimonthly publication of the not-for-profit Society to Improve Diagnosis in Medicine. The opinions expressed in this publication are not necessarily those of the Society to Improve Diagnosis in Medicine or its Board of Directors.