Analyzing Errors: Improve Quality, Reduce Risk by Identifying Underlying Causes

Two common methods to examine errors within patient care processes are root cause analysis (RCA) and failure mode and effect analysis (FMEA). These non-statistical quality review techniques can help clinicians and administrators gain a systemic understanding of both the what and the why of adverse patient outcomes.

This edition of inBrief® provides an overview of RCA and FMEA. An at-a-glance chart on page 4 summarizes the basic steps involved in each type of error analysis.

**CORE ELEMENTS OF RCA**

RCA is a multi-disciplinary method of analysis used retrospectively to determine why unexpected events occurred. Patient care-related RCAs typically proceed as follows:

1. **Determine the causal factors** most directly associated with the event, which may include flaws in
   - clinical protocols and procedures
   - diagnostic testing and analysis
   - equipment safety
   - facility maintenance and environmental safety
   - patient tracking and referral
   - scheduling and staffing
   - staff skills training

2. **Identify key process points** that are susceptible to error or breakdown, and ascertain their role in the event by
   - drafting an event flow diagram to define what occurred, highlighting the time and location of the event, as well as the support areas and personnel involved
   - determining primary causes of the event, both immediate and proximate
   - creating a causal chain for each of the identified primary causes (e.g., shortage of resources leads to reduced staff, which increases the likelihood of delayed environmental maintenance, resulting in a fall due to inadequate lighting)
   - summarizing findings regarding root causes, contributing factors and reasons why problems were not recognized and addressed earlier

3. **Assess the role and performance of operational areas**, such as
   - **leadership** – Does the culture foster safety-awareness and risk-reduction efforts?
   - **environmental management** – Is the physical setting safe for the process in question?
   - **human resources** – Are staffing levels adequate and employees qualified and competent?
   - **information management** – Are complete and accurate data easily and quickly accessible?

4. **Develop an action plan** to reduce the likelihood of recurrence. The plan should
   - incorporate input of knowledgeable staff members
   - address root causes and contributing factors
   - be specific and concrete, and written at a layperson’s level
   - outline action items in a clear and concise manner
   - undergo testing prior to implementation, using hypothetical scenarios

**FEATURES OF FMEA**

FMEA is a prospective methodology used to identify potential problems of a system, process or technology.* When implemented by a multi-disciplinary team, an FMEA can effectively address the following questions:

- What could go wrong, and why?
- How severe could possible adverse outcomes be?
- How can such outcomes be avoided?

FMEA can help identify the failure modes that pose the greatest risk in a process or system. It involves

- estimating the frequency of a specific adverse occurrence (O), the severity of its effects (S) and the probability of its detection (D)
- calculating the criticality index (CI) based on the formula, CI = O x S x D
- prioritizing the failure modes with the highest CI values for quality review

*(See the process chart on page 4 for additional information on calculating the CI.)*

*The U.S. Department of Veterans Affairs’ National Center for Patient Safety offers a trademarked version of the FMEA uniquely adapted to healthcare settings. It is available at www.patientsafety.gov.*
Keys to success

Effective error analysis requires enterprise-wide commitment. The following strategies can help produce better results:

- **Team structure.** Depending upon the facility’s resources, teams should include two or more employees – preferably with systems analysis experience – from the affected areas. When conducting an RCA, it is prudent to include one person without direct knowledge of the event, in order to minimize “hindsight bias.”

- **Consistent outcome measurement.** Successful analysis involves the establishment of practical outcome measures to gauge the success of safety initiatives, and the integration of these measures into risk management and quality improvement programs.

- **Meaningful reports.** Reports should employ visual analysis tools – such as flow charts and process mapping – to better document cause-and-effect relationships, illustrate root causes and organize action items into a logical sequence. In addition, reports should focus primarily not on assigning individual blame, but rather on identifying the cultural, administrative and operational factors that can negatively affect safety, such as:
  - budgetary pressures and priorities
  - chronic understaffing
  - unrealistic scheduling practices
  - lax maintenance standards
  - poor communication

- **Leadership support.** Every team should include a champion who can explain to senior leaders why error analysis increases value and how risk assessments produce a measurable return on the time and resources invested in them.

- **Avoidance of blame.** To overcome fear of reporting errors or near misses, management must demonstrate to staff that honest and timely reporting will not have negative repercussions.

- **Effective management.** For best results, teams require a facilitator experienced in the chosen method of analysis to chair meetings, compile a clear and agreed-upon action plan, and ensure that deadlines for corrective actions are met.

- **Clear communication.** Information uncovered during error analysis may be difficult to convey. A straightforward, non-accusatory, safety-focused approach to communicating errors made can help reduce distrust and encourage openness.

Healthcare delivery in any setting involves a complex sequence of steps, each of which presents opportunities for deviation. Analytical tools such as RCA and FMEA can help organizations learn from errors, identify potential system weaknesses and enhance the overall quality of patient care.

**SELECTING THE RIGHT METHOD**

RCA is well suited to determine the underlying factors of inpatient, outpatient and home care sentinel events, such as cases involving wrong patient or treatment, home fires, equipment failures, patient falls or incorrect test results. An RCA also should be conducted after a “near miss” event, such as mislabeling of a specimen or incorrect medication dosage ordered and filled but not given to the patient.

If, however, an organization is considering operational changes, or examining apparent problems in a specific clinical area, RCA should be used in conjunction with FMEA. FMEA is appropriate for:

- deciding whether to initiate or terminate a service
- addressing deficiencies identified through an audit or accreditation/licensing process
- delineating system and process functions in high-risk, error-prone procedures
- introducing a new medical record, documentation, coding or billing system
- changing medication administration procedures
- responding to incidents or managing high-risk processes as reported by healthcare organizations and regulatory agencies, such as the Institute for Safe Medication Practices’ Medication Safety Alerts or the Joint Commission’s Sentinel Event Alerts

**KEYS TO SUCCESS**

The following example – a hypothetical failure in laboratory test reporting – illustrates in simplified form how FMEA and RCA function together to help administrators detect possible system weaknesses and minimize the likelihood of future error:

- **Identify a potential failure:** Laboratory test results ordered by a physician are not reported in a timely manner, a relatively common occurrence.
- **Examine possible failure modes:** Test report is not entered into tracking log.
- **Ascertain the possible effects of failure modes:** Delay in seeking additional consultation and treatment results in worsening of patient’s medical condition, a serious and evident outcome.
- **Conduct a root cause analysis and determine the underlying problems:** Patient identifiers are not confirmed on order requisition prior to submission to laboratory.
- **Test and implement risk-reduction strategies:** Safeguards for data-entry process are revised; ordered lab tests are cross-checked against manifest of sent specimens.
- **Monitor the effect of actions implemented to reduce risk:** Laboratory specimen audit system is tracked on a monthly basis by quality assurance coordinator.
RESOURCES
- Accreditation Association for Ambulatory Health Care (AAAHC), at www.aaahc.org
- Institute for Safe Medication Practices (ISMP), at www.ismp.org
- The Joint Commission Sentinel Event site, at www.jointcommission.org/SentinelEvents/
- National Patient Safety Foundation® (NPSF), at www.npsf.org
- U.S. Food and Drug Administration (FDA), at www.fda.gov

Preliminary Stages of Healthcare Error Analysis

HAS AN ERROR OR FAILURE OCCURRED OR NEARLY OCCURRED?
(Note that the Joint Commission considers an error any unintended act, either of omission or commission, or any act that does not achieve its intended outcome.)

WHAT IS THE SUSPECTED SOURCE OF THE DEFICIENCY?
Does it stem from an oversight in any of the following areas?
- administration and management
- recruitment and hiring
- supervision and coaching
- education and training
- policies and procedures
- technology controls
- compliance planning
- auditing and monitoring

IS THE ERROR/Failure ACTIVE OR LATENT?
Is it due to the action or inaction of an individual who is directly involved in providing patient care (i.e., active), or due to an administrative or operational deficit (i.e., latent)?

IS THE ERROR/Failure DUE TO INTENTIONAL OR UNINTENTIONAL ACTIONS?
Is it due to high-risk behavior or willful violation of policy and procedure (i.e., intentional), or due to lack of skill, information, equipment or proper supervision (i.e., unintentional)?

IS THE ERROR REAL?
I.e., has it already occurred?
BEGIN ROOT CAUSE ANALYSIS
See page 4.

IS THE ERROR POTENTIAL?
I.e., is it likely to occur?
BEGIN FAILURE MODE AND EFFECT ANALYSIS
See page 4.

Comparing the Basic Elements of Root Cause Analysis and Failure Mode and Effect Analysis

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<th>ROOT CAUSE ANALYSIS</th>
<th>FAILURE MODE AND EFFECT ANALYSIS</th>
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<td><strong>STEP 1</strong> Assemble a multi-disciplinary team to collect data about the event through interviews, document review and field observation. The team should focus on determining what existing safeguards failed and whether necessary safeguards were lacking.</td>
<td><strong>STEP 1</strong> Assemble a multi-disciplinary team to collect and organize information about the process, via direct observation and staff input. Prepare an event line for the process, showing both ideal and real-world performance.</td>
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<td><strong>STEP 2</strong> Divide the event into a sequence of stages, in order to ascertain what precisely went wrong (i.e., active failures) and why the deficiency was not identified earlier (i.e., latent failures).</td>
<td><strong>STEP 2</strong> Identify subprocesses that are important from a safety or efficiency perspective, and which require review.</td>
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| **STEP 3** Analyze the data using cause-and-effect diagrams and detailed process flow charts, and answer the following questions:  
  - Why did the event occur at the specific time and location?  
  - Why were certain personnel and not others involved?  
  - Are existing safeguards likely to prevent a recurrence? | **STEP 3** Determine how these subprocesses may fail (i.e., specific failure modes). Modes to consider include  
  - equipment failure  
  - human error  
  - miscommunication  
  - unavailable supplies |
| **STEP 4** Determine the root causes of the event, progressing from special causes in clinical processes (e.g., unpredictable human error) to common causes in organizational processes (e.g., varied levels of training among staff). Solicit input from providers and staff members to determine the clinical, administrative and operational factors most directly associated with the event. | **STEP 4** For each failure mode, define how the failure could affect patient safety and disrupt the overall process. |
| **STEP 5** Identify clinical, administrative and/or operational deficiencies that require correction, as well as potential improvements to the process or system. Incorporate recognized patient safety standards and benchmarks, if applicable. | **STEP 5** Using a scoring matrix, rank failure modes according to  
  - detectability – from 1 (immediate detection) to 5 (remote detection).  
  - probability – from 1 (highly unlikely) to 5 (almost inevitable).  
  - severity – from 1 (slight patient harm) to 5 (permanent patient harm).  
  (See the National Center for Patient Safety sample matrix at www.va.gov/ncps/SafetyTopics/HFMEA/HFMEA_SAC.html.) |
| **STEP 6** Implement changes, including staff training and redesign of process features. The following system improvements, among others, should be considered:  
  - Alert staff more rapidly to patient compromise.  
  - Automate the process when possible.  
  - Incorporate equipment safeguards to mitigate potential harm.  
  - Standardize the steps of the process. | **STEP 6** Compute a criticality index (CI) for each failure mode by multiplying the frequency of the specific adverse occurrence (O), the severity of its effects (S) and the probability of its detection (D).  
  Apply this formula: CI = O x S x D |
| **STEP 7** Prioritize the failure modes with the highest CI, severity and severity x probability score. Then, determine the root causes of the high-priority failure modes, as noted in RCA Step 4. | **STEP 7** Recommend redesigned safeguards within the process that support prevention and mitigation. Test process changes through hypothetical scenarios and measure for desired outcome before implementation. |

For more information, please call us at 888-600-4776 or visit www.cna.com/healthpro.