Healthcare

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Adverse Event Review: Enhancing Analysis, Safeguarding Data

By carefully reviewing clinical errors, aging services administrators and caregivers can improve processes and help prevent recurrence. One established means of investigating adverse occurrences is *root cause analysis* (RCA). RCA offers a consistent, structured approach to examining incidents, and should be incorporated into every facility's resident safety and quality improvement efforts. For those facilities certified to participate in the Medicare program, RCA also serves as an integral element of quality assurance and performance improvement (QAPI) programs, which are a condition of Medicare participation.

Investigative methods such as RCA can help reveal hazards and process flaws, thus reducing liability exposure. However, these techniques also involve creating potentially sensitive reports. If such documents and associated data are not managed appropriately and protected against disclosure, they may ultimately be used against the organization in the event of litigation.

This edition of *AlertBulletin*® focuses on adverse event management, including strengthening reporting and review processes, as well as developing techniques to safeguard quality improvement data from legal discovery. This issue addresses the following specific topics:

- **Essential components** of the RCA process.
- **Common events** requiring investigation and reporting.
- **Effective methods** to improve adverse event review.
- **Strategies for protecting safety-related data** when sharing it both internally and with outside entities, such as professional liability (PL) insurance companies and patient safety organizations.

The RCA Method

Root cause analysis (sometimes referred to as root cause analysis and action, or RCA2*) is a multidisciplinary system analysis technique that can help providers and administrators understand both the *what* and the *why* of clinical errors. Resident care-related RCAs typically include five components, as depicted on page 2.

Reportable Events

Aging services settings that participate in Medicare and/or Medicaid are required to compile and report resident safety-related information to state regulatory agencies. A written protocol should guide decisions about the types of adverse events that require reporting and review, generally including situations involving serious harm to residents or staff, recurring incidents, clinical error and events that attract media attention.

Reportable events – many of which also should undergo RCA and review by safety and quality improvement programs – include the following:

- **Injuries due to falls** or wandering/elopement.
- **Resident-on-resident altercations** and other acts of violence.
- **Serious burns** caused by spills, immersion or smoking.
- **Poisoning** subsequent to ingestion of dangerous chemicals or drugs.
- **Medication errors** leading to harm.
- **Abuse and neglect** by caregivers or other residents.
- **Acute changes in condition** that go unnoticed.
- **Pressure injuries** potentially reflecting inadequate care.
- **Errors in infection prevention** and control.

* See *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm*. Issued by the National Patient Safety Foundation, 2015.

Components of Root Cause Analysis

Event Selection and Risk Prioritization

Select a sentinel error or adverse medical event and determine whether a root cause analysis is required.

Ascertain if the event stems from an operational oversight, involving education/training, recruitment/hiring, administration, information management or other key areas.

Assemble a multidisciplinary team knowledgeable about the issue or process under examination.

Fact-finding

Direct the team to collect data about the event through interviews, document and equipment reviews, and field observation, focusing on the absence or ineffectiveness of procedural safeguards.

Divide the event into a sequence of stages in order to identify what went wrong (i.e., active failures) and ascertain why process deficiencies were not identified earlier (i.e., latent failures).

Causal Link Analysis and Root Cause Identification

Analyze the data using cause-and-effect diagrams and detailed process flow charts, focusing on the following questions, among others:

- **Why did the event occur** at the specific time and location?
- **Who was involved** in the event, and why those individuals rather than others?
- **What were the primary causes** of the event, both immediate and proximate?
- **What was the causal chain** for each primary cause (e.g., high turnover contributed to staff shortages, which in turn led to delayed response to resident requests, resulting in an unsupervised resident fall)?
- **Have improvements been implemented,** and are they likely to prevent a recurrence of the error?

Determine the root cause(s) of the error, progressing from clinical events (e.g., unpredictable human error) to systemic issues (e.g., training deficiencies among staff).

Identify risk factors most directly associated with the event, which may include flaws in clinical protocols, equipment safety, facility maintenance, scheduling and staffing, and skills training, among other areas.

Corrective Action

Develop an action plan to reduce the likelihood of recurrence. The plan should …

- **Incorporate a wide range of input** from staff members.
- **Address root causes** as well as contributing factors.
- **Be logically organized,** specific and concrete, and written as clearly and simply as possible.
- **Undergo testing** prior to implementation, using hypothetical scenarios.

Implementation and Outcome Measurement

Enact changes, including staff training, redesign of process features and adoption of equipment safeguards.

For each corrective action, identify outcome measures to be used, as well as the frequency of measurement and the individual(s) responsible for reporting results to senior management.

Error Analysis Strategies

Numerous resources offer specific advice on performing successful RCAs (see Quick Links for a selection). Thorough and effective error analysis requires broad input, as well as multidisciplinary, organization-wide collaboration. The following strategies and techniques can help enhance the RCA process and results:

Leadership education. Explain to ownership and senior management why error analysis represents an essential risk management function, and how it produces a measurable return on the time and resources invested in it.

Team structure. Depending upon the facility's size and scope, RCA teams should comprise from six to eight employees, representing a range of expertise and experience. Include at least one individual without direct knowledge of the event, in order to minimize "hindsight bias," which may occur when team members involved in an event perceive it afterwards as more predictable than it actually was, thus leading to an oversimplified analysis. (For additional information on team selection, click here.)

Clear problem statements. Initiate the review process with a clear, specific, focused and unambiguous problem statement, e.g., *"Resident X missed three of seven medications on the afternoon shift for four consecutive days."* A sound problem statement is factual and objective, accurately describing situations without assessing causes, assigning blame or offering commentary.

Meaningful reports. Reports should employ visual analysis tools – such as flow charts and process maps – to capture cause-and-effect relationships, illustrate proximate and root causes, and itemize action directives. Remember that reports should focus not on assigning individual blame, but rather on identifying the cultural, administrative and operational factors that can negatively affect safety, such as communication breakdowns, unrealistic expectations and conflicting organizational priorities. The "Five Whys" analysis technique, which involves posing sequential "Why?" questions, can help reviewers examine the root causes of an error.

Effective outcomes measurement. In order to evaluate the success of safety initiatives, useful metrics must be devised, implemented, and integrated into risk management and quality improvement programs. The following questions can help guide the process of creating a sound outcomes assessment process:

- *What safety-related quantities, percentages or rates should be tracked (e.g., the number of residents who undergo a complete skin assessment within 12 hours of admission)?*
- *What are the current outcomes?*
- *What are the desired outcomes?*
- *What is the timeline for achieving the desired outcomes?*

Constructive communication. To be useful, information revealed during the error analysis process, however pejorative, must be shared with others. A straightforward, non-accusatory, resident-focused approach to reporting findings can help minimize potential defensiveness and discord; strengthen openness and rapport; and sustain a constructive, safety-oriented atmosphere and culture. For a communications plan worksheet issued by the Centers for Medicare & Medicaid Services, click here.

Protected Work Product

Patient Safety Organizations (PSOs) are federally designated bodies designed to create a secure environment where providers and administrators may collect, analyze and share resident safety data without being subject to legal discovery. As a condition of Medicare participation, many aging services organizations partner with a PSO, thereby obtaining certain legal protections granted by the Patient Safety and Quality Improvement Act of 2005 (PSQIA). RCAs and other resident safety-related reports, records, memoranda, analyses, and written or oral statements are generally considered "resident safety work product" and, as such, are protected from disclosure under the PSQIA.

In order to qualify as protected work product, RCA and other QAPI-related deliberations must be clearly dated and conducted within the structure of a resident safety evaluation system. For example, if an RCA is performed to determine the reason for an error, but the findings are not reported to the PSO, the information it includes may be discoverable, depending upon state laws.

Documents clearly labeled as protected work product are typically not subject to disclosure by the Centers for Medicare & Medicaid Services and state or other surveyors. However, these parties may have access to non-protected documents, including resident, billing and discharge records, as well as action plans or corrective actions taken as a result of an evaluation.

Note that whether or not a setting enjoys PSO- or QAPI-related confidentiality protections, RCA is a valuable tool that should be incorporated into resident safety and quality improvement efforts. In a non-QAPI context, it may be possible to shield RCA and other safety-related data from disclosure via attorney-client privilege or other traditional legal protections.

Thorough and **effective error analysis requires broad input**, as well as multidisciplinary, organization-wide **collaboration**.

Data Sharing Safety

Adverse occurrences should not be treated as isolated events, discussed only within the unit, floor or department where the event occurred. Instead, findings should be shared across the enterprise, so that all staff may benefit from lessons learned. However, widespread dissemination raises concerns about discoverability of documents and reports.

The following basic principles can help protect the confidentiality of safety-related information when it is shared internally or with authorized external parties, such as PL insurance company representatives:

- **Documents prepared within an organization's established QAPI system typically qualify as protected resident safety work product**, and should be clearly labeled as such. As noted above, facilities lacking a formal QAPI process may be able to safeguard potentially compromising reports from discovery using other legal protections.
- **Incident reports, in general, are *not* viewed as work product** because they are produced in the ordinary course of business or in response to state regulatory requirements, rather than being generated solely for resident safety and quality improvement purposes.
- **Standard incident report forms should be used solely for initial documentation.** If additional investigation becomes necessary following a serious injury, a separate report should be created, stored and secured similar to other quality control-related documentation and shared only with legal counsel and/or PL insurance company representatives.
- **Risk management reviews precipitated by a resident's/family's/guardian's declared intent to sue may be protected by the attorney-client work product privilege**, which applies to materials created by risk managers for use by legal counsel in anticipation of litigation.
- **Risk-related reports and other documents shared with PL insurance company representatives should be conspicuously marked as such**, in order to assert protection under the attorney-client work product privilege.

Analysis of adverse events is a pillar of risk management and quality improvement efforts. The suggestions presented herein are intended to help leaders evaluate and enhance the incident reporting and review processes of their organizations, as well as to better understand the rules regarding confidentiality of documentation used for quality and safety purposes.

Quick Links

- "Guidance for Performing Root Cause Analysis (RCA) with Performance Improvement Projects (PIPs)," issued by the Centers for Medicare & Medicaid Services.
- Gupta, K. and Lyndon, A. "Rethinking Root Cause Analysis." *Annual Perspective*, January 1, 2016. Published by the Patient Safety Network (PSNet).
- "Root Cause Analysis in Aging Services," a white paper issued by ECRI.
- "Root Cause Analysis (RCA) Step-by-Step Guide." VA National Center for Patient Safety, revised July 1, 2016.

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