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ISMP

Long-Term Care
Advise ERR™

Educating the Healthcare Community About Safe Medication Practices

Building your error investigation skills

Common pitfalls when conducting a root cause analysis

Healthcare professionals in long-term care (LTC) may be acquainted with the root cause analysis (RCA) process and may have participated in one or more in the past since regulatory and accreditation bodies often require its use to investigate sentinel events (adverse events that reach the patient and result in death, permanent harm, or severe temporary harm). RCA is the most basic type of event investigation; an analytical approach to problem solving that seeks to identify *numerous* contributing factors as to why an adverse event happened and how to establish effective safeguards to prevent the same type of error from happening again. The process is also valuable for potentially serious, non-sentinel adverse events.

Through our consultation services, ISMP has had an opportunity to conduct and review many RCAs associated with medication-related events. While we have seen a steady rise in the use of this method for the evaluation of errors and close calls that could lead to a severe adverse or sentinel event, we continue to observe common pitfalls encountered while conducting a RCA, often rendering the process less useful than it could be. Several of these pitfalls are described below.

Skipping the chronology

Many RCAs do not include a sequence of events, flow chart, and/or narrative that adequately describes what actually happened. To be effective, a RCA must start with identification of the undesirable outcome, and then an accurate sequence of events and timeline that led to the outcome, to help uncover all the gaps where human error or unsafe behavioral choices were made. This helps ensure that all aspects of the event are analyzed. Although developing an event chronology is time consuming, it is a step that should not be skipped despite a desire to quickly "get to the bottom" of the event or "jump to a solution."

Reliance on policies and procedures

Some RCAs fail to uncover "real life" conditions that led to an event because the team relies too much on what is written in policies and procedures to illustrate what happens when care is provided. **Table 1** lists basic questions that should be answered during a RCA. Question #2—What normally happens?—is often skipped, and the team moves on to Question #3—What do the policies and procedures require? Knowing what normally happens—the "real life" practices—helps determine the reliability of current processes and how often staff cut corners to get the work done. ISMP has also observed over-reliance on policies and procedures by some regulatory and licensing agencies that investigate events. When these agencies issue no citations because the policies and procedures appear to be perfect on paper, the organization or RCA team may feel compelled to simply educate staff to just follow the existing policies and procedures instead of digging deeper into the problem.

Table 1. Basic questions to answer during a RCA

What happened?
What normally happens?
What do policies/procedures require?
Why did it happen?
How was the organization managing the risk before the event?

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Severe underdosing of insulin with U-500 pen. An emergency department (ED) pharmacist was talking to a patient about his U-500 insulin dose. The patient, who had been using a U-500 insulin pen, told the pharmacist that his dose was 75 units but proceeded to show the pharmacist how he turned the dose knob on the pen to "15" to deliver each dose. The patient thought his physician had told him to dial to "15" to deliver 75 units of insulin, but he was only receiving 15 units of the insulin.

Before U-500 syringes or pens were available, patients using U-500 insulin were commonly taught to use a U-100 insulin syringe and to measure their dose in "syringe units," meaning the U-100 scale was used for dose measurement, but the actual dose was 5 times more than the measured dose. Thus, before using the U-500 insulin pen, the patient had been drawing up his U-500 insulin from a vial into a U-100 syringe, measuring the dose to the "15" units mark to deliver a dose of 75 units. Now that a U-500 insulin pen had been prescribed, the patient did not know that the actual dose of 75 units needed to be set on the dose knob, not "15" units.

Dangerous underdosing with a U-500 insulin pen should be considered in residents who exhibit severe hyperglycemia or diabetic ketoacidosis, especially if the dose prescribed was based on an admission history. Patient and provider confusion about the dose is common when patients have previously used a U-100 syringe to inject U-500 insulin.

Nurse order entry error. A physician wrote an order for a hospice patient for morphine sulfate concentrated oral solution 100 mg per 5 mL, 5 mg (0.25 mL) every 4 hours sublingually as needed for shortness of breath. The nurse called the pharmacy right away to request the morphine 100 mg per 5 mL oral solution, promising

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Failure to conduct at-risk behavior investigation

RCAs often fail to closely examine the quality of behavioral choices that led up to an error, a critical omission. When an event involves staff who use workarounds, breach a policy, or did not follow a procedure, the conditions that led to these at-risk behaviors are rarely investigated. This means the incentives that encourage the behavior and the unintended consequences that discourage safe behavior may not be uncovered and addressed. Instead, the investigation stops with the identification of the workaround or breached policy, which often results in punitive action for the individuals directly involved in the event. Each at-risk behavior should always be investigated further to determine its causes, which most often reside in the organization's culture and design of systems.

Failure to conduct human error/human factors investigation

The investigation of an event sometimes ends when "human error" or "a knowledge deficit" has been identified as the cause. However, a human-error investigation should always occur to uncover any preexisting performance shaping factors (e.g., task complexity, workflow, time availability/urgency, process design, experience, training, fatigue, stress) or other environmental conditions, system weaknesses, or equipment design flaws that allowed the error to happen and reach the resident. The investigation is incomplete if it ends with human error as the root cause because it fails to uncover how the system may have contributed to the error—information that is critical when planning the redesign of systems.

Failure to identify deep-seated latent failures

Many RCAs do not dig deep enough to uncover the deep system-based causes of events, or latent failures. To learn about latent failures, probing questions must be systematically asked about how the organization was managing information, the environment, human resources, equipment/technology, and associated human factors at the time of the event. See **Table 2**, on page 3, for examples of probing questions for drug events.

Failure to seek outside knowledge

RCA teams may get so involved in analysis of the specific event that they fail to recognize the value of looking outward for similar occurrences or related literature to see what could be learned. Internal error databases might uncover related events that have not led to harm, which can help clarify risks. Also, professional literature, including research and anecdotal case reports, often helps in the analysis of the event and the selection of high-leverage, evidence-based, risk-reduction strategies. Applicable regulations, standards, professional guidelines, and consultation with clinical and safety experts can greatly enhance the RCA process and lead to success with interventions. We have also encountered RCA teams that are so entrenched in discussions that they fail to move out of the meeting room to visit the clinical areas involved in the event to observe the environment and normal processes firsthand or conduct a simulation of the event, when possible.

Not linking the causation to the actions

The RCA action plan sometimes fails to clearly show a link between the proposed actions and the causative factors. To achieve buy-in for the action plan, it is important for administration and staff to be able to follow the logic of the RCA team. Each intervention should be clearly linked to one or more causative factors. Another issue is the veil of secrecy under which most RCAs are performed. Although confidentiality is important during a RCA, enough information needs to be shared with staff so they understand the purpose and importance of the changes that they will be required to implement.

Selecting weak risk-reduction strategies

The most effective risk-reduction strategies involve redesigning systems to make them more resistant to human error, and enabling staff to make safe behavioral choices by

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to send an electronic order soon afterwards. The pharmacy dispensed the medication as requested, and the nurse then attempted to enter the order into the electronic health record (EHR). But she could not find the prescribed strength of morphine from the pull-down menu of available morphine products. Feeling rushed, she selected what she thought was closest to the prescribed strength, "morphine sulfate solution 10 mg/5 mL," and added the instructions, "2.5 mL (5 mg)" in the resident's record. Then, in her haste, she selected "SC" (subcutaneous) for the route of administration. This information was transmitted to the pharmacy and also appeared on the electronic medication administration record (eMAR).

When the pharmacist received the electronic order, she called the nurse to question it, at first focusing on the wrong route of administration. During the discussion, the pharmacist also learned that an improvised strength of morphine had been selected since the desired strength could not be found, and that the volume (2.5 mL) listed in the comments section had been based on the improvised strength of morphine, not the strength of the morphine pharmacy had dispensed. In addition, the pharmacist learned that the order had been entered by the nurse and never verified. The pharmacist thought the electronic order had been entered by the prescriber because the facility's EHR automatically placed the name of the physician in the field, "doctor signed electronically."

The nurse didn't recognize the ramifications of entering an order that did not match exactly what the physician ordered and what the pharmacy dispensed. If another nurse had followed the instructions on the eMAR to administer 2.5 mL, a 10-fold overdose could have occurred. Fortunately, the order was quickly corrected before the drug was administered, and a potential error was adverted.

ISMP strongly recommends that physicians enter orders directly into electronic prescribing systems, thus avoiding the extra step of requiring nurse order entry. Also, some electronic prescribing systems are

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Table 2: Probing questions to identify proximate causes of medication events* with examples

Was critical information about the resident missing or unknown?
Age, sex, measured weight (kg), height, allergies, vital signs, lab values, resident location and identity, diagnosis, chronic conditions (e.g., renal/liver impairment), swallowing issues/presence of a feeding tube, ability to pay for prescriptions, medication reconciliation upon admission/transfer/discharge
Was critical information about the drug missing or unknown?
Maximum dose, typical dose, mg/kg dose, route, precautions, contraindications, special warnings (e.g., do not crush), drug interactions, cross allergies, availability of drug references, computer screening, pharmacist not accessible to provide drug information, availability/use of protocols/order sets
Was written or verbal information miscommunicated or not communicated?
Illegible, ambiguous, incomplete, misheard, or misunderstood orders or medication administration record (MAR/eMAR) entries, nonstandard documentation/communication, intimidation, unclear transmission of orders, failure to communicate, incomplete handoff, warnings bypassed, error-prone abbreviations or dose expressions
Was there a drug name, label, or packaging problem?
Look-/sound-alike names, look-alike packaging, unclear/absent labeling, faulty drug identification, pharmacy labeling issue, label that obscures information, label not visible, warning labels missing/inconsistently applied
Was there a problem with how the drug was acquired, stored, dispensed, or delivered?
Turnaround time, taking drug from emergency box/kit, borrowed medication, pharmacy delivery issue, dose missing/expired, multiple/nonstandard concentrations, bulk drug supplies, lack of patient-specific dosing, access to hazardous chemicals/unauthorized access to drugs, nurse preparation
Was there a drug delivery device problem?
Device design flaw, unsafe default settings, device unavailability, device not functioning, device maintenance, failure to use available technology, line mix-ups/misconnections
Were there problems in the physical environment, staffing patterns, workflow, or supervision?
Lighting, noise, clutter, organization of unit, physical barriers, foot traffic, interruptions, staffing levels and skills, work schedules, inadequate supervision, supervisory support issue, inadequate breaks, workload and shift patterns, inefficient workflow and bottlenecks, employee safety
Did lack of staff education play a role in the error? Was there a knowledge deficit?
Inexperience, orientation, competency validation, new or unfamiliar drugs/devices, feedback about safety/hazards/errors/prevention, widespread knowledge deficit, low compliance with mandatory education, required certification, support for advanced certification and education
Did lack of resident education play a role in the error? Was there a knowledge deficit?
Lack of information, non-adherence, not encouraged to ask questions, lack of investigating inquiries, incomplete discharge instructions, complex drug regimen, medication reconciliation problem, health literacy/language barrier or other communication problem, intimidated by staff, mental health issue
Were there issues related to quality control or independent verification systems?
Equipment quality control checks, manual independent double-checks for selected high-alert drugs/high-risk patient populations
Did elements of the organizational/facility culture contribute to the error?
Fear of retribution, management of behavioral choices, focus on productivity and volume throughput, feedback about errors, regulatory conditions, financial resources/constraints, organizational priorities
Other human factors issues (staff and resident)?
External examples: task and information complexity, ergonomics, time urgency, familiarity with task/product/equipment; Internal examples: mental/physical health of staff/patient, fatigue, fitness for duty/self-administration, stress, motivation
Other technology/supply issues?
Technology workaround, technology malfunction, design flaw, misinterpretation, user error, technology and devices not meeting needs, information access and drug security issues

**Adapted from ISMP's Key Elements of the Medication Use System™ and the ISMP Assess-ERR™, a Medication Safety Worksheet available at: www.ismp.org/Tools/AssessERR.pdf. Issues identified using the above questions represent proximate causes requiring additional analysis.*

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set up to only issue alerts to prescribers if the safety of a medication order is in question (e.g., dose exceeds a safe maximum, serious drug interaction). If nurses must enter orders into prescribing systems, they must have a clear understanding of the process; avoid improvised selections, edits placed in the comments section, or shortcuts; and enter orders without being rushed.

As occurred in this case, a copy of the prescriber's order should also be sent to the pharmacy to serve as a double-check so the accuracy of nurse order entry can be verified. Ideally, this should occur before the pharmacy dispenses a medication to the Long-Term Care (LTC) facility. ISMP is also opposed to an "auto verification" process in which the physician's signature appears on nurse-entered orders before they are verified. Finally, work with your EHR vendor to ensure that drug descriptions on pull-down menus are clear to make selection easier.

Resident dies from oxyCODONE overdose. In February, we received a report of a long-term care (LTC) resident who died after having received 20 times the prescribed dose of oxy**CODONE**. The resident, who had cancer and chronic obstructive pulmonary disease, had been admitted to the LTC facility with an order for oxy**CODONE** concentrated oral solution 20 mg per mL, with directions to give 20 mg orally every 4 to 6 hours as needed for pain rated as 5 to 7 on a scale of 1 to 10, and 30 mg orally every 4 to 6 hours as needed for pain rated as 8 to 10 on the pain scale. The LTC pharmacy dispensed a bottle of oxy**CODONE** concentrated oral solution 20 mg per mL. The nurse was more familiar with regular strength oxy**CODONE** oral solution (1 mg per mL) and failed to verify the concentration when she became distracted by other residents. She administered 30 mL of the concentrated oxy**CODONE**, a 600 mg dose. The resident was later found unresponsive on the floor of his room and pronounced dead by emergency medical service professionals (paramedics).

To prevent this type of tragedy, nurses should make sure the drug concentration is listed on the medication administration record (MAR) for all orders. Also, the nurse should verify the concentration on both

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removing the system- and cultural-based incentives for cutting corners. Yet, developing new rules and educating staff—considerably weak although necessary interventions—are among the most common risk-reduction strategies found in RCAs. Next in line is often a manual downstream double-check that does little to prevent the errors upstream. Strategies that rely heavily on human memory and vigilance are much weaker than strategies that prevent staff from carrying out tasks the wrong way, "force" them to carry out tasks the correct way, or involve automation to provide just-in-time decision support, verify accuracy, and halt progress when errors are likely to be made. Layering action plans with multiple strategies helps ensure success.

Failure to carry out the action plan and measure success

A RCA is only useful if it results in positive change. Yet, we sometimes encounter RCA action plans with critical interventions that have not been implemented or are without realistic strategies for future implementation. Progress with reaching goals has not been monitored, and a structured format does not exist to support implementation of the action plan and to monitor accountability. Some changes that have been implemented are later abandoned because they were designed without consideration of the workflow, barriers were encountered and not addressed, and the reason for change was not clearly communicated to staff. Staff members require motivation to initially implement change, and data that links the change to positive resident outcomes to sustain the change. Some interventions need to be tested on a small scale and revised as necessary, and then spread throughout the organization in all applicable areas. Even the best laid plans don't always work out; if that happens, the RCA team needs to develop new ways to deal with the identified risks.

Focus too narrow

Sometimes RCA teams don't look broadly enough at the risks they uncover to determine if the same risks are present in other parts of the organization, or among other similar processes of care. For example, a deadly mix-up between look-alike products in one area of the facility could happen in another area of the facility. Yet, we often see interventions targeting just a single unit, service, or department. Or the RCA team may not address other procedures within the organization that are similar to the ones that were not followed. Once risks are identified, the focus that was appropriately narrow during the initial analysis of the event needs to widen to analyze the same or similar risks throughout the organization and among other care processes. Likewise, interventions addressing these risks should not be narrowly defined for implementation only in the immediate area involved in the event.

Unjust punitive action

Some RCAs have been weakened by unjust punitive action taken against involved staff. This is largely due to hindsight bias and a prevailing but unfair practice in healthcare in which the resident's outcome dictates the degree of punishment. We have also observed organizations holding the involved staff accountable for duties that did not exist before the event or were not applicable given the situation, such as performing a double-check that might have averted the bad outcome but was not a required procedure, or calling a physician when the individual was unaware conditions warranted such an action. In either case, the RCA team is more inclined to focus on shortcomings of the individuals and less inclined to uncover system causes of these actions.

Conclusions

These problems associated with RCA are not surprising given the lack of well-designed patient safety and quality improvement curricula available to healthcare professionals during their training and post-graduation. Many learn the science and skills associated with quality improvement and patient safety—including RCA—through informal, on-the-job training. Some attend workshops, but when they leave or are reassigned, it is often assumed new staff are familiar with the process. Little has been done to prepare healthcare professionals to anticipate, identify, analyze, and resolve resident safety problems.

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the medication container and MAR before administration. When concentrated products are dispensed, pharmacists should highlight the concentration on the label and the MAR (if created by the pharmacy), and affix a warning label to the bottle indicating its concentrated strength.

Estimating volumes for narcotic counts. A long-term care (LTC) nurse reported that the sight gauge on the side of a 30 mL bottle of Morphine Sulfate Oral Solution (100 mg per 5 mL), by Westward Pharmaceuticals, was unusable because the medication was clear and the bottle was opaque (**Figure 1**). The clear medication could not be easily seen on the sight line (**Figure 2**) and, therefore, an accurate estimate of the remaining volume of medication could not be determined for the narcotic count at each change of shift. The nurse said she had to empty the medication into a graduated cylinder to determine the remaining amount to record on the narcotic record. She expressed concern about the extra time needed to do this, the risk of spills, the potential loss of volume from transferring the liquid to another container to measure the volume, and potential contamination of the product. She thought the liquid medication should be a distinctive color so it would be easier to see the amount left in the bottle on the sight gauge.

Figure 1: Opaque bottle of Morphine Sulfate Oral Solution (100 mg/5 mL) by Westward Pharmaceuticals.

Figure 2: Sight line making accuracy of measuring the remaining amount of clear solution inside difficult.

In the past, surveyors from the Centers for Medicare & Medicaid Services (CMS) had required exact amounts of remaining liquid medications to be recorded, but this was met with a lot of resistance for the same

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We hope the observations described above will prompt organizations to think critically about their RCA process and make changes, when necessary, to ensure that the results improve resident safety. For more information about conducting an effective RCA, read the National Patient Safety Foundation *RCA²—Improving Root Cause Analyses and Actions to Prevent Harm* (www.ismp.org/sc?id=3097). For information about how ISMP can help your organization conduct a RCA, go to: www.ismp.org/Consult/default.aspx.

Label confusion with Stalevo

The anti-Parkinson's drug **STALEVO** is a combination product that contains levodopa, carbidopa, and entacapone. The drug is labeled Stalevo 50, Stalevo 75, Stalevo 100, Stalevo 125, Stalevo 150, and Stalevo 200. The numbers that follow the brand name Stalevo correspond to the dose of levodopa in each tablet. The entacapone dose of 200 mg remains the same in all tablet strengths, but the amount of carbidopa is not listed as part of the name even though it also changes.

In the Stalevo strengths listed above, the carbidopa strength is increased respectively as follows: 12.5 mg in Stalevo 50, 18.75 mg in Stalevo 75, 25 mg in Stalevo 100, 31.25 mg in Stalevo 125, 37.5 mg in Stalevo 150, and 50 mg in Stalevo 200 (**Table 1**).

The method of expressing Stalevo tablet strengths is confusing and error prone. For example, a patient who had been taking Stalevo 100 at home was admitted to the hospital. That strength tablet was not available in the hospital. The pharmacist was not familiar with the Stalevo products and did not know the various strength combinations. A bottle of Stalevo 50 was available so he dispensed two tablets of Stalevo 50 for the patient's dose of Stalevo 100. Two Stalevo 50 provided the correct amount of carbidopa (25 mg) and levodopa (100 mg), but twice the intended amount of entacapone (400 mg). Two doses were given before the patient exhibited agitation, which eventually led to discovery of the error. The dose was corrected, and the patient experienced no further problems.

Another confusing issue with Stalevo is that, when a prescription for Stalevo 50 is received, one can't tell if the 50 refers to the carbidopa or levodopa component since there is a tablet containing 50 mg of levodopa (Stalevo 50) and another containing 50 mg of carbidopa (Stalevo 200). The medication should instead be labeled similar to other carbidopa-levodopa products (e.g., **SINEMET**), which includes both drug strengths in association with the product name (e.g., Sinemet 25-100 contains 25 mg of carbidopa and 100 mg of levodopa).

Table 1. Content of levodopa, carbidopa, and entacapone in each strength of Stalevo

Product	Levodopa (mg)	Carbidopa (mg)	Entacapone (mg)
Stalevo 50	50	12.5	200
Stalevo 75	75	18.75	200
Stalevo 100	100	25	200
Stalevo 125	125	31.25	200
Stalevo 150	150	37.5	200
Stalevo 200	200	50	200

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reasons expressed by this nurse. As a result, CMS issued a guidance letter to State Survey Agency Directors in 2015, and then revised the State Operations Manual, Appendix PP—Guidance to Surveyors for Long Term Care Facilities (Rev 11-22-17) (www.ismp.org/sc?id=3066). On page 462, of Appendix PP, the guidance states:

Liquid controlled medications are often dispensed in multi-dose containers which indicate approximate volume. The containers may also be opaque to protect the medication from light. It should be noted that absolute accuracy in tracking volume and use of liquid controlled medications may not be possible.... The general standard of practice for documenting usage of liquid controlled medications is to record the starting volume from the label, record each dose administered, subtract the dose administered from the previously recorded volume, and record the remaining amount.

Therefore, there is no need to use a graduated cylinder or other means to measure liquid oral controlled substances during the narcotic count at change of shift.

Special Announcement

ISMP releases third video newsletter. ISMP, in conjunction with Temple University, has released the third in a series of "video newsletters" featuring short interviews with medication safety experts and a summary of top content from the *ISMP Medication Safety Alert!* newsletter. This video focuses on: safe administration of concentrated insulin products, errors with confusing product labeling, and educating patients/residents about safe medication practices. To view the video, please visit: www.2020visualmedia.com/ismp.

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