Rooting Out Errors in Your Pharmacy

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Supporter

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Disclosures

• Donna Horn and Karen Ryle declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Learning Objectives

• Target Audience: Pharmacists and Pharmacy Technicians
• ACPE#: 0202-9999-16-051-L05-P
  0202-9999-16-051-L05-T
• Activity Type: Knowledge-based

• Describe how to analyze a medication error using a specific set of steps and associated tools to identify the contributing factors and root causes of the event.
• Specify how to use information gathered during a Root Cause Analysis (RCA) to minimize the reoccurrence of medication errors.
• Prepare an action plan from the RCA which includes risk-reduction strategies, communication, and implementation strategies as well as ways to measure effectiveness.
• Identify common pitfalls that may occur during an RCA.
• Explain how the use of technology can help prevent medication errors from occurring.
Self-Assessment Question 1
What is the first step for conducting a Root Cause Analysis?
   a) Create a flow chart
   b) Formulate a team
   c) Develop an Action Plan
   d) Identify root-reduction strategies

Self-Assessment Question 2
All adverse events that occur at the pharmacy must be investigated using the RCA method
   a) True
   b) False

Self-Assessment Question 3
Which statement is false in regards to a successful RCA?
   a) Continuously asks 'why' until all root causes have been identified
   b) Focuses primarily on individual performance
   c) Identifies changes to reduce the risk of reoccurrences or close calls
   d) The RCA team includes organization's leadership and individuals closely involved in the incident

Self-Assessment Question 4
All of the following basic questions must be asked during the RCA process but which is the most critical to answer?
   a) What happened?
   b) What normally happens?
   c) What do the policies and procedures require?
   d) Why did it happen?

Self-Assessment Question 5
When an event involves staff who cut corners, breach a policy, or did not follow a procedure, the RCA process can be stopped since the root cause leading to the error event has been discovered.
   a) True
   b) False

Case Study
• It is a Friday afternoon
• Pharmacist-in-charge had a stroke
• Pharmacist covering is from a temporary agency
• The technician has left for the day (from out of state)
• One pharmacist on duty
• This is his first full week working in the pharmacy
Case Study

- “Martin” went to the pharmacy to refill his prescription
- Ziprasidone 20 mg #120
- Take one cap in the morning and 3 caps in the evening
- Total dose = 80 mg
- The pharmacist told Martin that he did not have enough of the medication but would give him some to “hold him over”
- Martin received #30 Olanzapine in the bottle labeled Ziprasidone
- Martin took the wrong medication following the directions on the label for approximately 1 week

Meet the Patient

- “Martin” is a 48 year old male
- Diagnosed with Schizophrenia
- Currently working nights delivering luggage
- Loved by his family, friends and co-workers
- Lived with his parents, saving up for an apartment to live on his own
- Enjoyed his nieces and nephews and Kentucky Fried Chicken
- Stable on Ziprasidone 80 mg for over 6 months
- Extremely compliant with his meds

Meet the Pharmacist

- “Richard”
- 10 years experience in a chain pharmacy
- “Worst mistake I have ever made in my life”
- Had minimal knowledge of the pharmacy operating system
- He did not know how to perform a prospective drug utilization review (DUR) on the operating system
- Admits to not checking the NDC, his normal process
- Felt rushed and distracted while trying to perform a DUR override on another patient’s prescription

Case Study

- “Martin” received 80 mg/day of Olanzapine for approximately 1 week, 4 times the maximum dose
- He was aware that the pills looked different but thought because the pharmacy didn’t have enough pills, the pharmacist was giving him a different generic
- He is not “feeling well”
- Calls in sick for 2 days, can’t move off the couch
- Mother is concerned

Case Study

- Mother returns to the pharmacy with a few tabs left in the bottle
- Pharmacist didn’t warn her of the dangers of her son taking the wrong medication for 7 days
- She leaves the pharmacy with the correct medication and an apology
- Medication was not quarantined
- “Duty to preserve evidence”
- Nurse Practitioner was notified and didn’t seem concerned

Case Study

- Olanzapine has a dose-dependent risk of thrombotic complications
- Martin died as a result of pulmonary thromboembolism from phlebothrombosis of the left leg
- Found by his parents on the floor of the bathroom
- Contributing factors: Obesity and Olanzapine Supratherapeutic levels of 230 ng/mL detected in postmortem blood

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Human Performance Factors

What type of Behavior?

- **Human Error**: mistakes, slips, lapses, and unintentional deviations from accuracy and correctness
  - Most errors are in this category
  - Action: Console
- **At-Risk Behavior**: Behavioral choices that increase risk where risk is not recognized, or is mistakenly believed to be justified
  - Increase situational awareness
  - Action: Coach
- **Reckless Behavior**: Conscious disregard of a risk of causing harm
  - Remedial and punitive action
  - Action: Punish

Patient Safety and the “Just Culture” David Marx JD

Human Error

At Risk Behavior

Reckless Behavior

What is RCA?

- A systematic process to identify the causal factors contributed to the occurrence of a sentinel event
- Goal - find out what happened, why it happened & what to do to prevent it from happening again
- Focus on pharmacy systems & processes - not individuals, does not assign blame
- Conducted by team of interdisciplinary individuals
- Recognizes the underlying and fundamental conditions that increase the risk of adverse events
- Implements effective strategies that target root causes
When is RCA Necessary?

- Not every adverse event
- Organizations should specify/define "require RCA?" or "investigate through case reviews or investigative techniques?"

**NOTE:** If the event is thought to be the result of a criminal or purposefully unsafe act or related to alcohol or substance abuse, stop the RCA process and report individual(s) to organization leader

http://www.ismp.org/Tools/Community_AssessERR/default.asp

Harm Scores from NCCMERRORP

A: Circumstances or events that have the capacity to cause error
B: An error occurred but the error did not reach the patient (An "error of omission" does reach the patient)
C: An error occurred that reached the patient but did not cause patient harm
D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

Harm Scores (cont.), an error occurred that...

E: May have contributed to or resulted in temporary harm to the patient and required intervention
F: May have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
G: May have contributed to or resulted in permanent patient harm
H: Required intervention necessary to sustain life
I: May have contributed to or resulted in the patient’s death

Root Cause Analysis Workbook for Community/ Ambulatory Pharmacy

- Describe the root cause analysis (RCA) process
- Prompt users to create an action plan from the RCA, including implementation strategies
- Describe common pitfalls when conducting RCA
- Provide examples of RCA with actual errors

Purpose of ISMP RCA Workbook and Associated Tools

- Incorporate RCA template and tools
- Adaptable for community, mail order or other ambulatory pharmacy practice settings
- Describes the RCA process to help identify the primary cause of a sentinel event
- Prompts users to create an action plan

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Basic Questions to Answer During RCA

1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

Definitions

- **Root Cause**: Most fundamental reason an event has occurred
- **Contributing Factor**: Additional reasons, not necessarily the most basic reason that an event has occurred

Characteristics of a Thorough and Successful RCA

- Focuses primarily on systems and processes, not individual performance
- Continuously asks ‘why’ until all root causes have been identified
- Identifies changes to reduce the risk of reoccurrences
- Participation:
  - Leadership of organization
  - Individuals closely involved
- Internally consistent
- Consideration of relevant literature

Purpose of RCA Action Plan

- Creates means to:
  - Develop risk-reduction strategies
  - Communicate and implement strategies
  - Measure effectiveness of strategies

Case Study: the Error

- Patient received 20 mg of olanzapine tablets instead of the 20 mg ziprasidone capsules
- The patient ingested the incorrect medication and within 7 days, died as a result of pulmonary thromboembolism from phlebothrombosis of the left leg

Definitions

- **Sentinel Event**: an unexpected occurrence involving death or serious physical or psychological injury or risk thereof
- **Medication Error**: any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer
Sentinel Event?

a. Yes
b. No

Steps in Conducting RCA

1. Form a team and complete STEP 1 on RCA template
   - Event Expert
   - Front-line worker
   - Personnel from an unrelated area
   - Optional: Technical RCA expert
   - Elect a leader to guide the process

Step 1: Formulate a Team

**Step 1 - RCA Name:** olanzapine 20 mg dispensed in error

**Date of Event:** 7-19-15

**Problem Statement:** Patient ingested the incorrect medication and died as a result of pulmonary thromboembolism from phlebothrombosis of the left leg

**Team Members**
- Team Leader: Ross Geller, DM
- Event expert (person involved in event): Chandler Bing, CPhT
- Front line worker familiar with process: Rachel Green, RPh
- Non-pharmacy personnel: Joseph Tribianni
- Technical RCA expert (optional): Phoebe Buffay

Steps in Conducting RCA

2. Determine what happened, then complete step 2 on RCA template
   - Review documentation
   - Assess the physical environment
   - Review labeling and packaging product
   - Interview pharmacy staff involved in incident

Review Documentation

- Pharmacy system documentation: refill number entered by pharmacist and product verified by pharmacist
- Patient counseling log: no documentation of counseling
- Staffing logs: temporary staff pharmacist on duty; one technician but left before her shift was over and not replaced
- Current policy and procedure manual

Review Labeling and Packaging

- Olanzapine vs. Ziprasidone
- Not located on the same shelf
- Not sound alike/look alike
- Packaged differently (bottle of #30, bottle of #60)
- Ziprasidone 20 mg NDC 64679-0991-02
- Olanzapine 20 mg NDC 00378-5713-93
Assess Physical Environment

- Pharmacy is located within a psychiatric practice
- 50 Rx's per day
- No bar code scanning
- No pill imaging
- No prescription scanning
- No local staff support

Interview Staff

- Important to interview all staff on duty at time of incident
- Use proper interviewing techniques without assessing blame
- Use interview to create timeline of events
- Create workflow chart

Step 2 - Details of Event

<table>
<thead>
<tr>
<th>Question</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the details of the event? (i.e., event description)</td>
<td>Patient went pharmacy to obtain a refill of his medication. His medication that was filled inadvertently with Olanzapine instead of Ziprasidone. Pharmacist processed the prescription in the pharmacy system, obtained the wrong drug off the shelf, labeled the wrong medication and completed the final verification of the medication while trying to resolve a DUR alert for someone else. Patient took the medication as prescribed on the label, which led him take the wrong medication at 4 times the dose. The label stated Ziprasidone 20 mg but the bottle contained Olanzapine 20mg. Patient's mother brought back wrong caps but pharmacist did not warn her Olanzapine at a dose that could be lethal and require immediate medical care.</td>
</tr>
<tr>
<td>When did the event occur? (e.g., date, day of week, time)</td>
<td>The patient picked up the Olanzapine on 7-19-15 and died on 7-26-15 as a result of pulmonary thromboembolism from phlebothrombosis of the left leg representing a complication of morbid obesity. A contributory cause of death was determined to be an inadvertent administration of Olanzapine with supratherapeutic levels of 230ng/ml detected in postmortem blood.</td>
</tr>
</tbody>
</table>

Step 3 - Flow Chart

<table>
<thead>
<tr>
<th>Question</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the steps in the process (complete a flowchart)?</td>
<td>Attach process flow chart to template</td>
</tr>
<tr>
<td>Why did it happen?</td>
<td>Attempting to resolve DUR at the time of verification; working alone; did not understand operating system</td>
</tr>
<tr>
<td>What events were involved in (contributed to) the event?</td>
<td>Did not follow verification procedures; Mother not counselled as to severity of error</td>
</tr>
</tbody>
</table>

Steps in Conducting RCA

3. Identify root causes

- Diagram the flow of events
- Describe how the event happened using a flowchart to illustrate
- Attach flow chart to RCA

Remember: When developing the flow chart of events, don’t jump to conclusions. It is essential to stay focused on what actually happened – not what the team thinks happened; construct a basic “time series” of the facts leading up to and including the adverse outcome.

http://www.ismp.org/communityRx/aroc/
Which Key Elements?

a. Drug information (2) and Environmental factors (7)
b. Staff competency (8) and Patient education (9)
c. Patient information (1) and Patient Education (9)
d. Staff competency (8), Environmental factors (7), and Patient Education (9)

And more.....

Steps in Conducting RCA

4. Identify Root Causes
   • Study the problem
   • Identify which elements/systems are involved from flow chart (7 & 8)
   • Review key element and contributing factors charts (AROC)

Steps in Conducting RCA

4(cont.) Identify Root Causes
   • Review key element and contributing factors charts (AROC)
   • Read and apply the five rules of causation
   • Complete Step 4 (I-X key elements)
   • Indicate if “contributing factor” or “root cause” and check “take action” if root cause

Proximate Factor Questions

<table>
<thead>
<tr>
<th>Proximate Factor Questions</th>
<th>Findings/Proximate Factors</th>
<th>Root Cause? (If yes, assign #)</th>
<th>Contributing Factor?</th>
<th>Take Action?</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Was critical drug information missing?</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Tip: Contributing factor statements must clearly address why something has occurred and there must be a clear focus on process and system vulnerabilities, never on individuals.
<table>
<thead>
<tr>
<th>Proximate Factor Question</th>
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<th>Root Cause? (If yes, assign #)</th>
<th>Contributing Factor?</th>
<th>Take Action?</th>
</tr>
</thead>
<tbody>
<tr>
<td>III. Miscommunication of drug order? (e.g., illegible; ambiguous; incomplete; misunderstood or misunderstood prescription; poor dictation; unable to clarify with prescriber; team communication issues; warnings bypassed; error-prone abbreviations or dose expressions)</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV. Drug name, label, packaging problem? (e.g., look-alike; sound-alike names; look-alike packaging; no drug image; pharmacy labeling issue; label that obscures information; label not visible; warning labels missing or inconsistently applied; NDC or barcode not available or not used; faulty drug identification)</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>V. Drug storage or delivery problem? (e.g., drug stocked incorrectly; crowded pharmacy; too much of product stored next to each other; adverse dosage forms for neonatal or pediatric patients)</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VI. Drug delivery device problem? (e.g., automated dispensing devices not calibrated or maintained; oral measuring device not dispensed)</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VII. Environmental, staffing or workflow problems? (e.g., poor lighting; excessive noise; clutter; foot traffic interruptions; turnover; workloads; insufficient workflow; inadequately scheduled staffing; flex and leave; work schedules; inadequate supervision)</td>
<td>Pharmacist not familiar with pharmacy layout Pharmacist working alone</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>VIII. Staff education? (e.g., competency validation; new or unfamiliar drugs or devices; orientation process; feedback about errors and prevention; experience; orientation; low compliance with mandatory education requirements; support for advanced certification and education)</td>
<td>Yes (1a) Yes (1b)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Steps in Conducting RCA

5. Write root cause statements
   - Focus on system-level vulnerabilities
   - Read and apply the five rules of causation

5 Rules of Causation

• Rule 2 - Negative descriptors (e.g., poorly, inadequate) are not used in causal statements
  - "carelessness" and "complacency" are bad choices; broad, negative judgments that do little to describe the actual conditions or behaviors that led to the error

Wrong: Policy and procedure manual was poorly written
Correct: The training manual was not indexed, used a font that was difficult to read, and did not include any technical illustrations; as a result, the manual was rarely used and did not improve performance by agency staff
5 Rules of Causation

- **Rule 4**: Each procedural deviation must have a preceding cause
  - Procedural violations are not directly manageable
  - It is the cause of the procedural violation that we can manage
  - If a technician is missing steps in a procedure because he is not aware of the formal checklist, work on education

Wrong: RPh did not follow procedure for product verification

Correct: Uncertainty with the pharmacy operation system and pressures to quickly complete dispensing increased the probability of bypassing the verification protocol; this resulted in the wrong drug being dispensed

Root Cause Statements

<table>
<thead>
<tr>
<th>Step 5 – Root Cause Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Using the findings identified as root causes in Step 4 above, write concise descriptions of the cause-and-effect relationship ensuring that the team has not focused on the actions of individuals or in any way placed blame.</strong></td>
</tr>
</tbody>
</table>

Tip: To determine whether a statement is effective, ask, "If this is corrected, will it reduce the likelihood of another adverse event?" The answer should be yes.

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Statement of Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (a,b)</td>
<td>Lack of knowledge of the pharmacy operation system and pressures to quickly complete dispensing increased the probability of bypassing the verification protocol</td>
</tr>
<tr>
<td>2 (a,b)</td>
<td>The absence of a culture of safety resulted in the pharmacist not counseling the mother on the severity of the error</td>
</tr>
</tbody>
</table>

Steps in Conducting RCA

6A. Develop Actions

- Formulate improvement actions for each identified root cause in Step 5
- Consider quality improvement actions for identified contributing factors
- Review key elements and suggested risk-reduction strategy charts (AROC) [http://www.ismp.org/communityRx/aroc/]
- Employ a mix of higher- and lower-leverage strategies that focus on system issues and address human issues

Use Variety of Strategies

- **Fail-safes and constraints** true system changes
  - Integrate pharmacy computer system and cash register; prevents the clerk from "ringing up" the Rx unless RPh final verification had occurred
- **Forcing functions** are procedures that create a "hard stop"
  - Rx computer system prevents overriding selected high-alert messages without a notation (e.g., patient-specific indication must be entered if high-alert medication selected)
- **Automation and computerization** reduce reliance on memory
  - True electronic systems receive eRx from a prescriber; eliminate data entry misinterpretation at the pharmacy
  - Robotic dispensing devices
- **Standardization** creates a uniform model to reduce the complexity and variation of a specific process
  - Create standardized processes for receiving phone orders
Use Variety of Strategies

- **Redundancies** incorporate duplicate steps to force additional checks
  - Include use of both brand and generic names
  - Patient counseling is an underutilized redundancy
- **Reminders and checklists** important information readily available
  - Rx blanks that include prompts for important information (e.g., medication indication, allergies, patient dob)
- **Rules and policies** guide staff toward an intended positive outcome
  - Use relies on memory; used as a foundation to support other strategies
- **Education and information** effectiveness relies on an individual’s ability to remember what has been presented
  - Read and review prescription verification policies and procedures

### Brainstorming Action Plan, RCA Team asks:

- How can we decrease the chance of the event occurring again?
- How can we decrease the degree of harm if the event were to occur again?
- When considering changing procedures or rules, ask: What is best practice?
- How can devices, software, work processes, or workspace be redesigned using a human factors approach?
- How can we reduce reliance on memory and vigilance by improving processes in the workplace?
- Does the organization have resources for the proposals?

### Steps in Conducting RCA

#### 6B. Establish Outcome Measures

- Establish a way to measure effectiveness of action plan over time
- Record methods to measure effectiveness over time

**Tip:** Discuss the proposed risk reduction strategies with the person who reported the incident to see if they believe that the RCA team is on the right track.

Ask: If these recommendations were in place at the time of the incident, do you think it likely that the incident may have been prevented from occurring?

### Action Plan- Root Causes

#### Step 6 – Action Plan

**Root Cause**

For each of the root causes identified in Step 5 above as needing an action, complete the following table. Check to be sure the selected measure will provide data that will permit assessment of effectiveness over time.

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Risk Reduction Strategy</th>
<th>Measure of Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.b</td>
<td>Provide practice site, competency-based orientation regarding stocking, dispensing, preparation, verifying and delivery procedures to all newly hired staff</td>
<td>Monitor staff scheduler to refer to documented levels of training before assigning tasks and shifts</td>
</tr>
<tr>
<td>2.a</td>
<td>Promote a culture of safety from top management down to staff in pharmacies</td>
<td>Promote and integrate management into pharmacy error reduction strategy and monitor effectiveness</td>
</tr>
<tr>
<td>2.b</td>
<td>Educate staff members that all patients, whether new or refill prescriptions, need an “offer to counsel”</td>
<td>Use a log book to document the incidence</td>
</tr>
</tbody>
</table>

### Almost Done! Review Common Errors in RCA

- **Avoid Common Pitfalls**
  - Start with accurate sequence of events and timeline to help uncover all gaps
  - Don’t rely on policies and procedures; illustrate what actually happens
  - Investigate **why** staff skipped steps
  - Uncover more deep-seated latent failures in the system
  - Uncover how human errors get through the system
Review Common Errors in RCA (cont.)
- Seek outside knowledge
  • Professional literature, regulations, standards, professional guidelines
- Each intervention should be clearly linked to one or more causative factors
- Effective risk-reduction strategies involve redesigning systems; don’t rely on:
  • Developing new rules, educating staff, double checks, “be more careful”
- Have realistic plans and measure outcomes
- Punitive action—not be available to provide important details

Last Step in Conducting RCA
7. Communicate the results
   • Provide leadership recommendations for improvement and preventative action plan
   • Share with the entire organization as a learning tool and to get buy-in to changes

Key Points
• RCA framework should be broken down into manageable steps:
  o Form a team
  o Review all documentation
  o Review physical environment
  o Review product labeling and packaging
  o Interview those involved in the incident
  o Determine sequence of events through flow charting on the medication use system
  o Ask ‘why’?
  o Determine contributing factors and root causes
  o Develop an Action Plan for each identified root cause
  o Measure effectiveness of Action Plan over time

Self-Assessment Question 1
What is the first step for conducting a Root Cause Analysis?
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a) True
b) False

References