ROOTING OUT ERRORS IN YOUR PHARMACY

8:00 - 9:00AM

ACPE UAN: 107-000-14-039-L05-P 0.1 CEU/1.0 hr
107-000-14-039-L05-T 0.1 CEU/1.0 hr

Activity Type: Application-Based

Learning Objectives for Pharmacists: Upon completion of this CPE activity participants should be able to:
1. Explain the root cause analysis (RCA) process in a pharmacy practice using predetermined steps and associated tools
2. Describe the importance of conducting an RCA following a sentinel event
3. Prepare an action plan from the RCA which includes risk-reduction strategies, communication, and implementation strategies as well as ways to measure effectiveness
4. Identify common pitfalls that may occur when conducting an RCA

Learning Objectives for Technicians: Upon completion of this CPE activity participants should be able to:
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3. Prepare an action plan from the RCA which includes risk-reduction strategies, communication, and implementation strategies as well as ways to measure effectiveness
4. Identify common pitfalls that may occur when conducting an RCA

Speaker: Donna Horn, RPh, DPh, is director of patient safety for community pharmacy at The Institute for Safe Medication Practices, a non-profit healthcare organization that specializes in understanding the causes of medication errors and providing error-reduction strategies to the healthcare community, policy makers, and the public. She directs ISMP’s patient safety activities in community/ambulatory practice. Donna serves as an author and editor of ISMP’s four newsletters for acute care providers, nurses, ambulatory/community care providers, and consumers, publications that reach over 2 million health professionals and consumers in the US, as well as regulatory authorities and others in over 30 foreign countries. Donna is also part of the consulting service at ISMP assisting in reviewing the medication use processes in pharmacies around the country. She has more than 25 years of experience in the retail/chain community pharmacy practice setting.

Speaker Disclosure: Donna Horn reports no actual or potential conflicts of interest in relation to this CPE activity. Off-label use of medications will not be discussed during this presentation.
Rooting Out Errors in Your Pharmacy

DONNA HORN, RPH, DPH
DIRECTOR,
PATIENT SAFETY – COMMUNITY PHARMACY
INSTITUTE FOR SAFE MEDICATION PRACTICES

Faculty Disclosure

• Donna Horn reports she does not have actual or potential conflicts of interest associated with this presentation
Learning Objectives

Upon completion of this activity, pharmacists and pharmacy technicians should be able to:

1. Explain the root cause analysis (RCA) process in a pharmacy practice using predetermined steps and associated tools
2. Describe the importance of conducting an RCA following a sentinel event
3. Prepare an action plan from the RCA which includes risk-reduction strategies, communication, and implementation strategies as well as ways to measure effectiveness
4. Identify common pitfalls that may occur when conducting an RCA

Pre-Assessment Question

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
Pre-Assessment Question

6

True or False?

All adverse events that occur at the pharmacy must be investigated using the RCA method.

Pre-Assessment Question

6

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
## Systems of Medication Use

<table>
<thead>
<tr>
<th>I. Patient information</th>
<th>VI. Device acquisition, use, and monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>II. Drug information</td>
<td>VII. Environmental factors</td>
</tr>
<tr>
<td>III. Communication of drug information</td>
<td>VIII. Staff competency and education</td>
</tr>
<tr>
<td>IV. Labeling, packaging, and nomenclature</td>
<td>IX. Patient education</td>
</tr>
<tr>
<td>V. Drug storage, stock, standardization, and distribution</td>
<td>X. Quality and risk management issues</td>
</tr>
</tbody>
</table>

## Definitions

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

Latent (System) Failures

- Incomplete information about a patient
- Unclear communication of a drug order
- Lack of computer warnings (interactions, allergies, dosages, etc.)
- Drug storage (look alike/sound alike medications, hazardous chemicals)
- Unclear policies/procedures
Latent Failure: Lack of Patient Information

Latent Failure: Mnemonics

<table>
<thead>
<tr>
<th>Mnemonic</th>
<th>Aggregate Description</th>
<th>Primary Brand</th>
</tr>
</thead>
<tbody>
<tr>
<td>D50</td>
<td>D50W DEXTROSE 50% IN WATER SOLP 50 ML</td>
<td>DEXTROSE 50% IN WATER (D50W)</td>
</tr>
<tr>
<td>D50</td>
<td>PHENYTOIN 50 MG CHEW 1 EA</td>
<td>DILANTIN INFATABS</td>
</tr>
<tr>
<td>ME40</td>
<td>METHYLPREDNISOLONE SODIUM SUCC (SOLU-MEDROL) 40 MG/ML SOLR 1 EA</td>
<td>SOLU-MEDROL (PF)</td>
</tr>
<tr>
<td>ME40</td>
<td>MEGESTROL ACETATE 40 MG TAB 1 EA</td>
<td>MEGACE</td>
</tr>
</tbody>
</table>
Latent Failure: Handwritten LTC

Filled for Humalog Kwikpen should have been Lantus
Assumed generic for Humalog because of the "HUMrec.anALOG"

Latent Failure: Unclear Order
Latent Failure: Label Design

Latent Failure: Packaging
Latent Failure: Storage Acute Care

Latent Failure: Storage Retail
Latent Failure: Compounding

Latent Failure: Workflow
Latent Failure: Tablet Identification

Latent Failure: Unclear Signage

Dispensing environment

2.7 Patient areas

Issues
- Confusion is not unusual when pill names sound similar.
- Waiting patients should not be creating the counter and be able to view other counter confidential conversations.
- Staff often talk to both staff and patients, preventing them from communicating effectively.
- Different colors can cause confusion and direct both patients and staff.

Recommendations
- Use less than confidential area on easy to read when confidential conversations may take place.
- Use good signage and techniques such as confidential counters. Suggest use of counter dividers, to designate areas when confidential conversations will take place.

Action
- Reduce signage, flooring and counter borders to decrease confidential areas.
- Separate the patient waiting area from the prescription retail and medication collection areas.

National Patient Safety Agency 2007 London UK
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59830 accessed 2/24/12
What is a Root Cause Analysis (RCA)?

- A systematic process to identify the causal factors that contributed to the occurrence of a sentinel event
- 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
  - Ask “require RCA?” or
  - Ask “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

Harm Scores

Category A:
Circumstances in which the patient's death was caused by the error.

Category B:
An error occurred but the patient is alive and the incident did not reach the patient.

Category C:
An error occurred that resulted in permanent patient harm.

Category D:
An error occurred that resulted in temporary patient harm.

Category E:
An error occurred that resulted in harm to the patient.

Category F:
An error occurred that resulted in the need for patient hospitalization.

Category G:
An error occurred that required intervention to prevent harm.

Category H:
An error occurred that may have contributed to or resulted in temporary patient harm.

Category I:
An error occurred that may have contributed to or resulted in the patient's death.

No Error
Error, No Harm
Error, Harm
Error, Death

IMPROVING MEDICATION SAFETY IN COMMUNITY PHARMACY:
ASSESSING RISK AND OPPORTUNITIES FOR CHANGE

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES
Assess-ERR™ Tool

- A three step medication system worksheet to assist with error report investigations
- A standardized approach to documenting error incidents
- Helps to reveal the underlying system deficiencies
- Utilizes recommendations from each Key Element to help identify the risk-reduction strategies
- Raises awareness of issues that have become so familiar in a particular practice setting that the issues are no longer even recognized as risks

Assess-ERR™ Tool: Step One

- Was indication for use on the prescription? Yes ☒ No
- Was the prescription obtained electronically? Yes ☐ No
- Were two unique patient identifiers used at pickup? ☒ Yes ☐ No
- Did the patient accept the offer to counsel? Yes ☒ No
- Did the error reach the patient? ☒ Yes ☐ No
- Was the prescriber notified of the incident? ☒ Yes ☐ No

- Brief description of the event (what, when, and why):
  Patient living in group home received the wrong medication. Lithium Citrate 8 mEq/5 mL was filled with Chloral Hydrate 500 mg/5 mL (Noctec) in error.

Found at:
http://www.ismp.org/Tools/Community_AssessERR/default.asp
### Assess-ERR™ Tool: Step 2

<table>
<thead>
<tr>
<th>Key Element</th>
<th>Possible causes</th>
<th>Y/N</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Critical patient information missing?</td>
<td>Y</td>
<td>No indication for use on hard copy prescription; no health condition information in pharmacy computer system; profile not reviewed</td>
</tr>
<tr>
<td></td>
<td>(age, weight, allergies, pregnancy, patient identity, address, indication for use)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>Drug name, label, packaging problem?</td>
<td>Y</td>
<td>Similar labels; both manufactured by MGP; similar look and packaging; both pint-size, plastic, amber-colored bottles with same-colored labeling</td>
</tr>
<tr>
<td></td>
<td>(look-/sound-alike names, look-alike packaging, no drug image, NDC or barcode not available or not used)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Assess-ERR™ Tool: Step 3

<table>
<thead>
<tr>
<th>Identified Problem (from Comments)</th>
<th>Key Element</th>
<th>Interventions Implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>No patient health condition listed in patient profile</td>
<td>I</td>
<td>Obtain indication to distinguish medications with similar packaging and look-alike or sound-alike names. (redundancy)</td>
</tr>
<tr>
<td>No indication on hardcopy</td>
<td></td>
<td>Match drug ordered to indication provided. (redundancy)</td>
</tr>
</tbody>
</table>
### Assess-ERR™ Tool: Step 3

<table>
<thead>
<tr>
<th>Identified Problem (from Comments)</th>
<th>Key Element</th>
<th>Interventions Implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similar labels, both manufactured by MGP; look alike packaging: both pint-size, plastic, amber-colored bottles with same-colored labeling</td>
<td>IV</td>
<td>Use auxiliary labels with exaggerated fonts. Use shelf dividers to separate LASA products. (standard) Identify stock bottle labels that are ambiguous or unsafe, and contact manufacturer or discontinue stocking from this manufacturer if safety features cannot be adequately employed; in addition, report these hazardous labels to ISMP. (standard)</td>
</tr>
</tbody>
</table>

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### Root Cause Analysis Workbook for Community/Ambulatory Pharmacy

[Image of ISMP logo]
ISMP RCA Workbook
and Associated Tools*

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

*ISMP is grateful to NABPF for funding of this project.

Basic Questions to Answer During RCA

<table>
<thead>
<tr>
<th>Basic Questions to Answer During RCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What happened?</td>
</tr>
<tr>
<td>2. What normally happens?</td>
</tr>
<tr>
<td>3. What do policies/procedures require?</td>
</tr>
<tr>
<td>4. Why did it happen?</td>
</tr>
<tr>
<td>5. How was the organization managing the risk before the event?</td>
</tr>
</tbody>
</table>
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
- Consideration of relevant literature

Tip: As a rule of thumb, it normally takes about 5 rounds of “why” to identify the root cause of a problem, but this is not laid in tablets of stone and you may sometimes ask “Why” more, or less than 5 times.

Purpose of RCA Action Plan

- Develop risk-reduction strategies
- Communicate and implement strategies
- Measure effectiveness of strategies
Case Study: the Error

- Patient received 100 mg of amitriptyline tablets instead of the 10 mg amitriptyline tablets
- The patient ingested the incorrect tablets and within 5 days, experienced signs and symptoms of a tenfold overdose of amitriptyline, and was hospitalized
- Sentinel event: harm requiring hospitalization
- RCA needed

Steps in Conducting RCA

1. Form a team and complete STEP 1 on RCA template
   - Event Expert
   - Front-line worker(s)
   - Personnel from an unrelated area
   - Optional: Technical RCA expert, patient or family member
   - Elect a leader to guide the process
A Note about Patient Involvement

- Patient centeredness: offer patients opportunity to provide input and participate
- RCA goal of organization: diagnose system failure; improve, repair, make system changes
- Is patient’s goal the same?
- No easy system fixes but patient might think there should be
  - Ford Recalls 129,000 Fusions and Mercury Milans After Studs Fracture on Steel Wheels

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
   - Use “Fact Gathering worksheet” to record comments/descriptions to complete RCA
Review Documentation

- Review prescription “hard copy”
- Pharmacy system documentation: entered by technician, verified by pharmacist; documentation that barcoding was skipped
- Patient counseling log: no documentation of counseling
- Staffing logs: regular staff except one technician called in sick and not replaced
- Current policy and procedure manual

Assess Physical Environment

- Data entry and drop off occur at same terminal
- Pick up window and counter for production not near each other
- Pharmacy verification area is small, crowded, cluttered
- Shelves for stock are crowded and messy
- Barcode system for product verification
Review Labeling and Packaging

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>The patient ordered her refill for amitriptyline via IVR system but did not indicate a pick up time. She arrived to the pharmacy shortly after placing the order. The technician looked in vain through the will call area for the prescription, but it had not yet been processed. The technician then went to the pharmacy computer system to determine where the prescription was in the filling process. She located the refill request in the refill queue, processed it through the insurance plan, and sent the label to production with a large “filling” note on it. This was a very busy Thursday morning and the production area was stacking high with March orders. The second technician had finished this queue earlier. The first technician tried to check the prescription through for the evening patient and went to the shelf to pick the stock bottle of amitriptyline 10 mg. In error she selected the 100 mg stock bottle, counted out the tablets, applied the label, placed it in the basket and sent it, without the stock bottle, to the pharmacist for verification. The technician did not scan the barcode on the stock bottle to verify the product. Because of a pop up warning on the verification screen, the pharmacist realized the barcode scan was not performed so he visually compared the tablet in the bottle to the tablet image on the computer screen. He did not notice any differences, bagged the prescription bottle, and gave the bag to the technician at the cash register. The patient paid for her prescription and went home. Since this was a refill prescription, the offer to counsel was not made. Within five days the patient began experiencing symptoms of amitriptyline overdose: extreme drowsiness, hallucinations, fast/irregular heartbeat, fainting, and slow/shallow breathing. Her neighbor brought her to the emergency department of the local hospital. During the medication reconciliation process at the hospital, it was discovered that the patient was supposed to be taking amitriptyline 10 mg but had taken amitriptyline 100 mg for the past five days. The admitting nurse at the emergency room called the local pharmacy to inform them of their error.</td>
</tr>
<tr>
<td>When did the event occur? (e.g., date, day of week, time)</td>
<td>The patient picked up the amitriptyline 100 mg on Monday and then was hospitalized 5 days later due to amitriptyline overdose</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/](http://www.ismp.org/communityRx/aroc/)
Step 3 – Flowchart Steps in the Process

Review of the Event: Process flow/steps (from interviews)
The queue is "flushed" so all the pharmacy labels are printed out.
The pharmacy opened an hour ago and it was a busy Monday morning.
The pharmacy only had 2 technicians on duty to assist the pharmacist.
The pharmacy was understaffed for the morning shift on a Monday.

Stock

Technician 1 retrieves 100 mg of amitriptyline instead of 10 mg.
The bottles are next to each other in the reverse order.
The bottles were misplaced incorrectly.
The stock bottle locations are infrequently checked for accuracy.
The stock bottle is not compared with pharmacy label information.

Why?

Product Scanning

Technician does not bar code scan the stock bottle / overrides it.
Technician is too busy to bar code scan the bottles.
The patient is waiting.
High volume of the pharmacy.
The pharmacy is understaffed.
The labels are applied and sent for verification.

Labels Applied

Why?
Step 3 – Flow Chart

**Step 3 – Flowchart Steps in the Process**

*In this step, describe how the event happened using a flowchart to illustrate. Tip: 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.*

<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? What events were involved in (contributed to) the event?</td>
<td>Findings from flow charting</td>
</tr>
</tbody>
</table>
Steps in Conducting RCA

4. Identify Root Causes
   - Study the problem
     - Review key element and contributing factors charts (AROC)
     - Identify which elements/systems are involved from flow chart
     - Complete Step 4 (I-X key elements)
       - Indicate if “contributing factor” or “root cause” and check “take action” if root cause

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**Step 4 – Identify Proximate (Contributing) Factors and Root Causes**

<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>IV. Drug name, label, packaging problem?</td>
<td>(e.g., look- and 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>Same manufacturer for both 10 mg and 100 mg strengths; Labels not significantly differentiated from one another in color or font size; Similar tablet appearance for both 10 mg and 100 mg</td>
<td>Yes (1)</td>
<td>Yes</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 1 - Causal Statements must clearly show the "cause and effect" relationship**
  - “pharmacist was fatigued” is deficient without description of how and why this led to a mistake

Wrong: Pharmacist was fatigued

Correct: Pharmacists are routinely scheduled for 12 hour work days; as a result, the level of pharmacist fatigue increased the likelihood of the instructions being misread, which led to incorrect data entry and subsequent incorrect labeled instructions for patient on prescription vial
5 Rules of Causation

• Rule 2 - Negative descriptors (e.g., poorly, inadequate) are not used in causal statements
  o "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 the technicians

5 Rules of Causation

• Rule 3 - Each human error must have a preceding cause
  o Investigate to determine WHY the human error occurred
  o System-induced error (e.g., step not included in procedure)
  o At-risk behavior (doing task by memory, instead of a checklist)

Wrong: The technician made a dosage error
Correct: Due to lack of automated software to check the dosage limits (teaspoonful entered and should have been mL), there was a likelihood of this dosing error, which resulted in five times the appropriate level of antibiotic suspension being administered
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: tech did not follow procedure for bar code scan
    Correct: Noise and confusion in the production area and pressures to quickly complete dispensing increased the probability of bypassing the barcode scan protocol; this resulted in the wrong dose being dispensed

5 Rules of Causation

• **Rule 5 - Failure to act is only causal when there was a pre-existing duty to act**
  - Find out why this mishap occurred in our system as it is designed today
  - The duty to perform may arise from standards and guidelines for practice; or other duties to provide patient care
    Wrong: The clerk did not call the pharmacist to the out window to counsel the patient when the high-alert mediation was being dispensed
    Correct: The absence of an established procedure insisting on mandatory counseling for patients receiving high-alert medications or for patients considered to be high-risk, resulted in the patient not realizing heating pads should not be used with fentanyl patches
Root Cause Statements

Step 5 – Root Cause Statements

Using the findings identified as root causes in Step 4 above, write concise descriptions of the cause-and-effect relationship. Ensure that the team has not focused on the actions of individuals or in any way placed blame.

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</td>
<td>The use of same manufacturers for amitriptyline 10 mg and 100 mg led to the wrong stock bottle being picked</td>
</tr>
<tr>
<td>2</td>
<td>The placement of the 100 mg before the 10 mg led to the wrong stock bottle being picked</td>
</tr>
<tr>
<td>3</td>
<td>The low resolution of tablet image on computer screen led to differences in tablet markings not being detected</td>
</tr>
<tr>
<td>4 a,b</td>
<td>Barcode scanning technology can easily be overridden and its utility is not emphasized enough; resulted in the mix up of amitriptyline 10 mg and 100 mg not being detected</td>
</tr>
<tr>
<td>5 a,b</td>
<td>Policy for using an alternate means for product verification i.e., using the stock bottle for verification process was not emphasized</td>
</tr>
</tbody>
</table>

Steps in Conducting RCA

6. 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/
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?
- Is the proposed action achievable within the limitations of the organization’s resources?

Steps in Conducting RCA

6. Develop Actions
   - Employ a mix of higher- and lower-leverage strategies that focus on system issues and address human issues

http://www.ismp.org/communityRx/aroc
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- if staff fired after event they may not be available to provide important details

Steps in Conducting RCA

7. 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 Causes

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</td>
<td>Provide shelf talkers</td>
<td>Ask pharmacy manager to fulfill this as soon as possible and then monitor patterns of effectiveness</td>
</tr>
<tr>
<td>2</td>
<td>Stock different strengths of same medication in ascending order</td>
<td>Perform daily to weekly checks of stock</td>
</tr>
<tr>
<td>3</td>
<td>Replace old technology with new and improved technology when available</td>
<td>Pilot test to ensure that technology meets the needs of the organization</td>
</tr>
<tr>
<td>4 a,b</td>
<td>Identify work-arounds of not scanning stock bottles and labels</td>
<td>Run override reports and follow up with staff, which staff chooses to override bar-code process and which situations prompt this behavior</td>
</tr>
<tr>
<td>5 a,b</td>
<td>Institute policy that stock bottle must remain for verification if barcode process by-passed</td>
<td>Supervisor observe and review at each store visit</td>
</tr>
</tbody>
</table>

Steps in Conducting RCA

8. 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 Practice Points

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

Post-Assessment Question

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
Post-Assessment Question

True or False?

All adverse events that occur at the pharmacy must be investigated using the RCA method

False

Post-Assessment Question

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) Team includes organization’s leadership and individuals closely involved
Final Post-Assessment Question

The ____ is used for any medication error whereas the ____ is used for sentinel and severe adverse events.

a) Root Cause Analysis; Assess-ERR™
b) Assess-ERR™; Root Cause Analysis
c) Root Cause Analysis; Root Cause Analysis
d) Assess-ERR™; Assess-ERR™
ISMP National Medication Errors Reporting Program

Operated by the
Institute for Safe Medication Practices
www.ismp.org

ISMP is a federally certified patient safety organization (PSO)