  
**ROOTING OUT ERRORS IN YOUR PHARMACY**

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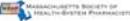
### Disclosures

- Donna Horn and Karen Ryle declare no conflicts of interest.



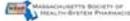
### Learning Objectives

- 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.
- Prepare an action plan from the Root Cause Analysis (RCA) which includes risk-reduction strategies, communication, and implementation strategies as well as ways to measure effectiveness.
- Identify common pitfalls that may occur when conducting an RCA.



### 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 and 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



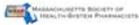
### Self-Assessment Question 3

- 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



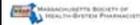
### Self-Assessment Question 4

- 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?



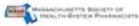
### Self-Assessment Question 5

- 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



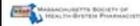
### Case Study

- “Bob” is a 53 year old male
- Recent below the knee amputation
- Experiencing phantom pain
- Currently prescribed:
  - ▣ OxyCONTIN 20 mg 1 tab twice a day
  - ▣ oxyCODONE 5 mg 1-2 tabs every 4-6 hours as needed for breakthrough pain
  - ▣ Alprazolam 2 mg 1 tab every 8 hours
  - ▣ Gabapentin 400 mg 1 tab every 8 hours



### Case Study

- Bob could not afford the OxyCONTIN and was doubling up on the oxyCODONE
- He went 4 days without oxyCODONE and was seen in the emergency room
- He was admitted to the hospital overnight
- He was discharged the next day with the following medications:
  - ▣ MS Contin 20 mg 1 tab twice a day
  - ▣ oxyCODONE 5 mg 1 tab three times a day
  - ▣ Gabapentin 300 mg 1 cap every 8 hours



### Case Study

- Bob is a regular customer of “Home Town” Pharmacy
- Home town pharmacy fills Bob’s prescription for MS Contin 20 mg with Morphine Sulfate ER 20 mg capsules (Kadian 20 mg)
- 9 days later, Bob goes to his follow up appointment
- He complains that the Morphine is taking too long to work



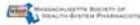
### Case Study

- Medical Record available at the follow-up appointment contains the discharge summary of previous hospital stay
- Discharge medications lists MS Contin 200 mg at the time of the visit
- The medical assistant checks off MS Contin 200 mg at the beginning of the appointment
- Physician prescribes MS Contin 200 mg at the time of the visit



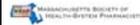
### Case Study

- Bob is expecting a different medication because he complained it was taking too long to work
- Bob presents new Rx for MS Contin 200 mg to his pharmacy
- Home Town pharmacy fills the prescription for MS Contin 200 mg, 1 tab twice a day only 9 days after dispensing a 30 day supply of Morphine Sulfate ER 20 mg (Kadian)
- Prescription was filled exactly as written



### Case Study

- Pharmacy claims that someone from the doctor's office called to see if they had MS Contin 200 mg in stock
- The patient's name is never mentioned
- Confirmation Bias
- Drug utilization Review (DUR) for duplicate therapy with 20 mg Morphine Sulfate ER (Kadian) is overridden
- Patient's wife picks up the prescription
- Counseling was not performed



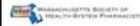
### Case Study

- That evening Bob takes 1 tablet of MS Contin 200 mg
- According to his wife, he was "not acting right"
- She calls the doctor's office the next day
- She was told that it was normal for him to be sleepy/drowsy on this medication and to monitor his respirations
- If his respirations fall below 14 per minute-take him to the ED

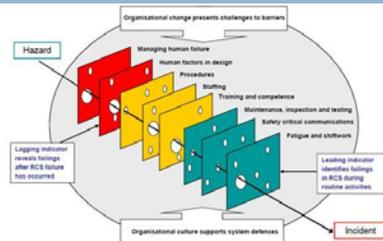


### Case Study

- Wife mentions she is concerned because he was taking 20 mg before and she read the bottle that stated 800 mg
- Later that afternoon , she called 911
- EMT administered Naloxone
- Total Morphine Level= 461 ng/ml
- Toxic level of morphine caused multi-organ failure
- Remained in coma for 5 days and pronounced dead
- Cause of Death: Opiate Toxicity



### Human Performance Factors



The original source for the Swiss Cheese illustration is: "Swiss Cheese" Model – James Reason, 1990. The book reference is: Reason, J. (1990) Human Error. Cambridge: University



### What is RCA?

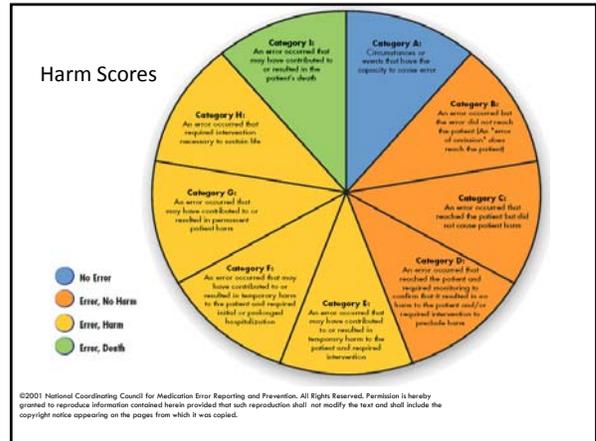
- A systematic process to identify the causal factors contributed to the occurrence of a sentinel event
- Goal - find out **what** happened, **why** it happened & what to do to **prevent** it from happening again
- Focus on pharmacy systems & processes - not individuals, does not assign blame
- Conducted 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](http://www.ismp.org/Tools/Community_AssessERR/default.asp)



## 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

## Basic Questions

### 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

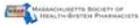
- **Root Cause:** Most fundamental reason an event has occurred
- **Contributing Factor:** Additional reasons, not necessarily the most basic reason that an event has occurred

## 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

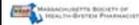
## Case Study: the Error

- Patient received MS Contin 200 mg instead of the 20 mg
- The patient ingested the incorrect medication which caused multi-organ failure
- Remained in coma for 5 days and pronounced dead
- Cause of Death: Opiate Toxicity



## Sentinel Event?

- a. Yes
- b. No



## Step 1 Formulate a Team

### Step 1 - RCA Name: Ms Contin 200 mg dispensed in error

Date of Event: 7-19-15

Problem Statement: Patient ingested the incorrect medication and died as a result of opiate toxicity

### Team Members

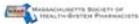
Team Leader: Ross Geller, Director of Pharmacy

Event expert (person involved in event): Chandler Bing, CPhT

Front line worker familiar with process: Rachel Green, RN

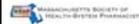
Non-pharmacy personnel: Joseph Tribianni

Technical RCA expert (optional): Phoebe Buffay



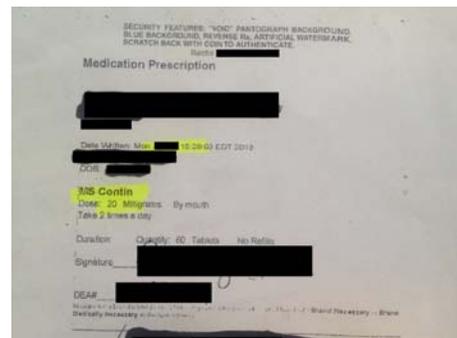
## Step 2 Determine What Happened

- Review documentation
- Interview medical and pharmacy staff involved in incident



## Review Documentation

- Prescription for MS Contin 20 mg filled with Kadian 20 mg at Home Town Pharmacy
- Patient counseling log; offer not accepted by friend
- Medical Record containing the discharge summary states MS Contin 200 mg
- New written Rx for MS Contin 200 mg
- Computer records: DUR for duplicate therapy shows 20 mg Morphine (Kadian) was overridden
- Patient counseling log; offer not accepted by wife



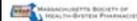
### Interview Staff

- Use proper interviewing techniques without assessing blame
  - Seek system issues; do not judge or interrupt
  - Make staff comfortable
  - Active listening: reflect, restate, summarize
  - Body posture, eye contact, nod appropriately
- Use interview to create timeline of events
  - Broad open-ended questions
  - If recall issues ask to describe what they usually do
- Create workflow chart



### Interview Staff

- PA wrote a prescription for MS Contin 20 mg at discharge because patient could not afford oxyContin 20 mg
- PA wrote the prescription for 20 mg which does not exist (a prescriber can free text a drug in the computer system for a strength that is not available)
- Rx filled with Kadian 20mg 30 day supply at local pharmacy
- Hospital transcription error



### Interview Staff (cont.)

- Occurred during dictation over the phone by the Physician Assistant
- Dictation service did not recognize MS Contin 20 mg
- Transcribed to MS Contin 200 mg
- Medical Record lists MS Contin 200 mg on discharge summary
- Discharge summary with the incorrect dose was signed by both the PA and the supervising physician
- New physician prescribes MS Contin 200 mg during follow up appointment



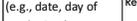
### Interview Staff (cont.)

- Pharmacy claims that someone from the doctor's office called to see if they had MS Contin 200 mg in stock
- DUR for duplicate therapy with 20 mg Kadian is overridden by pharmacist
- RPh fills Rx for MS Contin 200 mg
- Counseling not performed but pharmacist remembers giving the wife the medication



### Step 2 (cont.) Details of Event

Step 2 - What Happened	
Question	Finding
What are the details of the event? (i.e., event description)	PA wrote prescription for MS Contin 20 mg at discharge Rx filled with 30 day supply Kadian 20mg at local pharmacy Medical Record lists MS Contin 200 mg on discharge summary Discharge summary with the incorrect dose was signed by both the PA and the supervising physician The medical assistant checks off MS Contin 200 mg at the beginning of follow up appointment Physician prescribes MS Contin 200 mg during appointment Pharmacy claims that someone from the doctors office called to see if they had MS Contin 200 mg in stock DUR for duplicate therapy with 20 mg Kadian is overridden by pharmacist RPh fills Rx for MS Contin 200 mg Counseling not performed but pharmacist remembers giving the wife the medication
When did the event occur? (e.g., date, day of week, time)	Patient took 1 tablet of MS Contin 200 mg, Total Morphine Level= 461 ng/ml Toxic level of morphine caused multi-organ failure Remained in coma for 5 days and then pronounced dead



### Step 3 Flow Chart

Step 3 – Flowchart Steps in the Process	
<i>In this step, describe how the event happened using a flowchart to illustrate.</i> <b>Tip:</b> When developing the flow chart of events, don't jump to conclusions. It is essential to stay focused on what <b>actually</b> happened – not what the team <b>thinks</b> happened; construct a basic "time series" of the facts leading up to and including the adverse outcome.	
Question	Finding
What are the steps in the process? (complete a flowchart)	Attach process flow chart to template
Why did it happen? What events were involved in (contributed to) the event?	?



### Step 3 (cont.) Flow Chart

- 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/arcoc/>

### Review of the Event: Process flow/steps (discharge date)

### Review of the Event: Process flow/steps (day after discharge)

\* <https://www.ismp.org/newsletters/acute/acute/articles/20090226.asp>

### Review of the Event: Process flow/steps (follow up appointment)

### Review of the Event: Process flow/steps (at the pharmacy)

### 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.*

Question	Finding
What are the steps in the process? (complete a flowchart)	Attach process flow chart to template
Why did it happen? What events were involved in (contributed to) the event?	Rx written for medication that does not exist; Transcription error at hospital DUR overridden at pharmacy Patient's wife not counseled about opiate warnings and her concerns not adequately addressed by nurse

## Key Elements of Medication Use

<ol style="list-style-type: none"> <li>1. Patient information</li> <li>2. Drug information</li> <li>3. Communication of drug information</li> <li>4. Labeling, packaging, and nomenclature</li> <li>5. Drug storage, stock, standardization, and distribution</li> </ol>	<ol style="list-style-type: none"> <li>6. Device acquisition, use, and monitoring</li> <li>7. Environmental factors</li> <li>8. Staff competency and education</li> <li>9. Patient education</li> <li>10. Quality and risk management issues</li> </ol>
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## 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), Drug information (2), and Patient Education (9)

And more.....



## Key Elements of Medication Use

<ol style="list-style-type: none"> <li>1. Patient information</li> <li>2. <b>Drug information</b></li> <li>3. <b>Communication of drug information</b></li> <li>4. Labeling, packaging, and nomenclature</li> <li>5. Drug storage, stock, standardization, and distribution</li> </ol>	<ol style="list-style-type: none"> <li>6. Device acquisition, use, and monitoring</li> <li>7. Environmental factors</li> <li>8. <b>Staff competency and education</b></li> <li>9. <b>Patient education</b></li> <li>10. Quality and risk management issues</li> </ol>
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## Steps 4 Identify Root Causes

- Study the problem
  - Identify which elements/systems are involved from flow chart (2,3, 8 & 9)
  - Review key element #2, 3, 8 and 9 and *contributing factors* charts <http://www.ismp.org/communityRx/arc>
- Complete Step 4 (1-10 key elements)
  - Indicate if “contributing factor” or “root cause” and check “take action” if root cause



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

*As an aid to avoiding “loose ends,” the last three columns on the right are provided to be checked off for later reference:*

- \* “Root cause?” should be answered “Yes” or “No” for each finding Each finding that is identified as a root cause should be considered for an action and addressed in the action plan. Number each finding that is identified as a root cause.
- \* “Contributing factor?” should be answered “Yes” or “No” for each finding.
- \* “Take action?” should be checked off for each finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan.

**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.**

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
<b>1. Was critical patient information missing?</b> <i>(e.g., age; sex; weight, allergies; pregnancy; patient identity; address; indication for use or health conditions)</i>		No	No	

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
<b>2. Was critical drug information missing?</b> <i>(e.g., inadequate computer alerts; typical dose; maximum dose; route; contraindications; precautions; special warnings; drug interactions; cross allergies; outdated or absent references)</i>	PA did not know drug not commercially available in dose she prescribed			

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
<b>2. Was critical drug information missing?</b> <i>(e.g., inadequate computer alerts; typical dose; maximum dose; route; contraindications; precautions; special warnings; drug interactions; cross allergies; outdated or absent references)</i>	PA did not know drug not commercially available in dose she prescribed	Yes 1A		Yes

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
<b>3. Miscommunication of drug order?</b> <i>(e.g., illegible; ambiguous; incomplete; misheard or misunderstood spoken prescription; poor fax quality; unable to clarify with prescriber teamwork issues; warnings bypassed; error-prone abbreviations or dose expressions)</i>	Computer system allows free texting;  Discharge summary listed wrong dose of MSContin prescribed; Dictation service used;  RPh overrode duplicate alert			

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
<b>3. Miscommunication of drug order?</b> <i>(e.g., illegible; ambiguous; incomplete; misheard or misunderstood spoken prescription; poor fax quality; unable to clarify with prescriber teamwork issues; warnings bypassed; error-prone abbreviations or dose expressions)</i>	Computer system allows free texting;  Discharge summary listed wrong dose of MSContin prescribed; Dictation service used;  RPh overrode duplicate alert		Yes	Yes
		Yes 1B		Yes
		Yes 2		Yes

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
<b>4. Drug name, label, packaging problem?</b> <i>(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)</i>		No	No	

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
<b>5. Drug storage or delivery problem?</b> <i>(e.g., drug stocked incorrectly; crowded shelves; look-alike products stored next to each other; adult dosage forms for neonatal or pediatric patients)</i>		No	No	

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
6. Drug delivery device problem? (e.g., automated dispensing devices not calibrated or maintained; oral measuring device not dispensed)		No	No	

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
7. Environmental, staffing or workflow problems? (e.g., poor lighting; excessive noise; clutter; foot traffic interruptions; human factors; workload; inefficient workflow; breaks not scheduled; staffing levels and skills; work schedules; inadequate supervision)		No	No	

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
8. Lack of staff education? (e.g., competency validation; new or unfamiliar drugs or devices; orientation process; feedback about errors and prevention; inexperience; orientation; low compliance with mandatory education; required certification; support for advanced certification and education)	PA not familiar with brand names of extended release morphine			

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
8. Lack of staff education? (e.g., competency validation; new or unfamiliar drugs or devices; orientation process; feedback about errors and prevention; inexperience; orientation; low compliance with mandatory education; required certification; support for advanced certification and education)	PA not familiar with brand names of extended release morphine	Yes 3		Yes

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor ?	Take Action ?
9. Patient education problem? (e.g., lack of information; non-adherence; not encouraged to ask questions; lack of investigating patient inquiries; patient barriers; complex drug regimen; medication reconciliation problem; health literacy; language barrier or other communication problem; intimidated by staff; mental health issue)	Could not afford OxyContin Counseling not offered for high alert drug Wife's issues not addressed adequately			

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor ?	Take Action ?
9. Patient education problem? (e.g., lack of information; non-adherence; not encouraged to ask questions; lack of investigating patient inquiries; patient barriers; complex drug regimen; medication reconciliation problem; health literacy; language barrier or other communication problem; intimidated by staff; mental health issue)	Could not afford OxyContin Counseling not offered for high alert drug Wife's issues not addressed adequately		Yes Yes Yes	Yes Yes Yes

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor ?	Take Action ?
10. Quality process and risk management? <i>(e.g., no culture of safety; fear of error reporting; system-based causes not analyzed; lack of equipment quality control checks; focus on productivity and volume; financial resources or constraints; organizational structure and priorities conflict; technology workaround and/or malfunction; design flaw; technology user error; technology and devices not meeting needs)</i> <i>(human factors issues: task and information complexity; ergonomics; time urgency; familiarity with task, product, or equipment; mental and physical health of staff; fatigue; fitness for duty; stress; motivation)</i>		No	No	

### Step 5 Write Root Cause Statements

- Focus on system-level vulnerabilities
- Read and apply the five rules of causation
  - Causal Statements must clearly show the "cause and effect" relationship
    - "Pharmacist was flustered" is deficient without description of how and why this led to a mistake
  - Negative descriptors (e.g., poorly, inadequate) are not used in causal statements
    - Broad, negative judgments that do little to describe the actual conditions or behaviors that led to the error
  - Each human error must have a preceding cause
    - Investigate to determine WHY the human error occurred
  - Each procedural deviation must have a preceding cause
    - It is the **cause** of the procedural violation that we can manage
  - Failure to act is only causal when there was a pre-existing duty to act
    - The duty to perform may arise from standards and guidelines for practice

### Root Cause Statements

#### Step 5 – Root Cause Statements

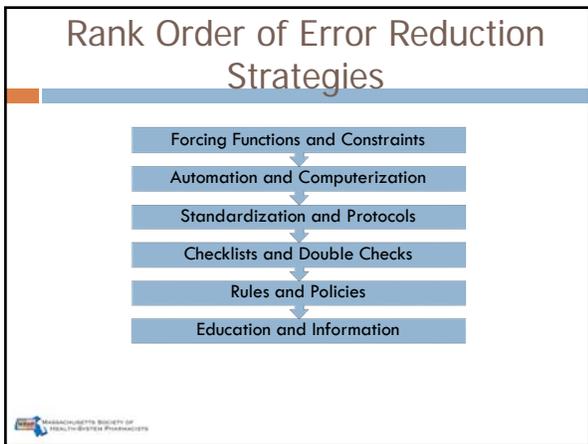
Using the findings identified as root causes in Step 4 above, write concise descriptions of the cause-and-effect relationship. Ensure that the team has not focused on the actions of individuals or in any way placed blame.

**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.

Root Cause #	Statement of Cause
1&3	Lack of knowledge and check systems for brand names of extended release morphine increased the probability of prescribing the wrong dose of medication
2	Since duplicate drug therapy for same opioid drug but different strengths are often appropriate the pharmacist was in the practice of overriding these alerts that were not deemed to be a problem

### Step 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



### 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?

### Step 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

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.

Root Cause#	Risk-reduction Strategy	Measure of Effectiveness
1 & 3	Medication reconciliation by pharmacist at discharge	Audit and Compare admission orders to discharge orders
2	High dose alert for patients taking over 120 MED	Ensure hard stops in place and review override reports



### Action Plan

#### Contributing Factors

For each of the contributing factor identified in Step 4 above as needing an action, complete the following table.

Contributing factor	Risk-reduction Strategy	Measure of Effectiveness
Prescriber can free text a drug in the computer system for a strength that is not available	POP up that alerts the prescriber that this drug is not “coded” which means it is not in the database and alerts that come along tied to drug (dosage alerts, D/D interactions) will not be active	Reports of drugs that are “free texted” in the electronic ordering system for education
Could not afford OxyContin	Discharge instructions include insurance discussion and payment options (free care, generics, 340B, etc.)	Compare Rx written vs Rx filled; IMS data



### Action Plan (cont.)

#### Contributing Factors

For each of the contributing factor identified in Step 4 above as needing an action, complete the following table.

Contributing factor	Risk-reduction Strategy	Measure of Effectiveness
Counseling not offered for high alert drug	Policy and procedures to include mandatory counseling of high alert medications	Review counseling log book
Wife’s issues not addressed adequately	Policy and procedure include mandatory follow up calls to reassess patients at high risk	Review nursing notes, phone logs and patient profile logs



### 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



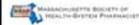
## Step 7 Communicate the Results

- 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 Takeaway #1

- RCA is intended to determine three things:
  - What happened?
  - Why did it happen?
  - What can be done to reduce the likelihood of a recurrence?



## Key Takeaway #2

- The RCA framework manageable steps:
  - Form a team
  - Review all documentation (written prescription, data entry, logs, policies, etc.)
  - 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
  - Communicate results
  - Measure effectiveness of action plan over time



## Key Takeaway #3

- RCA does not assign blame
  - RCA is an outcome-directed process emphasizing specific, high-leverage actions that take into account the need to integrate safeguards into system design and the need to consider human capabilities and limitations

