Preventing Medication Errors in a Changing Healthcare System

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Disclosures
• Angela Cassano, PharmD, declares no conflict 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.
• Patricia Kienle is an employee and stock holder of Cardinal Health

Learning Objectives
• Target Audience: Pharmacists and Technicians
• ACPE#: 0202-0000-13-024-L05-P
• ACPE#: 0202-0000-13-024-L05-T
• Activity Type: Knowledge-based

Self-Assessment Questions
1. At which point in the medication use system are medication errors occurring?
   a. Dispensing
   b. Administration
   c. Monitoring
   d. Prescribing
   e. All of the above

2. True or False External factors can influence internal focus on patient safety and medication error reduction

Self-Assessment Questions
3. A “near miss” in terms of a medication error is defined as which of the following?
   a. Any injury resulting from medical intervention related to a drug
   b. Any preventable event that may cause or lead to inappropriate medication use or patient harm
   c. Unexpected occurrence involving death or serious physical injury
   d. Error that was detected and corrected before it reached the patient
Self-Assessment Questions

4. True or False: A root cause analysis can evaluate a program that will be implemented for potential failure points.

5. When implementing a new technology like e-prescribing or automated dispensing, an organization should take time to conduct which of the following:
   a. Root cause analysis
   b. A train the trainer session
   c. Failure mode and effects analysis
   d. An internal audit to determine who will work with the technology

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Agenda

- Medication Use System
- Kicking it Up a Notch: What Changed?
- Developing a Quality System
- Case Study: RCA of a Medication Error in Transitions of Care
- Another Safety Net: Extending Pharmacy Services
- Case Study: FMEA of a New Computer System
- Wrap-Up

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Medication Use System

- What is our role in the medication use system?

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Contemporary Approaches

- Medication safety issues in every phase
- Traditional concentration has been on dispensing
- Expanded approach
  - Patient safety awareness
  - Third party mandates
  - Holistic approach
- New approaches require understanding of multidisciplinary components and impact each has on patient safety
Med Use System: Planning

• Prospective way to best position upcoming changes for success

Med Use System: Selection

• What to stock
  – Hospital – formulary
  – Community – more complex
• Brand v. generic
• Preferred agents
• Dosage forms

Med Use System: Storage

• Neat, uncluttered area
• High alert medications
  – Insulin
  – Anticoagulants
  – Opioids
  – Concentrated electrolytes
• Look- and sound-alike medications
• Hazardous medications
  – NIOSH – hazardous to personnel
  – EPA – hazardous to the environment

Med Use System: Ordering

• Handwritten prescriptions
• Electronic prescribing
• Texting
• Evolving technologies

Med Use System: Dispensing

• Independent double checks
• Technology
• Counseling
  – REMS

Med Use System: Administration

• Traditional approach
  – Hospital – nurses administer
  – Community – patients administer
• Pharmacy expanded services
• Many other clinicians administer medications
  – Medical personnel
  – Caregivers
Med Use System: Monitoring

- Clinical
  - Efficacy
  - Adverse drug reactions
  - Formal
  - Informal
- Incidents
  - Medication errors
  - Incompatibilities

Med Use System: Evaluation

- Traditional approach: what went wrong
- Contemporary approach: what works well and can be expanded to other areas

Summary

- Using the medication use system approach, how can we break down the silos of medical practice
  - Expand our role
  - Introduce new safety nets to protect patients

KICKING IT UP A NOTCH: WHAT CHANGED?

External Forces Impact Safety

Modern Medication Safety

- Medicare Modernization Act
- Pharmacy Quality Alliance Established
- CMS Never Events
- Accountable Care Organizations

- Institute of Medicine
- To Err is Human
- CMS Readmissions Reduction Program
- Affordable Care Act Signed into Law
- Institute of Medicine
- Crossing the Quality Chasm
- The Joint Commission
- Medication Reconciliation
- Patient Safety Organization

External Forces Can Drive Improvement of Internal Processes

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Healthcare Research and Quality

“Charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services.”

National Quality Forum (NQF)

- Created in 1999
- Part of NQF’s vision:
  - Be a major driving force for, and facilitator of continuous quality improvement of American healthcare quality

E-prescribing

- Medicare Modernization Act of 2003
- CMS endorses e-prescribing as a means for reducing medication errors
  - Endorsement comes in the form of financial incentives
  - Financial incentives vs. disincentives
  - 2006 IOM report builds awareness of e-prescribing’s role in patient safety

“Never” Events

- Events that should never occur
  - Classic example—wrong site surgeries
- 2008
  - CMS “No Pay” conditions
    - Hospital-acquired conditions (HAC)
    - Updated annually
    - Many are or could be medication related
      - DVT/PE
      - Hospital-acquired infections
      - Falls
      - Glycemic control

Pharmacy Quality Alliance (PQA)

Created in April 2006 to develop strategies for measuring performance at the pharmacy and pharmacist-level in order to improve patient outcomes

Mission: To improve the quality of medication management and use across healthcare settings with the goal of improving patients’ health through a collaborative process to develop and implement performance measures and recognize examples of exceptional pharmacy quality.

Just Culture

- Blame Free Culture
- Highly Punitive Culture

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Patient Safety Organizations

- Patient Safety Act of 2005
  - Administered by AHRQ
  - Approximately 75 PSOs currently

- Encourages VOLUNTARY reporting of quality and patient safety information without fear of legal discovery

Public Reporting

- www.medicare.gov

Accountable Care Organizations (ACOs)

- Coordinated care and disease state management while lowering costs

Medication Reconciliation

- 2005-The Joint Commission
  - NPSG #8
  - Medication reconciliation requirements at care transitions

- 2009-2011
  - TJC suspends scoring of medication reconciliation during on-site reviews
  - Decision based on lack of proven strategies for accomplishing medication reconciliation

- 2011
  - NPSG #3 incorporates medication reconciliation

Affordable Care Act

- Signed into law 2010

- Significant Provisions
  - Preexisting condition exemptions
  - Insurance coverage regulations
  - Preventive care
  - Community care transitions program
  - Integrated Healthcare systems
  - Linking payment to quality outcomes

ACA and Transitions of Care

- Effective October 2012
- Readmission payment adjustments for:
  - Acute myocardial infarction (AMI)
  - Pneumonia
  - Congestive heart failure (CHF)
Modern Medication Safety: Where is Pharmacy’s Role?

- Plan
- Select
- Store
- Monitor
- Order
- Administer
- Dispense
- Evaluate

DEVELOPING A QUALITY SYSTEM

Medication Use Safety and Quality

- Does safe medication use mean the same thing as quality?

Triad of Medication Use

- Safety
- Efficacy
- Quality
- Cost

Evolution

- Faith in the medical system
- Believe what you are told
- Safety
- First, do no harm
- Quality
- Consistent, evidence-based practice

Quality Terms

- Quality control
  - Things you can objectively check
- Quality assessment
  - Evaluating the system
- Quality improvement
  - Making change for the better
Retrospective Reviews

- Root Cause Analysis
  - What went wrong?

Root Cause Analysis

- Gather the data
- Describe the facts of the event
- Ask why each contributing cause occurred
- Drill down to identify the root cause
- Implement changes to mitigate the root cause

Prospective Approach

- Failure Mode and Effects Analysis (FMEA)
  - What are all the things that can go wrong with something new?

FMEA

- Analyze the process
  - Identify the process flow
- Evaluate each step to see what could go wrong
- Use a ranking scale to determine:
  - The probability of each failure occurring
  - The severity of the effects of each failure
  - The probability of each failure being detected
- Calculate the Criticality Index (CI) for each failure mode
- Assign a priority ranking for each failure mode by listing in decreasing order of CI value
- Identify strategies to improve safety

Ranking Scales

- Probability
  - Unlikely to frequent
- Severity
  - Minor to catastrophic
- Detection
  - Certain to undetectable

CASE STUDY: RCA OF A MED ERROR
Event to Review

- 77 year old female found unresponsive in her specialty hospital room. Attempts to intubate and oxygenate are unsuccessful and she is pronounced dead at 10 PM Sunday night.
- Family is notified and questions the cause of death and is told the cause is acute myocardial infarction.
- Family arrives at the hospital and asks to speak to the administrator on call as they are unhappy with the events leading up to the patient’s death and are questioning what happened.

What Happened?

- Autopsy Findings
  - Cause of death = multiple pulmonary emboli
- What types of questions are appropriate to ask?
  - What was her admitting diagnosis?
  - What comorbidities did she have?
  - What were her medications?

Patient Information

- BD was transferred to the specialty hospital s/p vertebral and shoulder abscess removal and repair
  - She had extensive spinal surgery
  - Was improving and becoming mobile in acute care facility
  - Transferred for long term rehabilitation and antibiotics
  - Original source of infection unknown
    - Spinal and shoulder cultures MSSA
    - Torulopsis glabrata line infection
- Patient is obese, and prior to hospitalization required medications for hypertension and a prior AMI
- Prior to current hospitalization, 16 days ago, patient was fully functional at home, driving, all ADLs on her own, completely independent
- No history of diabetes or CHF
- No anticoagulation due to spinal surgery, pneumatic compression devices and ambulation=DVT prophylaxis

Medication History at Transfer

Scheduled Medications to Continue

- Metronidazole
- Caspofungin
- Cefazolin
- Fentanyl patch
- Insulin glargine
- Regular insulin
- Furosemide for 24 more hours
- Metoprolol
- Allopurinol
- Lovastatin
- Ramipril
- Timolol maleate

Gather the Data

- Blood pressures
- Heart rate
- Pertinent laboratory values
- Ambulatory status
- Medication dispensing history
- Pain scores
Data Gathered…

• Blood Pressures
  – Well controlled upon admission, but began climbing 2-3 days after transfer
• Heart Rate
  – Similar to blood pressure
• Laboratory Values
  – All within normal limits with exception of hypokalemia despite replacement
• Ambulatory Status
  – Was up in a chair and able to stand for short time on day 1 and 2 after transfer
  – Since then, has been in too much pain to participate in rehab

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Fentanyl Patch Omission

• Last placed 9/9 at acute care facility
• Was marked as "continue" on discharge
• Not ordered on admission to specialty hospital
• 9/14 non-dated patch found on patient's chest
  – Powder under edges of patch
  – Barely stuck to patient
  – None had been dispensed since admission on 9/11
  – Assumption, this patch was from 9/9 at other hospital

Pain Control vs. Ambulation

Clinician's Response

• Patient needs to get up out of bed to ambulate to prevent DVTs
  – Reduce pain medications to stimulate ambulation, might be too sleepy to move
• Increase blood pressure medications to control increased BP
  – Unsure of why BP increased since patient admitted

What Does the Data Say?

• Medication error involving fentanyl patch has occurred
• Omission at transition of care
  – Due to lack of medication reconciliation at admitting facility
  – Also due to lack of patient assessment
  – No one questioned the presence of a non ordered narcotic patch on the patient’s chest for 4 days
• Uncontrolled pain is likely cause for:
  – Decreased ambulation
  – Increased blood pressure
 Did the Medication Error Contribute to Patient Death?  

**Yes**  
- Patient could not ambulate  
  - Primary means of DVT prophylaxis in this patient  
- Patient having difficulty breathing  
  - Assumed to be due to pain so no work up done

**No**  
- Patient with complicated medical history  
- Patient unable to take anticoagulants  
- Patient with multiple risk factors

• RCA of pulmonary emboli has uncovered a critical error that may or may not have contributed to the cause of death; however, it is still a medication error that caused severe pain and suffering to the patient…  
• Continue RCA to determine how to prevent similar outcomes for future patients

What Should Have Happened According to Policy and Procedures?  

- No policy on medication reconciliation on admission  
- Pain scale policy:  
  - Assess pain scale every time vital signs assessed  
  - For this patient, vitals to be checked every 2 hours  
  - Pain was assessed at best every 8 hours  
  - Pain can be documented in 3 different places  
  - Physician only reviews one place  
  - Pain scores of >4 require further intervention and assessment  
  - This is documented directly on the pain scale, but not followed currently

• Determine one place for pain score documentation  
• Make reassessment after medication a mandatory part of the documentation  
• Initiate a standard assessment and reassessment protocol for pain  
• Educate nursing, medical staff, and physical therapists about pain management  
  - How should pain be managed in a patient that never drops below 5 despite increasing doses of narcotics  
  - What signs other than pain scores should be evaluated to determine patient response to pain  
  - How do pain concerns get communicated to another discipline?

What Will Prevent it From Happening Again?  

• Initiate medication reconciliation program  
• Educate nursing and medical staff about patient assessment  
  - Question items affixed to patients with no corresponding documentation  
• Educate nursing and medical staff about fentanyl transdermal patches  
  - Where they should be located  
  - Importance of dating of the patch  
  - Onset of action and need for cross covering with oral or IV narcotics

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What Will Prevent it From Happening Again?  

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**Next Steps**
- Document changes
- Rewrite policies and protocols
  - Possibly order sets
- Educate staff
- Reevaluate

**Key Points**
- RCA can be as complex or as simple as you need it to be
- One person can do it, but best to involve others
- Let the facts speak
- The deeper you drill the more likely you are to find something that can be improved

**ANOTHER SAFETY NET: EXTENDING PHARMACY SERVICES**

**Getting Started...**
- Develop and implement system of reporting
- Determine data collection process
- Decide where data will be reported
- Determine follow-up procedures

**Reporting MUSTs**
- Be well outlined
- Be in place prior to collecting data on errors
- Have participation from senior leadership
- Be user friendly and not take too much time to complete

**Just Culture Refresher**
- Human Error
  - Inadvertent action
  - Console
- At-Risk Behavior
  - A choice
  - Counsel
- Reckless Behavior
  - Disregard
  - Punish
Reporting in a Just Culture

- Does not mean that data won’t be evaluated
- Discuss the idea at staff meetings
  - As a manager, show your support
  - Explain the reasons for reporting and how you plan for it to be evaluated
  - Does it mean that you won’t approach someone who made an error?
  - Does it mean that repeat offenders won’t be counseled or remediated?
  - Focus on the positive changes, not the negative occurrence

Approaches to Medication Errors

- Reactive
  - Reports filed when an error reaches a patient
  - Changes made if error is serious enough
- Proactive
  - All errors are reported, even near misses
  - Evaluation of all new processes completed prior to implementation

Data Collection

- Paper or computerized
- Home grown or industry supplied
- Available products
  - All capture similar items
  - Need to meet your specific needs
  - Must provide the reports you need
- Determine policies and procedures
- Determine who will do the collecting and reporting

Reporting

- What should you report?
  - JUST THE FACTS
    - Too much information adds time, bias, and potential for unfounded legal ramifications
  - Errors AND Near Misses
    - Include the following in the report:
      - Identifier (Patient and reporter)
      - Event facts
        - Drug(s) involved, type of error, etc.
        - Patient outcome

Got Data?

- How to report…
  - Raw numbers
  - Break down using NCC MERP Taxonomy
  - Charts and Graphs
  - FMEA
  - RCA
  - If possible, report a way to make a change in practice

Categorizing Reports

- According to severity
- According to National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)
  - Harm? If so, to what degree
  - Reports are useful even if there was no harm to the patient
  - Investigate and act upon if appropriate

NCC MERP Index for Categorizing Medication Errors

Definitions

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

Categories

1. Adverse drug event
2. Medication error
3. Error in medication therapy management
4. Medication administration error
5. Medication dispensing error
6. Medication prescribing error
7. Medication compounding error
8. Medication transcription error
9. Medication monitoring error
10. Medication disposal error
11. Medication communication error
12. Medication documentation error

Prevention Strategies

- Implement improvements to prevent or reduce the likelihood of similar events
- Improve systems, processes, and procedures
- Use technology
- Educate staff on medication error prevention
- Develop policies and procedures
- Conduct audits and reviews
- Implement feedback mechanisms
- Conduct medication reconciliation
- Educate patients and families
- Conduct medication education
If a tree falls in the woods and no one is there, does it make a sound?

Does an error need to cause harm or reach a patient in order to make a difference?

Near Misses
So much to say, seldom heard…

- Levels A and B on NCC MERP
- Uncovers dangerous situations
- Highlights system breakdowns prior to harm being caused
- Difficult to capture
- Reported less often
  - Some don’t consider them errors and don’t file a report

Reporting

- To whom to report…
  - Internal supervisors and management
  - Risk management
  - Corporate level, if applicable
  - Malpractice insurance company
  - State Board of Pharmacy, if applicable
  - Regular staff meetings
  - External groups, ISMP, etc.

I hear what you are saying, but I don’t have time…

Student Projects

- Integrate medication safety into rotations
  - Medication safety project each month
    - Have students collect data
    - Research a type of medication error
    - Complete a RCA or FMEA
    - Newsletter or staff meeting presentation (5-10 minutes)

- Potential for longitudinal projects and presentations
- Ask their opinion, do they see room for improvement?
  - Great resource for how things are done elsewhere
Pharmacy Technicians

• Include medication safety in new hire training
• Train pharmacy technicians in leadership roles
  – Ensure consistency in the message
  – Allow increased responsibility in non-clinical functions

Pharmacy Technicians

• Include entire pharmacy team in new program development
  – Include team in process and quality improvement
  – Include team in FMEA
• Encourage open communication and reporting at all levels

APhA/ISMP Website

• Website provides FREE access to medication safety lectures
  – Based on Michael Cohen’s book *Medication Errors, 2nd Edition*
  – Lectures are modifiable
  – Provided in 45 minute to 1 hour format
  • May be decreased to any length needed
  • Promotes the addition of curriculum on Medication Safety to schools and colleges of pharmacy

CASE STUDY: FMEA OF A NEW SYSTEM

A New Computer System

• Conversion to a new computer system is planned for July 1
• You have been tasked with leading a small group of users to identify the key components that need to be addressed
• Identify four to five major elements
• Using the grid on the next slide, identify the two with the highest criticality index

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Questions