

# Hallmarks of Patient Safety and Quality Improvement Programs in Pharmacy Practice

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Wednesday, May 10, 2017



Kimberly McDonough Spring Seminar  
Rhode Island Pharmacy Foundation

## Disclosure

- ▶ I have no relevant financial or non-financial relationships to the content of this CPE activity to disclose at this time.

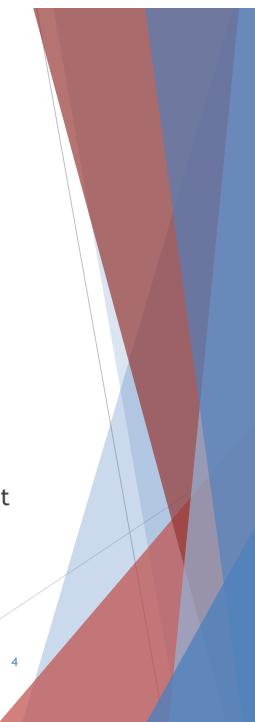
## Learning Objectives

- ▶ Pharmacist Objectives:
  1. Explain the overall process for detection, analysis, response, and improvement of discovered medication errors.
  2. Explain the principles of Just Culture and its relation to patient safety and quality improvement opportunities within pharmacy practice.
  3. Describe an appropriate response and apology to a patient or patient's family regarding a medication error.
- ▶ Technician Objectives:
  1. Explain the overall process for detection, analysis, response, and improvement of discovered medication errors.
  2. Explain the principles of Just Culture and its relation to patient safety and quality improvement opportunities within pharmacy practice.



## Why do we care?

- ▶ Medication errors account thousands of injuries and deaths each year.
- ▶ We are one of the very last lines of defense in the healthcare system before a patient takes a drug.
- ▶ Many states' regulations require continuous quality improvement within pharmacy systems and continuing education for pharmacy staff.
- ▶ Quality is always on everyone's mind and from different perspectives
  - ▶ Patients, employers, boards of pharmacy, payers, etc
- ▶ Malpractice claims continue to be at a high level
- ▶ Quality and safety are the center of delivering exceptional patient care



## Definitions

- ▶ Medication error (NCC-MERP)
  - ▶ “A medication error is 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. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.”

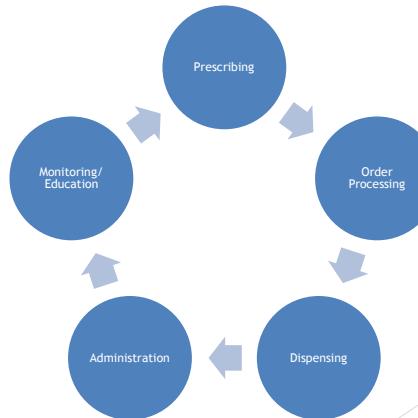


5

National Coordinating Council for Medication Error  
Reporting and Prevention

## Definitions

- ▶ Medication use system



6

## Definitions

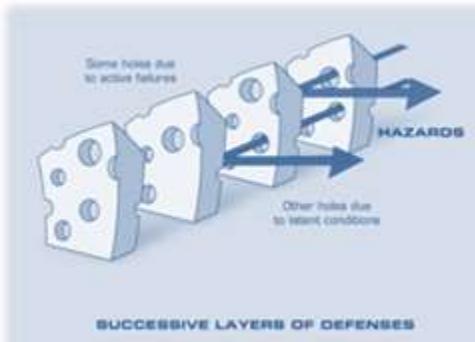
- ▶ Healthcare quality
  - ▶ Institute of Medicine Crossing the Quality Chasm (2001)
    - ▶ SAFETY - avoiding patient harm
    - ▶ EFFECTIVENESS - evidence based medicine
    - ▶ PATIENT CENTEREDNESS - patient is in control of own care
    - ▶ TIMELINESS - avoidance of needless delay
    - ▶ EFFICIENCY - eliminating waste such as duplications
    - ▶ EQUITY - closure of the health disparity gaps



7

## How do errors typically occur?

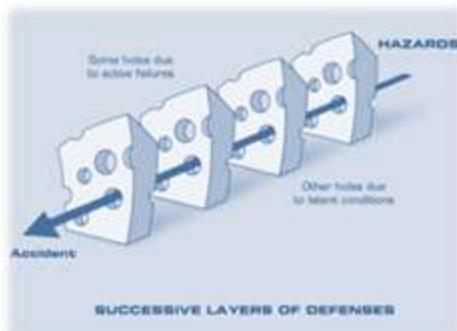
- ▶ “Swiss Cheese” model of human error (J Reason 1990)



8

## How do errors typically occur?

- ▶ “Swiss Cheese” model of human error (J Reason 1990)



## How many errors occur each year?

- ▶ Unfortunately, there is no actual number available in the industry but only estimates.
- ▶ U.S. Food and Drug Administration
  - ▶ *“Medication errors cause at least one death every day and injure approximately 1.3 million people annually in the United States.”*
- ▶ Johns Hopkins Medicine patient safety experts (3/2016)
  - ▶ Calculated >250,000 deaths per year (9.5% of all deaths) due to medical errors, making it 3<sup>rd</sup> leading causing of death in U.S.
  - ▶ JHM Physicians claim medical errors are an under-recognized cause of death and have advocated for it to be a reportable cause of death recognized/analyzed by Centers for Disease Control (CDC)

## QUALITY HALLMARK #1

- ▶ Recognition that quality improvement is an on-going process and error-free status is never reached, requiring
  - ▶ Continuous event reporting
  - ▶ Analytical tracking
  - ▶ Persistent decrease in reporting bias

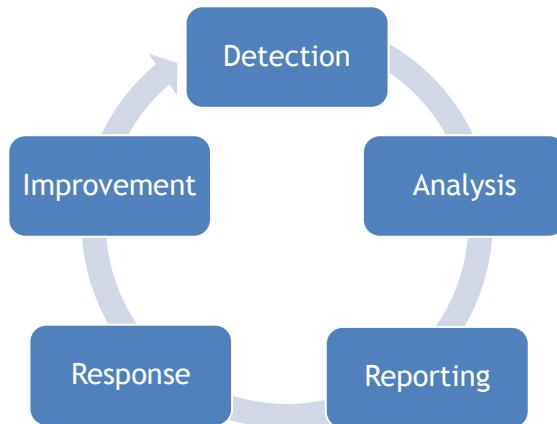


11

## Regulation review

- ▶ Patient Safety and Quality Improvement Act (2005)
  - ▶ Encourages voluntary reporting of patient safety events and medical errors
  - ▶ Creation of Patient Safety Organizations (PSOs)
  - ▶ Privilege and confidential protections for *patient safety work product*
- ▶ Healthcare organizations and institutions should feel empowered to collect and analyze error data for the purpose of quality improvement and preventing errors

## Patient safety error process



## Patient safety error process

- ▶ After an error, investigate the following
  - ▶ Patient(s) involved
  - ▶ Justify the clinical effects of the error
  - ▶ Determine the root cause
  - ▶ Research any contributing factors that might have led to the error
  - ▶ Formulate a plan of action to prevent the error in the future

## Reporting bias

- ▶ Why might an individual not report an error(s)?
  - ▶ Fear of punishment
  - ▶ Embarrassment
  - ▶ Concern about error rate metrics
  - ▶ Possible improper use of information
  - ▶ Admission of fault or guilt
  - ▶ Ideology that no change will come from reporting

Reporting errors within your health system today will improve quality and safety for your patients tomorrow

15

## Knowledge Check: Question 1

- ▶ The Patient Safety and Quality Improvement Act of 2005 fosters a culture of patient safety by providing what?
  - A. Government oversight of medication errors
  - B. Federal privilege and confidentiality protections
  - C. Requiring healthcare providers to collect, aggregate, and analyze confidential information to prevent future medication errors

16

## QUALITY HALLMARK #2

- ▶ Culture of organization and/or individual pharmacy team is one that is conducive to safe practices
  - ▶ Patient safety is of the highest importance
  - ▶ Blame for errors is placed first on the overall system and not directed at the individual
  - ▶ Behaviors are routinely evaluated



17

### Safety culture of pharmacy team

- ▶ Take inventory of current safety culture with pharmacy (ISMP)
  - ▶ What are the organization's primary and secondary values?
  - ▶ Do managers' behaviors demonstrate safety as primary (high value)?
  - ▶ Is safety a value or a priority?
  - ▶ How does the organization respond to human error, at-risk behavior, and reckless behavior?
  - ▶ Are individual accountabilities documented in job descriptions, performance evaluations, and/or policies, communicated to staff?
  - ▶ Is the culture tolerant of at-risk behaviors?
  - ▶ Does the organization tend to punish safe behavior and/or reward at-risk behavior?
  - ▶ Is there visible evidence of coaching around at-risk behaviors?<sup>18</sup>

18

## Just Culture behavior descriptions

Human Error	At-Risk Behavior	Reckless Behavior
<ul style="list-style-type: none"> <li>• Unintentional</li> <li>• Unpredictable</li> <li>• Not a behavior choice</li> </ul> <p>• Consoling/Coaching</p>	<ul style="list-style-type: none"> <li>• Mistakenly believe risk is justified</li> <li>• Lose of perception of risk of a routine task</li> <li>• Often considered “the way we do things around here”</li> </ul> <p>• Coaching/Monitoring</p>	<ul style="list-style-type: none"> <li>• Behaving intentionally but unable to justify behavior</li> <li>• Previously coached</li> <li>• Knowledge that others are not engaged in same behavior</li> <li>• Conscious behavioral choice</li> </ul> <p>• Remedial/disciplinary action</p>

19

## Knowledge Check: Question 2

- Technician Tommy has been working at your pharmacy for 3 years. During a shift with him, you realize that he is not performing barcode scanning of stock bottles when filling prescriptions. You stop him to show him the safe way to fill a prescription and counsel him on the importance. Later that week you see him reverting back to unsafe practices. Following the principles of Just Culture which would be most appropriate?
- Counsel him again
  - Counsel him again and consider remedial actions
  - Don't say or do anything as his behavior isn't likely to change.

20

\*Illustrative purposes only. Please follow your employer's policies.

## QUALITY HALLMARK #3

- ▶ Creating lasting change is typically best achieved by implementing system changes and/or forced-functions rather than relying on updated training or education



21

## Selection of error reduction strategy after events

- ▶ ISMP states that fail-safes and forcing function are among the most powerful and effective error prevention strategies
- ▶ Strategy selection depends on what type of change you are trying to implement in your pharmacy

Error-Reduction Strategy	Power (leverage)	Reliance on Human Vigilance
Fail-safes and constraints	↑	
Forcing functions		↓
Automation and computerization		
Standardization		
Redundancies		
Reminders and checklists		
Rules and policies		
Education and training		
Suggestion to be more careful		

22

## Retail quality DUR study finds retail pharmacy industry has opportunity for improvement

- ▶ “Watch dog: Pharmacies miss half of dangerous drug combinations”
  - ▶ Published by Chicago Tribune 12/15/2016
  - ▶ Conducted by a team of investigative reporters in partnership with a local prescriber
  - ▶ 255 pharmacies were tested whether pharmacists would intervene or warn of selected drug-drug interactions.
  - ▶ Pharmacies tested were both national chain locations and independent pharmacies
  - ▶ 52% of pharmacies sold the interacting drug combinations without mentioning the potential interactions to the prescriber or patient
  - ▶ Study video link - <http://www.chicagotribune.com/news/media/92128156-132.html>

Chicago Tribune. 2016.

23

## Drug combinations used in study

- ▶ Clarithromycin + Ergotamine
- ▶ Simvastatin + Clarithromycin
- ▶ Colchicine + Verapamil
- ▶ Tizanidine + Ciprofloxacin
- ▶ Norgestimate/ethinyl estradiol + Griseofulvin

Chicago Tribune. 2016

24

## Pharmacies visited by ownership

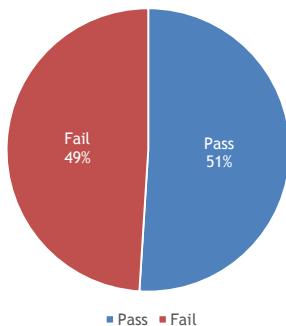
- ▶ Independent pharmacies - 32
- ▶ Walgreens - 30
- ▶ Walmart - 30
- ▶ K-mart - 30
- ▶ CVS pharmacy - 30
- ▶ Target - 13
- ▶ Jewel-Osco - 30
- ▶ Mariano's - 30

Chicago Tribune. 2016

25

## Study overall results

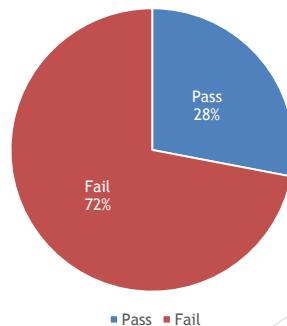
Overall Performance of Chain Pharmacies



Chicago Tribune. 2016

26

Overall Performance of Independent Pharmacies



26

## How can this safety performance be improved?

- ▶ Chicago Tribune collected responses from pharmacies used in study
- ▶ Multiple companies responded indicating that they would review training related to drug-drug interactions
- ▶ Three chains responded by saying they would either review their “system” or “pharmacy alert system” for opportunities to improve
- ▶ One national chain vowed to update its system to force pharmacists to either call prescriber or counsel patients on specific warnings

*Chicago Tribune. 2016*



27

## Knowledge Check: Question 3

- ▶ One day during your shift, you learn about a prescription error that was made the day before. Concentrated oral morphine sulfate solution was dispensed with the wrong directions resulting in a 20-fold overdose. Which of the following enhancements would have the most power and rely least on human vigilance?



28

## Knowledge Check: Question 3

- One day during your shift, you learn about a prescription error that was made the day before. Concentrated oral morphine sulfate solution was dispensed with the wrong directions resulting in a 20-fold overdose. Which enhancement would have the most power and rely least on human vigilance?
- Tell all pharmacists at your store about the error and suggest that they be more careful.
  - Create a checklist of safety steps to go through each time when filling the product and keep it by the stock bottle.
  - Have one of your pharmacist interns make a training presentation and present at the next staff meeting

*\*Illustrative purposes only. Please follow your employer's policies.*

29

## QUALITY HALLMARK #4

- Appropriate response, follow-up, and apologies to patients and/or family are encouraged following medication errors



30

## Why talk about apologies?

- ▶ Patients expect errors to be responded to professionally
- ▶ There are right and wrong ways to respond to an error
- ▶ Malpractice and medical error lawsuits are on the rise



31

*Modern Healthcare. October 2012.*

## Always be prepared to respond to an error

- ▶ Institute for Safe Medication Practices (ISMP)
  - ▶ When patients report medication errors to ISMP, they are usually **MORE UPSET** about the response, or lack of response, they receive from the pharmacist or pharmacy management than with the actual error itself.



32

*ISMP Medication Safety Alert! November 2009.*

## How to slow the increase of liability claims

- ▶ Veterans Affairs Medical Center, Lexington, KY
  - ▶ Developed a comprehensive process designed to proactively identify and remedy medical errors
    - ▶ Widely publicized the disclosure policy throughout the hospital
    - ▶ Apologized after each medical error
    - ▶ Fully disclosed investigation results to patient and/or family
    - ▶ Fair remedy including appropriate compensation
  - ▶ Led to liability claim costs that were the same or lower than those of similar VA centers that did not practice full disclosure

*Innovations Exchange. Agency for Healthcare Research and Quality. Updated 6/4/2014.*

33

## How to slow the increase of liability claims

- ▶ Veterans Affairs Medical Center, Lexington, KY
  - ▶ A 15-year analysis (1987-2002) revealed an average payout of \$14,500 per case in Lexington, KY
  - ▶ Average payout across all VA facilities was \$413,000 per case (\$98,000 pretrial; \$248,000 during trial)
  - ▶ By the late 1990's, all VA hospitals adopted the full disclosure policy

*Innovations Exchange. Agency for Healthcare Research and Quality. Updated 6/4/2014.*

34

## Case Study - A Dangerous Dispensing Error

DS is an 8 year-old boy who was prescribed cetirizine for his allergies actually received clopidogrel intended to be dispensed to a 60 year-old patient. DS was given 3 doses before his mother realized the medication was different from usual and there might be a problem. DS's mother is worried and calls the pharmacy concerned about this happened and what she should do.

How do you appropriately respond to DS's mother and properly investigate the error?

35

## How do you respond when an error is made?

- ▶ Sample pharmacist-patient interaction

**Sample Error Response #1**

36

## How do you respond when an error is made?

- ▶ Points of improvement for the pharmacist
  - ▶ Address clinical needs of the patient
  - ▶ Increase empathy and show concern
  - ▶ Apologize?

37

## Agency for Healthcare Research and Quality

- ▶ Lead federal agency for conducting healthcare quality research
- ▶ AHRQ Healthcare Innovations Exchange
  - ▶ Innovations and tools to improve quality and reduce disparities
  - ▶ Provides a tool from the Canadian Medical Protective Association (CMPA)
    - ▶ *Communicating With Your Patient About Harm*

38

Agency for Healthcare Research and Quality

# Agency for Healthcare Research and Quality

- ▶ Communicating with your patient about harm (CMPA)
  - ▶ Attend to clinical care needs first!
    - ▶ Handle any emergencies
    - ▶ Consider next clinical steps
    - ▶ Provide emotional support
    - ▶ Document care provided
  - ▶ Plan a disclosure discussion
    - ▶ Express regret and apologize for the error
    - ▶ Only present facts, no assumptions or conjectures
    - ▶ Avoid blame or speculation
    - ▶ Arrange follow-up and provide contact information
    - ▶ Document all disclosure discussions in medical record

*Agency for Healthcare Research and Quality*

39



# University of Michigan Health System

- ▶ Implementation of an “apology” policy since 2004
  - ▶ *In short, we’re trying to “do the right thing” for our patients, our medical staff, and the public interest. We believe that court should be the last resort, not the first, when a medical mishap, complication or near-miss occurs.*
  - ▶ *Our approach can be summarized as: “Apologize and learn when we’re wrong, explain and vigorously defend when we’re right, and view court as a last resort.”*

*University of Michigan Health System*

40



# University of Michigan Health System

- ▶ Dramatic decrease in claims and lawsuits
  - ▶ Pre-suit claims fell from average of 260/yr to 100/yr
- ▶ Legal costs decreased \$2 million after first year of implementation
- ▶ It's all about treating people right



41

*University of Michigan Health System*

## How do you respond when an error is made?

- ▶ Sample pharmacist-patient interaction

**Sample Error Response #2**

42



## Knowledge Check: Question 4

- ▶ True/False - It is advisable to apologize to the patient or caregiver when a medication error takes place in the pharmacy.

**True**

43

Questions?

44

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45

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46