Medication Errors, Public Safety and Protecting Your License

• Kevin McCarthy, RPh
• Vice President, PharmCon Inc.
Objectives

- 1. Identify the most common types of medication errors and medications involved in fatalities
- 2. Assess the potential impact of a given error on the patient, practitioner, and health care system
- 3. Describe how continuous quality improvement can be used to prevent medication errors in various pharmacy settings
- 4. Implement at least 2 changes to minimize errors in your practice area.

“It was estimated that a pharmacist who is 99% accurate over 40 years of practice, in which 480,000 prescriptions are dispensed, will likely cause the death of six patients.”

US Pharmacist: A Systematic Approach to Preventing Medication Errors.
To Err is human......

Please type in your medication error experience in the chat box!

Medical Errors

“The majority of medical errors do not result from individual recklessness or the actions of a particular group—this is not a “bad apple” problem.

More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.”

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.

The National Coordinating Council for Medication Error Reporting and Prevention
Estimates of Medication Errors

- In an average week, 4 out of 5 US adults will use prescription medicines, OTC drugs, or dietary supplements, and nearly one third of adults take 5 or more different medications.
- ~1.5 million serious, preventable medication errors occur every year in the U.S.
Medication Errors in Pharmacies

- Error estimates
  - 4 errors/day (250 rxs/day)
  - 51.5 million errors in the 3 billion rxs/year
  - potential for 3.3 million important errors in the U.S. annually

- That REACH the patient
  - 1.7% error rate
  - 0.2% with bar coding
  - 0.075% in highly automated mail-service pharmacy


Medication Errors in Hospitals

- 5.07% error rate
  - Includes all professions
  - A medication error every 22.7 hours and every 19.73 admissions

- Serious errors - 0.25% of all patients admitted each year
  - 1 every 19.23 days (or every 401 admissions)

1.6 Million Nursing Home Residents in U.S.

Estimates of Medication Errors

- Pediatrics
  - 2.5% incidence of medication errors resulting in harm
  - 4.5 - 5.7 errors per 1,000 medication orders in hospitals
  - 5.6% potentially fatal

Joint Commission Sentinel Event Alert
Most Common Errors

- Dosing errors
- Inappropriate dosage forms
- Improper dispensing (wrong drug or dose)
- Prescribing medications to which the patient was allergic


POLL QUESTION # 1

- Click what you think is the right answer and hit the “submit” button.
Case Study

- A 3-day-old infant was prescribed total parenteral nutrition containing heparin.
- Blood glucose level of 17 mg/dL was reported 6 hours after the TPN infusion was started.
- Despite multiple boluses of dextrose and an infusion of dextrose 20%, the hypoglycemia did not completely resolve until discontinuing the TPN.

What medication was likely in the TPN which should NOT have been?
### Medications Most Commonly Involved in Serious or Fatal Errors

- Morphine
- Warfarin
- Insulin
- Heparin
- Potassium chloride
- Fentanyl

MEDMARX 5th Anniversary Data Report. 2004

How Many Error Contributors Can You Spot?
## Contributors to Medication Errors

- Prescription volume
- Distractions/interruptions
- Shortage of support personnel
- Look alike/sound alike drug names
- Prescriber’s handwriting
- Inadequate time to counsel
- Fatigue
- Verbal orders
- Product labeling and packaging
- Abbreviations

### Volume as a Contributor

- Volume is increasing in retail pharmacy
- Relationship to errors is not simple
- Workload ≠ Performance
Case Study 2

- Steve is a 58 year old with a first gout attack
- He fills a prescription for colchicine 0.6 mg
- Directions
  - Take 2 tablets, then 1 tablet every 2 hours until pain relief or diarrhea

What would happen if he never developed diarrhea or got pain relief and took 1 tablet every hour x 10?
Case Study

- Steve presents to ER 24 hours after starting the colchicine with nausea, vomiting, profuse diarrhea, and chest pain.
- Admitted to the hospital for rehydration and continued observation
- During the next 48 hours, he experienced leukopenia, thrombocytopenia, renal insufficiency, rhabdomyolysis, and lactic acidosis

Health Consequences of Medication Errors

- Deaths
  - ∼ 7,000/year
- Long term organ/system dysfunction
  - Hearing loss
  - Kidney failure
- Liver failure
- Loss of a limb
Financial Consequences

- Total costs related to medical errors, including health care and disability expenditures as well as lost income and productivity, are estimated at $37 to $50 billion per year

Preventable medical errors are estimated to represent as much as 2% of total health care costs

Psychological Consequences

- Errors impact patient, health care provider, employer, and public perception
- For the pharmacist
  - Anxiety, depression, etc
  - Stress related illness
  - Reduced confidence in skills
  - Worries about job loss
Legal Consequences

- Lawsuit
  - Employer and/or individual
  - Civil
    - Professional negligence
    - Mechanical vs intellectual
      - OBRA 90

Legally Speaking

- Pharmacists are responsible for technical accuracy in dispensing.
- Pharmacies are responsible for institutional controls over the environment in which pharmacists practice.
- Pharmacy technicians generally are not liable for errors, although this may change
Legally Speaking

- No generalized duty to warn of adverse drug effects
  - varies by state and job description (dispensing vs “clinical” pharmacist)
  - Duty to warn and counsel is changing

Substantial Damage Awards

- Rph dispensed glipizide instead of a drug for gout
  - patient went into a coma and eventually suffered a stroke and died
  - pharmacy chain paid $31.3 million

- Patient mistakenly received a dose of warfarin 10 times too high
  - cerebral hemorrhage and death
  - family received $25.8 million
Legal Consequences

- Lawsuit
  - Criminal
    - Criminal intent
    - Unlawful act
    - Possible in the case of medication errors

Board of Pharmacy

- Typically patient or family complaint
- Actions
  - No action
  - Reprimand / Fines
  - License Suspension
  - License Revocation
5 minute break !!!

REMINDER:
IF YOU HAVE QUESTIONS, TYPE THEM IN THE CHAT BOX AND SUBMIT THEM.
ALL QUESTIONS WILL BE ANSWERED AT END OF PRESENTATION AS TIME PERMITS.

The presentation will resume in 1 minute
Tools to Reduce Errors

- Prescription/Medication Specific
- Environmental/workplace
- Technology
- Continuous quality improvement programs

Prescription or Medication Specific
Error-Prone Notations

- Ambiguous medical notations are one of the most common and preventable causes of medication errors.
- Misinterpretation may lead to mistakes that result in patient harm.
- Delay start of therapy due to time spent for clarification.
- What error-prone notation is not used in your pharmacy?

Implement “Do Not Use” List

- The Institute for Safe Medication Practices (ISMP) and the FDA recommend that ISMP’s list of error-prone abbreviations be considered whenever medical information is communicated.
- Complete list is located at:
  www.ismp.org/tools/errorproneabbreviations.pdf
Never Use Notations*

The following notations should NEVER be used.

<table>
<thead>
<tr>
<th>Notation</th>
<th>Reason</th>
<th>Instead Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;U&quot;</td>
<td>Mistaken for 0, 4, cc</td>
<td>“unit”</td>
</tr>
<tr>
<td>&quot;IU&quot;</td>
<td>Mistaken for IV or 10</td>
<td>“unit”</td>
</tr>
<tr>
<td>&quot;QD&quot;</td>
<td>Mistaken for QID</td>
<td>“daily”</td>
</tr>
</tbody>
</table>

*Comprises “do not use” list required for JCAHO accreditation

Other Example Error-Prone Notations

<table>
<thead>
<tr>
<th>Notation</th>
<th>Reason</th>
<th>Use Instead</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;QOD&quot;</td>
<td>Mistaken for QID, QD</td>
<td>every other day</td>
</tr>
<tr>
<td>Trailing zero (X.0 mg)</td>
<td>Decimal point missed</td>
<td>X mg</td>
</tr>
<tr>
<td>&quot;MS&quot;</td>
<td>Can mean morphine sulfate or magnesium sulfate</td>
<td>Full drug name</td>
</tr>
</tbody>
</table>
Consider All Communication Forms

- Written orders
- Internal communications
- Telephone/verbal prescriptions
- Computer-generated labels
- Labels for drug storage bins
- Medication administration records
- Preprinted protocols
- Pharmacy and prescriber computer order entry screens

ISMP’s Recommendations for Healthcare Professionals

- Avoid ambiguous abbreviations in all written communications.
- Work with computer software vendors to make changes in electronic order entry programs.
- Provide examples when educating staff on how using error-prone abbreviations have led to serious patient harm.
- Provide staff with ISMP’s list of error-prone abbreviations.
- Introduce healthcare students to the list.
## High Alert Medications

### Injectables

- adrenergic agonists, IV (e.g., epinephrine)
- adrenergic antagonists, IV (e.g., propranolol)
- anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)
- antiarrhythmics, IV (e.g., lidocaine, amiodarone)
- cardioplegic solutions
- chemotherapeutic agents, parenteral and oral
- dextrose, hypertonic, 20% or greater

<table>
<thead>
<tr>
<th>High Alert Medications</th>
<th>Injectables</th>
</tr>
</thead>
<tbody>
<tr>
<td>antithrombotic agents (IV unfractionated heparin, Factor Xa inhibitors (fondaparinux), direct thrombin inhibitors (e.g., argatroban, lepirudin, bivalirudin), thrombolytics (e.g., alteplase, reteplase, tenecteplase), and glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide))</td>
<td></td>
</tr>
<tr>
<td>dialysis solutions</td>
<td></td>
</tr>
<tr>
<td>epidural or intrathecal medications</td>
<td></td>
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<tr>
<td>inotropic medications, IV (e.g., digoxin, milrinone)</td>
<td></td>
</tr>
</tbody>
</table>
### High-Alert Medications

#### Injectables
- liposomal forms of drugs (e.g., liposomal amphotericin B)
- moderate sedation agents, IV (e.g., midazolam)
- narcotics/opiates, IV
- neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium)
- radiopaque agents, IV
- total parenteral nutrition solutions
- epoprostenol (Flolan), IV
- insulin, IV

- magnesium sulfate injection
- oxytocin, IV
- nitroprusside sodium for injection
- potassium chloride for injection concentrate
- potassium phosphates injection
- promethazine, IV
- sodium chloride for injection, hypertonic

#### Oral - Subcutaneous - Etc
- antithrombotic agents (e.g., warfarin, low-molecular-weight heparin)
- narcotics/opiates, transdermal, and oral (including liquid concentrates, immediate and sustained-release formulations)
- hypoglycemics, oral
- hypoglycemics, subcutaneous

- methotrexate, oral, non-oncologic use
- opium tincture
- sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more
Strategies for Reducing Errors with High-Alerts

- Improve point of care access to information about these medications
- Limit access to high-alert medications
- Utilize auxiliary labels and automated alerts
- Standardize ordering, storage, preparation, and administration
- Employ redundancies such as automated or independent double checks

Look Alike/Sound Alike

- More than 1,400 commonly used drugs are involved in errors linked to drug names that look alike or sound alike, including all of the 10 most commonly prescribed drugs
Common Sound Alike Problems

- Serzone (nefazodone) - Seroquel (quetiapine)
- Lamictal (lamotrigine) - Lamisil (terbinafine)
- Taxotere (docetaxel) - Taxol (paclitaxel)
- Zantac (ranitidine), Zyrtec (cetirizine), Zyprexa (olanzapine)
- Celebrex (celecoxib) - Celexa (citalopram)

Case of Insulin/Heparin Mix-up

- Infant who received insulin instead of heparin as a result of IV admixture room mistake

What might have been contributing factors in this error (i.e. how does one mistake insulin for heparin)?
Insulin/Heparin Case

- Both dosed in units
- Both are used widely in hospitals
- Both are often placed on the same counter, drug cart, or under a laminar flow hood.
- Humulin brand - heparin

Strategies for Reducing Errors with Look/Sound Alikes

- Change the appearance of look-alike product names on computer screens, storage areas, dispensing machines, pharmacy product labels, and MARs using bold face, color, or tall man letters
  - hydrOXYzine, hydrALAzone
- Separate them on the shelves
What drugs would come up when you enter MET as a mnemonic in your pharmacy order entry system?

Strategies for Reducing Errors with Look/Sound Alikes

- Indication on prescription
- Maintain awareness of problem pairs and provide updated information to professional staff regularly.
- Computerized alerts
Environmental/Workplace Tools

- Adequate staffing
- Breaks
- Adequate lighting
- Organized workspace
- Automatic refill processing
- Limit hours/volume per pharmacist

Technology
Computerized Prescriber Order Entry (CPOE)

- Helps prevent transcription, interpretation, and contraindicated medication type errors
- Studies have had positive and negative results
  - reduction in both preventable and potential ADEs
  - dosage errors ↓ 23%, errors associated with known allergies fell 56%
- work arounds
- alert overload/overrides

J Am Med Inform Assoc. 1999; 6:313-21

An Emerging Trend -
look-alike drug names in computerized order entry systems are an increasing source of confusion for prescribers

MEDMARX® Data Report 2008
Available at www.usp.org
Bar Coding

- Error rate of about 1 in 10 million but still has a human factor
- Reduces dispensing, administration, and filling of robotic/medicine cabinets errors
- Problems
  - not checking each item
  - misreading by device
  - workarounds

Bar Coding

- 15 types of workarounds,
  - affixing patient-ID-barcodes to computer carts, scanners, doorjambs, or nurses' belt-rings
  - carrying several patients' pre-scanned medications on carts.
- 31 causes of workarounds,
  - unreadable medication-barcodes, malfunctioning scanners; unreadable or missing patient-ID-wristbands; non-barcoded-medications

Computerized Medication Administration Records

- May be part of CPOE or may be printed from pharmacy order entry
- Reduce transcription and illegible writing errors
- Reduce notation errors (abbreviations, etc) if appropriately programmed
- Only as good as the data put in

Automated Dispensing Machines

- Community pharmacies, hospitals, nursing homes
- Mixed results in studies
- Reduce timing errors
- Problems
  - filling/bar coding errors
  - work arounds
  - overrides
POLL QUESTION # 2

- Click what you think is the right answer and hit the “submit” button.

Continuous Quality Improvement (CQI)
Continuous Quality Improvement

- Comprehensive approach to improve patient safety that allows pharmacies to create a proactive, non-punitive environment that encourages the identification of error, evaluating causes, and designing systems to prevent future errors.

CQI Programs

- Six Sigma
  - Originally a business management strategy
  - Define - Measure - Analyze - Improve - Control
  - Focus is centered on reducing, and hopefully removing, failure and defects within work processes.
Root Cause Analysis

- Method which can help individuals learn as much as possible from adverse events or poor outcomes of processes in systems.
- WHY something happened
- Retrospective analysis

Failure Mode and Effects Analysis (FMEA)

- Anticipating problems with new medication, process, service, etc.
- Determining points of potential failure and what their effect would be – before any error actually happens
- Proactive rather than reactive
<table>
<thead>
<tr>
<th>Processes &amp; Subprocesses</th>
<th>Failure Modes (what might happen)</th>
<th>Causes (why it happens)</th>
<th>Effects</th>
<th>Severity/Probability/Hazard</th>
<th>Actions to Reduce Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Send order to pharmacy</td>
<td>Order not received/processed in pharmacy</td>
<td>Unaware of order on unit; medication used from floor stock, so order not sent; order entered onto wrong form or screen; verbal orders not documented</td>
<td>Drug therapy omitted; Overdose; under-dose; ADR; allergic response if wrong drug used</td>
<td>3/3/9</td>
<td>Flaging system for new orders; policy to send all orders to pharmacy; physician review of new orders with unit staff; shift chart checks; standard verbal order receipt/documentation process</td>
</tr>
<tr>
<td></td>
<td>Delay in receiving/processing order</td>
<td>Order not flagged; inefficient process for sending orders to pharmacy; order not seen/misplaced after reaching pharmacy</td>
<td>Delay in dispensing drug; use of floor stock before pharmacy order screening; delay of drug therapy</td>
<td>3/4/12</td>
<td>As above; standard, efficient process for pharmacy order receipt; timely review and triaging of orders received in pharmacy</td>
</tr>
</tbody>
</table>

Complete example at [http://www.ismp.org/Tools/FMEAOfPCA.pdf](http://www.ismp.org/Tools/FMEAOfPCA.pdf)

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**Are you aware of any CQI activities related to medication errors in your current workplace?**
Managing Medication Errors

- Explain the error to the patient/family without any excuses. Counsel on potential side effects of the error
- Correct the mistake and if possible retrieve the incorrect prescription
- Offer a sincere apology
- Thank them for their patience and understanding, or for noticing an error, if that was the case
- Document the occurrence and your actions.

Reporting Medication Errors

- Important for improving patient safety and developing valuable educational services for the prevention of future errors
- Internally
- Externally
  - ISMP Medication Errors Reporting Program
  - MedMarx
- National, anonymous, internet-accessible database that hospitals and health care systems use to track and trend adverse drug reactions and medication errors.
- Hospitals can compare themselves to others
- Data shows hospitals across the country share similarities in errors
- www.medmarx.com

What can I do to prevent errors?

- Suggest appropriate changes to the people in power
- Manage your individual work environment
  - Reduce distractions
  - Phone, clutter, extraneous people, etc
  - Have as complete info as possible
    - Allergies, Monitor computer alerts
  - Look for and reduce at risk behaviors
A Few Ideas .....  

http://ismp.org/selfassessments/Book.pdf

- Magnifying box or lens in a fixed location and used to facilitate readability of prescriptions and labels.
- Device to hold prescription information near the computer monitor, at eye level, in order to improve visibility when entering orders.
- Rotate items in fast mover area(s) to reduce the risk of error due to familiarity with placement on shelves.

A Few Ideas .....  

- Remove high-alert medications from fast mover area
- Require medication counseling for targeted high-alert drugs, narrow therapeutic index drugs, and/or high-risk patient populations
A Few Ideas .....  

- Show the medication at pick-up  
- Triple check plus two  
- Specifically identify and segregate drugs that have a non-oral route of administration  

Resources for More Information  

  - Medication Safety Alert!® Newsletter  
    - Community/Ambulatory Care and Acute Care Editions  
  - Ambulatory Care Action Agenda  
  - Medication Safety Self Assessment for Community/Ambulatory Care
Resources for More Information

- Institute of Medicine - www.iom.edu
- Joint Commission – www.jointcommission.org
- Institute for Healthcare Improvement (IHI) – www.ihi.org
- The National Coordinating Council for Medication Error Reporting and Prevention - www.nccmerp.org

Bottom Line

- Errors will always occur in any system, but it is essential to identify causes and attempt to minimize risks.
- Medication errors occur infrequently but are often avoidable
- Many of the consequences of these errors can be prevented by the intervention of pharmacists.
- Technology can help but it creates new errors

Case Wrap-up

- What system changes could be made to prevent insulin and heparin mix-ups?
- What system changes could be made to prevent colchicine prescription errors?

Starting tomorrow, what 2 changes can you implement in your workplace?
It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives, and meet the challenges ahead.

To Err Is Human: Building a Safer Health System. 2000

IF YOU ARE PARTICIPATING IN OUR NEXT WEBCAST STARTING AT 11:30 AM, YOU MUST LOG OFF THIS CLASS, CLOSE YOUR BROWSER, AND THEN LOG INTO WWW.FreeCE.com AGAIN.