Don’t Get Sued for Medication Errors: Assess Your Risk Using Case Studies

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Target Audience: Pharmacists and Pharmacy Technicians

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Activity Type: Knowledge-based
Disclosures

Donna Horn and Karen Ryle declare no conflicts 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.

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Learning Objectives

- List allegations made against pharmacists in malpractice lawsuits.
- Recognize the application of the 2017 ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy to identify gaps in providing safe pharmacy systems.
- Identify key risk management items that pharmacists can incorporate into their practice.
- Describe the 3 types of behaviors; human error, at-risk behavior and reckless behavior as it applies to medication errors involved in lawsuits.
1. Assessment Question

32% of all medication related malpractice cases involve a patient death, compared with 18% of all other cases

A. True  
B. False  

ACPE#  
Activity Type:
2. Assessment Question

According to CRICO, between 2010-2014, Which category of medications caused the most harm?

A. Cardiovascular
B. Antibiotics
C. Analgesics
D. Anticoagulants
3. Assessment Question

The Learned Intermediary Doctrine is between

A. The manufacturer, prescriber and pharmacist
B. The manufacturer, prescriber and patient
C. The prescriber and pharmacist
D. The pharmacist and patient
4. Assessment Question

To be opioid tolerant a patient must have taken

A. 60 mg of oral morphine daily
B. 30 mg of oral oxycodone daily
C. 8 mg of oral HYDROMorphone daily
D. Any of the above for at least a week
5. Assessment Question

Purposefully overriding a high dose alert that results in patient harm is an example of

A. Human error
B. At-risk behavior
C. Reckless behavior
D. It depends, we need more information
Session Outline

- Background: Error facts
  - RCA vs Lawsuit
    - Define each, show differences
- The science behind error: human factors, system, human behavior
- How to find risk
- How to prevent risk-CQI
- Duty to warn
- Case examples
  - Findings of fact for negligence- leading to lawsuit
  - Risk control recommendations-from RCA
- RCA case example
Medications Causing the Most Patient Harm

Malpractice Risks with Medication

1 in 9 malpractice cases involves a medication-related problem

We examined 28,527 cases asserted from 2010–2014 and identified 3,067 in which medication issues contributed to patient harm.

The most commonly identified categories were:

18% analgesics
17% anticoagulants
13% antibiotics
8% cardiovascular

N=2,187 cases in which the specific medication was identified

Source: CRICO 2016 Benchmarking report
Medication Malpractice Results in Death

32% of medication-related malpractice cases involve a patient death, compared to 16% of all other cases.

Source: CRICO 2016 Benchmarking Report
Hospital Medication Error Cases

**Analgesics**
- 18% of Med Cases
- $451K Avg Payment

**When**
- 30% ordering
- 1% dispensing
- 13% administering
- 76% managing

**Where**
- 81% ambulatory
- 40% inpatient
- 9% emergency

**Injury Severity**
- 10% low
- 32% medium
- 8% high
- 52% death

**Top Medications**
- 24% Dilaudid
- 12% oxycodone
- 17% morphine
- 12% fentanyl

*Includes permanent grave, permanent major, and permanent significant injuries.

**Antibiotics**
- 13% of Med Cases
- $360K Avg Payment

**When**
- 61% ordering
- 4% dispensing
- 12% administering
- 38% managing

**Where**
- 52% ambulatory
- 38% inpatient
- 10% emergency

**Injury Severity**
- 4% low
- 56% medium
- 19% high
- 21% death

**Top Medications**
- 12% vancomycin
- 11% Bactrim
- 9% gentamicin

*Includes permanent grave, permanent major, and permanent significant injuries.

**Anticoagulants**
- 17% of Med Cases
- $598K Avg Payment

**When**
- 43% ordering
- 3% dispensing
- 9% administering
- 67% managing

**Where**
- 34% ambulatory
- 63% inpatient
- 3% emergency

**Injury Severity**
- 1% low
- 26% medium
- 24% high
- 49% death

**Top Medications**
- 50% Coumadin
- 20% heparin
- 9% Plavix

*Includes permanent grave, permanent major, and permanent significant injuries.

Source: CRICO 2016 Benchmarking Report
### Hospital Claims

**Which factors affect the probability of patient death?**

To identify the strongest predictors that a medication-related malpractice claim would involve a patient who died, 3,087 cases asserted from 2010–2014 were assessed.

- **ANALGESIC-RELATED ERRORS**
  - Increase the odds of a case involving a patient death by 163%

- **ANTICOAGULANT-RELATED ERRORS**
  - Increase the odds of a case involving patient death by 68%

Source: CRICO 2016 Benchmarking Report

**Which factors affect the probability of payment?**

To identify the strongest predictors that a medication-related malpractice claim would resolve with an indemnity payment, 5,279 cases closed from 2005–2014 were assessed.

- **MEDICATION ADMINISTERING ERRORS**
  - Increase the odds of a case closing with a payment by 99%

- **MEDICATION DISPENSING ERRORS**
  - Increase the odds of a case closing with a payment by 89%

**Which factors affect the magnitude of indemnity payment?**

To identify the strongest predictors for the magnitude of a medication-related malpractice claim payment, 2,079 cases closed with a payment from 2005–2014 were assessed.

- **MEDICATION ORDERING ERRORS**
  - Increase the average indemnity payment by 18%

- **INPATIENT MEDICATION ERRORS**
  - Increase the average indemnity payment by 15% compared to ambulatory medication errors

Source: CRICO 2016 Benchmarking Report
## CRICO Benchmarking Report 2016

<table>
<thead>
<tr>
<th></th>
<th>Medication Cases</th>
<th>All Cases</th>
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<tr>
<td><strong>Cases Closed</strong></td>
<td>5,279</td>
<td>43,521</td>
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<td><strong>Closed with Payment</strong></td>
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<td>32%</td>
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<td><strong>Closed with Payment &gt;$1M</strong></td>
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<td>2%</td>
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<td><strong>Average Indemnity</strong></td>
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*Source: CRICO 2016 Benchmarking Report*
Pharmacists Mutual Claims Study 2016-Community Pharmacies

Wrong Drug, Wrong Strength, Incorrect Directions

66% of drug claims are from wrong strength

#1 drug involved in claims is Warfarin

#2 drug involved in claims is Levothyroxine
Two Possible Actions after an Error Causes Harm

Root Cause Analysis

- Doesn't assign blame
- Development of robust strategies for preventing future patient harm
- Knowledge gained from data analysis could benefit other healthcare providers and organizations, if shared
- What circumstances led a reasonable person to make reasonable decisions that resulted in an undesirable outcome?

Law Suit

- Assigns blame based on negligence
- Does not prevent future errors
- Finding of facts entered but not always shared due to gag orders
- Appropriate in cases of negligence or willful harm
What is RCA?

- Systematic process to identify the causal factors that contributed to the occurrence of a **sentinel event**
- Focuses primarily on systems and processes, not individual performance
- Finding and identifying root causes during an investigation adds considerable value by pointing out significant underlying and fundamental systemic conditions that increase the risk of adverse events
Harm Scores: used to identify sentinel event

- **Category I:** An error occurred that may have contributed to or resulted in the patient's death.
- **Category A:** Circumstances or events that have the capacity to cause error.
- **Category B:** An error occurred but the error did not reach the patient (An "error of omission" does reach the patient).
- **Category C:** An error occurred that reached the patient but did not cause patient harm.
- **Category D:** An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.
- **Category E:** An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.
- **Category F:** An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.
- **Category G:** An error occurred that may have contributed to or resulted in permanent patient harm.
- **Category H:** An error occurred that required intervention necessary to sustain life.
- **No Error**
- **Error, No Harm**
- **Error, Harm**
- **Error, Death**
Characteristics of a Thorough and Successful RCA

- Identifies system and process changes needed to improve performance and reduce the risk of recurrences
- Focuses primarily on systems and processes, not individual performance
- Continuously asks “why” until all root causes have been identified
- Includes participation by individuals most closely involved in the processes and systems under review who are knowledgeable in human factors error and error prevention measures
- Internally consistent (i.e., does not contradict itself or leave obvious questions unanswered)
- Consideration of relevant literature—was a similar error reported and published?
Accountability in “System Based” Analysis

- It shifts the focus from BLAME to ANALYSIS!
- It works to prevent the next error, not punish the last
When Can You be Sued?

For a finding of **negligence** on a law suit there must be:

- Duty
- Breach of duty
- Proximate cause
- Damages
Duty

- Standards of care – Where do they come from?
- Required – legal duty
- Common law
- Community standards – What would the reasonable, prudent pharmacist do under the same circumstances and with the same knowledge?
What is Criminal Negligence?

“Criminal negligence” requires that the defendant ought to have been aware of a substantial and unjustifiable risk that his conduct could result in the type of harm that did occur, and that this risk was of such a nature that the failure to perceive it was a gross deviation from the reasonable standard of care exercised by ordinary people.

V.T.C.A., Penal Code § 6.03

http://codes.findlaw.com/tx/penal-code/penal-sect-6-03.html
But what if it was just a mistake?
Consider: the people, the system, the behavioral choice
Human Factors (the person) that Contribute to Errors
Latent Failure (the system): Tablet Identification, Packaging

**Latent**
(lā'tent), Not manifest, dormant, but potentially discernible. [L. _lateo_, pres. p. _latens_ (-ent-), to lie hidden]

These are less apparent failures of organization or design that contribute to the occurrence of errors or allow them to cause harm to patients
Behavior of the Person When the Error Occurred

- **Human Error**: mistakes, slips, lapses, and unintentional deviations from accuracy and correctness
  - Most errors are in this category
  - Human error is NOT a behavioral choice

- **At-Risk Behavior**: Behavioral choices that increase risk where risk is not recognized, or is mistakenly believed to be justified
  - Increase situational awareness

- **Reckless Behavior**: Conscious disregard of a risk of causing harm
  - Remedial or punitive action

Source: Patient Safety and the “Just Culture” David Marx JD
Human Error
At Risk Behavior
Reckless Behavior
Concepts of Human Behavior in Healthcare

- **Human error**: inadvertently causes an undesirable outcome

- Negligent conduct: term used when individual has been harmed by health system; **subjectively more culpable than human error**

- Criminally negligent conduct: an objective determination that a person **should have been aware** that they were taking a substantial and unjustifiable risk toward causing an undesirable outcome

- Reckless conduct: gross negligence, involves a higher degree of culpability than negligence. Conscious disregard of risk...differs from negligent conduct in **intent**

- Intentional rule violations: individual chooses to knowingly violate a rule while he is performing a task; shows that an individual knew of or **intended to violate a rule, procedure, duty**...
Types of Behavior

**RCA**
- Human Error: console
- At risk Behavior: coach
- Reckless Behavior: discipline/punish

**Law Suit**
- Human Error: negligence?
- At risk Behavior: negligence?
- Reckless Behavior: negligence!
How to Find Risk

- ISMP Self Assessment®
  - Heighten awareness of a safe community pharmacy practice
  - Recognize distinctive characteristics of safe pharmacy systems
  - Create a baseline of pharmacy efforts to enhance medication safety
  - Evaluate safety efforts over time

- Apply Assessment Results - Prioritize
  - Target the System, not the Workforce
  - Do not rely heavily upon human memory and vigilance
  - Target high alert medications
  - Simplify complex, error-prone processes
  - Safeguard high-risk patient populations
  - Solve several medication-error related problems at the same time
  - Use in CQI program
How to Control Risk: Continuous Quality Improvement Programs (CQI)- what it is:

- Reduces errors
- Improves systems
- Focuses on learning
- Requires a culture change
  - Report for learning purposes
  - Reward error reporting
  - “Good Catch”
  - Does not punish or ridicule personnel

Culture change towards safety and education
CQI - what it does:

- Leads to prevention
- Incorporates “safety” as part of the thinking process during dispensing
- Aimed specifically at preventing well-known and repetitive dispensing errors categories

Detects, documents, assesses, and **eventually** prevents future medication errors
CQI - what it does **NOT**:  

- Eliminate all errors  
- Find incompetent people  
- Focus on blame  
- Result in punishment - disciplinary action on license or job in jeopardy
Pharmacist Duty to Warn: Before

- Historically, many courts protected RPh from being exposed to liability for the duty to warn:
  - RPh was not expected to understand or have access to patients’ medical history
  - RPh had no duty to monitor and intervene with patients’ continuing course of treatment
  - Requiring pharmacist to warn patients would undermine the doctor-patient relationship
  - Protected by the “Learned Intermediary Doctrine” where drug manufacturers have a duty to provide general warnings to physicians and then physicians have a duty to warn their patients about the drugs they prescribe
  - “Pharmacists owe no independent duty to customers, beyond exercising due and proper care in filling prescriptions.”
Pharmacist – Limited Duty: Now

- Some courts have ruled there is limited duty in certain circumstances
- Pharmacists have a duty to warn:
  - About known contraindications
  - Drug/allergy interactions
  - Drug/drug interactions, excessive dosages
  - Clear errors on the face of the prescription

- Pharmacists have a duty to exercise “due and proper care in filling a prescription”
- Pharmacist has specific knowledge of potential harm to specific persons in particular cases
- Pharmacists owe their customers a duty beyond accurately filling prescriptions do so based on the presence of additional factors, such as known contraindications, that would alert a reasonably prudent pharmacist to a potential problem

Morgan v. Wal-Mart Stores, 30 S.W.3d 455, 466
Happel v. Wal-Mart Stores, 766 N.E.2d 1118
Duty to Warn Case
Nail v. Public Super Markets

- Alabama 2011

- Court rejected a motion to dismiss a duty to warn case based on the Learned Intermediary Doctrine; plaintiff claimed that RPh had a duty to warn her of increased drug dosage vs. a duty to warn of drug side effects, which may impact the doctor/patient relationship

- Alice Nail was prescribed Warfarin after suffering a Pulmonary Embolism following a total knee replacement

- Patient was receiving Warfarin 1 mg tablets with directions to take “as directed” but was instructed to take 5 tablets daily

- Rx was refilled for 1 year

- Pharmacy called doctor’s office for Rx renewal
Nail v. Publix Super Market

- Pharmacy suggested to change the RX to Warfarin 5 mg for ease of use to patient; directions still indicated “as directed”
- Patient picked up the new RX and started to take 5 tablets daily, total dose of 25 mg for 9 days
- Nail stated she was not informed by the pharmacy of change from 1 mg to 5 mg
- Counseling was declined by Ms. Nail
- Patient went to ER; diagnosed with “Coumadin toxicity” and suffered an epidural hematoma of the cervical spine; surgery to remove the hematoma
- Defendant “Publix negligently and wantonly failed to counsel Ms. Nail on the effect of the change in dosage of her Coumadin prescription”
- There was evidence of the standard of care applicable to a pharmacist, i.e., that a pharmacist has a duty to counsel customers on a change in dosage of any medication
Pharmacy Expert

- Expert in pharmacy practice, standard of care for a community pharmacist, hospital pharmacist, long term care pharmacist, etc.
- Training
- Only be an expert in the area that you are an expert in
- Not a causation expert
- Expert reports
- Expert testimony-deposition
- Expert Testimony-trial
Pharmacist: Warfarin Known Risk Factors

- Narrow therapeutic index drug
- Potentially sub-therapeutic or toxic effects with advanced age, comorbid illness, or multiple medications
- Serious drug interactions common
- Requires close monitoring INR for proper dosing
- “take as directed” can result in mis-communication and harm
Negligence - findings of fact

- Duty to warn? Mandatory counseling state?
- Breach of duty? Patient refused counseling
- Proximate cause: “Take as directed”
- Damages: epidural hematoma of the cervical spine
You decide – What was the pharmacist’s behavior?

- **Human Error**: Inadvertent, slip, mistake
  - “Console”: manage through systems changes

- **At-Risk Behavior**: Choice made by worker who didn’t recognize risk or believed it justified
  - “Coach”: remove incentives for at-risk behaviors, increase situational awareness

- **Reckless Behavior**: Conscious disregard of unreasonable risk
  - “Punish”: remedial or punitive action

Marx, Outcomes Engineering
Just Culture Algorithm
Should the Pharmacist be Deemed Negligent?

Questions to ask yourself when considering this case:

- Do you think the pharmacist was negligent?
- Do you think any other practitioners were negligent?
- Do you think the patient was negligent?
- Do you think any indemnity and/or expense payment was made on behalf of the pharmacist?
- If yes, how much?
- Settlement $$???
Risk Control Recommendations

- **Mandatory counseling for all** HIGH-ALERT MEDICATIONS

- *Counsel each patient regarding his/her medication* and document the process, including patient refusals of counseling

- Electronic **HARD STOPS** to restrict completion of the sale until patient education has occurred for high-risk patient populations

- **Document all discussions with the patient, family members, the prescribing practitioner and appropriate healthcare personnel**
  - *Employ documentation capture technology to add counseling points in patient profile*

- **Encourage patients to ask questions regarding their medications.** Respond to all such questions until they are able to correctly repeat back the information, and document this in their pharmacy record
### Classes/ categories

- **antiretroviral agents** (e.g., abacavir, lamivudine, ritonavir)
- **chemotherapeutic agents, oral** (excluding hormonal agents) (e.g., cyclophosphamide, mercaptopurine, temozolomide)
- **hypoglycemic agents, oral**
- **immunosuppressant agents** (e.g., azathioprine, cyclosporine, tacrolimus)
- **insulin, all formulations**
- **opioids, all formulations**
- **pediatric liquid medications that require measurement**
- **pregnancy category X drugs** (e.g., bosentan, isotretinoin)

### Specific medications

- **carbamazepine**
- **chloral hydrate liquid, for sedation of children**
- **heparin, including unfractionated and low molecular weight heparin**
- **methotrexate, non-oncologic use**
- **midazolam liquid, for sedation of children**
- **propylthiouracil**
- **warfarin**

Patient: Warfarin Safety Recommendations

Know signs of bleeding or clot

Do not start or stop any RX, OTC medicines, herbals, and vitamins

Keep your eating habits and exercise regularly

Get periodic blood tests (INR)
Do people understand “balanced diet”?

“eat a normal, balanced diet”
97% could understand information
85% less likely to make mistake

http://www.ismp.org/tools/highaler
tMedications/warfarin.pdf
Duty to Warn: DEE v. Wal-Mart Stores

- Nicole Dee received a prescription for a 50 mcg Fentanyl patch from her physician following a Cesarean section.

- More than four months later Mrs. Dee had the prescription filled at Wal-Mart's pharmacy and used it to treat pain from a fractured ankle.

- Mrs. Dee died in her sleep as a result of a toxic overexposure to Fentanyl.

- Pharmacy filled the prescription that was 4 months old.

- Pharmacy must use due and proper care in filling a prescription.

- The prescription for Fentanyl is unreasonable on its face because it was 4 months old, even though lawful as written, filling it was a breach of duty.
Pharmacist: Known Fentanyl Risk Factors

- Treat moderate to severe chronic pain, not acute pain
- Patients must be opioid-tolerant
Fentanyl Alerts

- Despite warnings from the FDA, manufacturers, and various patient safety agencies, fentanyl transdermal patches continue to be prescribed inappropriately to treat acute pain in opiate-naïve patients, sometimes in large doses or in combination with oral or intravenous opiates.

- In hospitals, physician offices or ambulatory surgery centers, where well-meaning but misinformed primary care physicians or surgeons have prescribed the drug for opiate-naïve patients under **contraindicated circumstances** such as acute post-operative pain.

- Unfortunately, pharmacists have often filled these prescriptions without question, and nurses caring for patients have applied the patches without recognizing the prescribing error.

- **Boxed Warning:** Fentanyl transdermal is contraindicated for use as an as-needed analgesic in nonopioid tolerant patients, in acute pain, and in postoperative pain. Keep out of the reach of children, risk with concomitant use of benzodiazepine, risk with exposure to heat (heating blankets, hot tubs, sauna’s, etc.)
Eliminate the prescribing of fentaNYL patches for opioid-naïve patients and/or patients with acute pain.

- Ensure the organization has a process in place to routinely document the patient’s opioid status (naïve vs. tolerant) and type of pain (acute vs. chronic) in the health record or prescriber orders.

- Implement a process to verify and prevent orders for fentaNYL patches in patients who are opioid-naïve or with acute pain. Examples: hard stops during order entry, electronic alerts, automatic interchange, and pharmacy interventions with prescribers.

- Eliminate the storage of fentaNYL patches in automated dispensing cabinets or as unit stock in clinical locations where acute pain is primarily treated (e.g., in the emergency department, operating room, post-anesthesia care unit, procedural areas).

Rationale for Best Practice

- The goal: prevent death and serious harm from the inappropriate use of fentaNYL patches to treat acute pain in patients who are opioid-naïve.

- FentaNYL patches are ONLY to be used in patients who are opioid-tolerant and are ONLY indicated for persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time that cannot be managed by other means.

- FentaNYL patches were the highest-ranking drug involved in serious adverse drug events (ADEs) reported to the US Food and Drug Administration (FDA) from 2008 through 2010.

- ISMP continues to receive reports, including fatalities, due to the prescribing, dispensing, and administration of fentaNYL patches to treat acute pain in opioid-naïve patients

Opioid Tolerant

- 60 mg of oral morphine daily
- 30 mg of oral oxycodone daily
- 8 mg of oral HYDROMorphone daily
- An equianalgesic dose of another opioid

For a week or longer!
Patient: Fentanyl Safety Recommendations

6. Signs of overdose. Call your doctor if you experience extreme fatigue, difficulty waking up, and/or shallow or very slow breathing.

- Remove old patch before applying another patch.
- Even used patches are lethal to children.
- Possible overdose if applied to broken skin or with heating pad.
You decide – What was the Pharmacist’s Behavior?

- **Human Error**: Inadvertent, slip, mistake
  - “Console”: manage through systems changes

- **At-Risk Behavior**: Choice made by worker who didn’t recognize risk or believed it justified
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- **Reckless Behavior**: Conscious disregard of unreasonable risk
  - “Punish”: remedial or punitive action
Should the Pharmacist be Deemed Negligent?

Questions to ask yourself when considering this case:

Do you think the pharmacist was negligent?

Do you think any indemnity and/or expense payment was made on behalf of the pharmacist?

If yes, how much?

Do you think any other practitioners were negligent?

Settlement $$ $$ $$ ??
Risk Control Recommendations

- Pharmacists are allotted time by management for patient counseling
- Patients are encouraged to ask questions
- The offer to counsel includes a clear explanation of how to take and store the medication, possible side effects, interactions with other medications and benefits
Risk Control Recommendations

- Patients are included as active partners in their care through education about their medications and ways to avert errors.

- The pharmacist ascertains the clinical purpose of each prescription before the medication is dispensed to ensure that the prescribed therapy is appropriate for the patient’s condition.

- The patient’s prescription container is opened with the patient/caregiver to verify the medication at the point of sale.

- Distribute ISMP/AHRQ high alert medication education sheets, FDA Med Guides.

2017 ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy
DUR Failure- Fentanyl Case #2

- 32 year old female
- Mother of 2 small children
- Worked for housekeeping in a luxury hotel
- Complained of back pain from making beds, bending over, carrying 2 small children

- Prescribed for back pain:
  - Tramadol 50 mg every 6 hours
  - Methocarbamol 750 mg QID
  - Carisoprodol 350 mg every 6 hours
  - Alprazolam 2 mg at bedtime
DUR Failure (cont.)

- Patient goes back to the doctor, medication not working
- Doctor prescribed Fentanyl 75 mcg every 3 days
- Patient expires within 48 hours
- Pharmacy dispensing the Fentanyl received an alert from the patient’s insurance:
  - Verify patient is not opiate naive
- Pharmacist believes that since she was taking Tramadol (synthetic opioid) that she was not opiate naïve and overrides the alert
- In the pharmacist’s deposition, she does not know exactly what it means to be opiate tolerant or opiate naïve
- Remember: Definition of opioid tolerant?
Opioid Tolerant

• 60 mg of oral morphine daily
• 30 mg of oral oxycodone daily
• 8 mg of oral HYDROMorphone daily
• an equianalgesic dose of another opioid

For a week or longer!
Risk Control Recommendations for DUR

- Document rationale when overriding a serious alert (e.g., exceeding a **MAXIMUM DOSE**, a serious drug interaction)
- Evaluate system for clinically insignificant and false positive alerts, and take action (where possible) to minimize alert fatigue
- A designated pharmacist routinely reviews (e.g., **MAXIMUM DOSE** alerts, serious drug interactions, allergy alerts) that have been overridden to ensure justification and appropriateness
Risk Control Recommendations for DUR

- Incorporate prompts for selected **HIGH-ALERT MEDICATIONS** to confirm the appropriateness of the medication, dose, dosage form, and directions.

- Ask for and document health condition or diagnosis in computer profile and on hard copy of prescription.

- Electronic **HARD STOPS** to restrict completion of the sale until patient education has occurred for high-risk patient populations.

2017 ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy
How Can We Engage the Patient?

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Fentanyl Patches

You decide – What was the pharmacist’s behavior?

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D. Marx, Outcomes Engineering
Just Culture Algorithm
Should the Pharmacist be Deemed Negligent?

Questions to ask yourself when considering this case:

- Do you think the pharmacist was negligent?
- Do you think any other practitioners were negligent?
- Do you think any indemnity and/or expense payment was made on behalf of the pharmacist?
- If yes, how much?
- Settlement $$??
Wrong Drug Case

- Patient with HIV
- Diagnosed with Toxoplasmosis
- Rx’s called in to the pharmacy
  - Pyramethamine 100 mg
  - Sulfadiazine 500 mg TID
  - Leucovorin 5 mg
- HIV specialty pharmacy records “Sulfasalazine 500 mg TID” in error
- Patient received the wrong medication for 3 months
- Toxoplasmosis advances and patient is hospitalized
- Did the pharmacist meet the standard of care?
Sound- Alike
Risk Control Recommendations for Wrong Drug

- Different manufacturers are sought for products with labels/packages that look similar
- Shelf tags or label enhancements for drugs with problematic names, packages, and labels
- LASA drug names and packaging are not stored next to one another, and a system clearly redirects staff to where the products have been relocated
- LASA drug names do not appear on the same pharmacy computer system screen when selecting a drug during order entry; or use **TALL MAN LETTERS** if they appear sequentially on the screen
Risk Control Recommendations for Wrong Drug

- Ensure adequate space to safely organize and separate the storage of medications and drug supplies; and utilizes dividers on stock shelves, in narcotic cabinets, and in refrigerators
- Do not stock **sound-alike** or look-alike drugs in the “fast mover” section
- To verify proper selection implement tablet/product imaging (or description) on the final verification screen
- Use barcode scanning to verify drug selection

2017 ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy
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- Do you think the pharmacist was negligent?
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- If yes, how much?
- Settlement $$$???
Root Cause Analysis: Case Study
Wrong Dose Results in Death
“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

- 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; admitted
- 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
Wrong Dose Case Study (cont.)

- 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)
- 9 days later, Bob goes to his follow up appointment
- He complains that the Morphine is taking too long to work
- 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
Wrong Dose 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 Morphine Sulfate ER 20 mg
- Pharmacy claims that someone from the doctors office called to see if they had MS Contin 200 mg in stock; patient’s name is never mentioned
- Confirmation Bias
- Drug utilization review (DUR) for duplicate therapy with 20 mg Morphine is overridden
- Patient’s wife picks up the prescription
- Counseling was not performed
Confirmation Bias

Accept information that agrees with our hypothesis; reject information that does not.

Perception is far from perfection!

We see what we expect to see.

What did you see first?
Wrong Dose Case Study (cont.)

- 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; 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
- Wife mentions she is concerned because he was taken 20 mg before and she read the bottle that stated 200 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
Pharmacy Discussion

- MS Contin 20 mg changed to Kadian
- Confirmation Bias with phone call
- DUR is overridden
- Counseling not performed even though pharmacist remembers giving the wife the medication
- Did the pharmacist meet the standard of care in this case?
Should the Pharmacist be Deemed Negligent?

Questions to ask yourself when considering this case:

- Do you think the pharmacist was negligent?
- Do you think any other practitioners were negligent?
- Do you think any indemnity and/or expense payment was made on behalf of the pharmacist?
- If yes, how much?
- Settlement $$$???
RCA Framework

1. Identify what happened
2. Review what should've happened
3. Determine causes
4. Develop causal statements
5. Generate list of recommended actions to prevent recurrence
6. Write and share summary with leadership and staff
1. Identify What Happened

Bob could not afford the Oxycontin and was doubling up on the Oxycodone

He went 4 days without Oxycodone went to ER then admitted

Discharged with MS Contin 20 mg 1 tab twice a day

Rx filled with Morphine Sulfate ER 20 mg capsules (Kadian)

PA enters discharge med as MS Contin 20 mg

MS Contin not available as 20 mg so system switches to 200 mg

MD signs discharge sheet with MS Contin 200 mg

Bob's record indicates he was prescribed MS Contin 200 mg

Follow up appointment 9 days later

Bob complains Morphine is taking too long to work

Discharge summary lists MS Contin 200 mg

MD prescribes MS Contin 200 mg

Bob brings new Rx for MS Contin 200 mg to his pharmacy

Rx filled as MS Contin 200 mg, 1 tab twice a day only 9 days after dispensing Morphine Sulfate ER 20 mg

MD office called pharmacy to see if they had MS Contin 200 mg in stock

DUR for duplicate therapy with 20 mg Morphine is overridden

No counseling
1. Identify What Happened (cont.)

Bob takes 1 tablet of MS Contin 200 mg

According to 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

Mentions she is concerned because he was taken 20 mg before and she read the bottle that stated 200 mg

Called 911

EMT administered Naloxone

Total Morphine Level= 461 ng/mL

Toxic level of morphine caused multi-organ failure
2. Review What Should've Happened

- Flowchart of what should've happened

- Bob received Rx for OxyContin
- Bob could not afford OxyContin
- Bob offered free care or coupon
- Bob goes home with OxyContin and pain is relieved

- Bob receives Rx for MS Contin 20 mg
- MS Contin 20 mg not available; RPh calls prescriber for generic morphine sulfate SR 20 mg
- generic morphine sulfate SR 20 mg entered into discharge notes
- Bob takes generic morphine sulfate SR 20 mg and pain relieved

- PA enters discharge med as MS Contin 20 mg
- MS Contin not available as 20 mg so system tries to switch to 200 mg
- PA does not accept changes and re enters order as generic morphine sulfate ER 20 mg
- Or discharge MD realizes should be 20 mg, not 200 mg and makes change before signing

- Bob's record indicates prescribed morphine sulfate ER 20 mg
2. Review What Should've Happened (cont.)

- Pharmacy received Rx for MS Contin 200 mg
- RPh reviews DUR and calls prescriber
- MS Contin 200 mg not dispensed

- RPh receives call from MD asking if 200 mg in stock
- RPh asks for prescriber and patient names
- RPh notes that name is not “Bob” and calls prescriber for DUR override

- Bob’s wife is counseled by RPh
- She is aware of signs of overdose and toxicity
- She calls 911 at first sign of overdose
3. Determine Causes

Fishbone diagram (also known as an “Ishikawa” or “cause and effect” diagram), a graphic tool used to explore and display the possible causes of a certain effect:

1. Write the effect (the thing you’re trying to change) in a box on the right.
2. Draw a long horizontal line to the left of the effect.
3. Decide on the categories of causes for the effect. These categories can vary depending on your project.
4. Draw diagonal lines above and below (these are the “fishbones”), and label categories.
5. Brainstorm and collect a list of causes for each category.
6. List the causes on each fishbone. If a cause has a secondary cause (for example, under “pagers,” you could list “hard to use” and “inadequate training”), draw a branch bone to show relationships among the causes.
7. Develop the causes by asking, “Why?” until you have reached a useful level of detail, i.e., when the cause is specific enough to be able to test a change and measure its effects.
3. Determine Causes (cont.)

- Identify Root Causes for each of 6 categories
- Why, because
- Categories for this case:
  1. **Patient** characteristics- don’t blame patient- but what is going on with patient that may have contributed to error/harm?
  2. **Personnel**- who was taking care of patient
  3. **Procedures**
  4. **Team/communication factors**- where most errors originate
  5. **Organizational factors** (protocols followed or not)
  6. **Health information technology** (HIT)
Opioid Toxicity

**Procedures**
- Discharge sheets are completed after patient leaves hospital
- DURs are common for opioids
- RPh is not part of medication reconciliation at discharge
- Counseling not offered for high alert medications

**Personnel**
- System allows RPh to override DUR alert for duplicate therapy
- System allows PA to enter wrong drug into discharge notes

**Patient**
- Patient’s ability to pay not discussed
- Patient “Bob’s” pain is not controlled
- Patient “Bob” can’t afford OxyContin

**Organization**
- No policy or procedure for counseling high alert medications
- Discharge MD does not see original notes and signs off on 200 mg at discharge

**HIT**
- PA can free-text drug into the computer system for a strength that is not available

Opioid Toxicity Causes Death
3. Determine Causes (cont.)

Opioid Toxicity causes death

Patient
- Bob can’t afford OxyContin
- Bob’s pain is not being controlled

Personnel
- System allows PA to enter wrong med dose into discharge notes
- Discharge MD does not see original notes and signs off on 200 mg
- System allows RPh to override DUR alert for duplicate therapy without making notation

Procedures
- Discharge sheets are completed after patient leaves hospital
- DUR overrides common for opioids
3. Determine Causes (cont.)

<table>
<thead>
<tr>
<th>Team/Communication</th>
<th>Organizational factors</th>
<th>HIT</th>
</tr>
</thead>
</table>
| • RPh not part of medication reconciliation at discharge  
  • Counseling not offered for high alert drug  
  • Patient ability to pay not discussed | • No policy/procedure for mandatory counseling on high alert meds | • No hard stops for dose exceeding 120 MED  
  • PA can free text a drug in the computer system for a strength that is not available  
  • No restrictions at POS until patient education has occurred for high-risk patient populations |
4. Develop Causal Statements

- Explain how the contributory factors – which are basically a set of facts about current conditions – contribute to bad outcomes for patients and staff (“This happened ...”), the effect (“ ... which led to something else happening ...”), and the event (“ ... which caused this undesirable outcome”).

- Lack of knowledge and check systems for brand names of extended release morphine increased the probability of prescribing the wrong dose of medication.

- 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.
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?
5. Generate List Of Recommended Actions To Prevent Recurrence

<table>
<thead>
<tr>
<th>Action to be taken</th>
<th>How implementation will be measured</th>
<th>Timeframe for when it should be completed (specific to action- may take time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication reconciliation by pharmacist at discharge</td>
<td>Audit and compare admission orders to discharge orders</td>
<td>This will be accomplished and reviewed within 3 months to determine staff participation</td>
</tr>
<tr>
<td>High dose alert for patients taking over 120 MED</td>
<td>Ensure hard stops in place and review override reports</td>
<td>IT will develop this ASAP</td>
</tr>
<tr>
<td>Contributing factor</td>
<td>Risk-reduction Strategy</td>
<td>Measure of Effectiveness</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Counseling not offered for high alert drug</td>
<td>Policy and procedures to include mandatory counseling of high alert medications</td>
<td>Review counseling log book</td>
</tr>
<tr>
<td>Wife’s issues not addressed adequately</td>
<td>Policy and procedure include mandatory follow up calls to reassess patients at high risk</td>
<td>Review nursing notes, phone logs and patient profile logs</td>
</tr>
<tr>
<td>Prescriber can free text a drug in the computer system for a strength that is not available</td>
<td>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</td>
<td>Reports of drugs that are “free texted” in the electronic ordering system for education</td>
</tr>
<tr>
<td>Could not afford OxyContin</td>
<td>Discharge instructions include insurance discussion and payment options (free care, generics, 340B, etc.)</td>
<td>Compare Rx written vs Rx filled; IMS data</td>
</tr>
</tbody>
</table>
6. Write and Share Summary with Leadership and Staff

- Generate report
- Who was involved in RCA process
- Narrative (Details!)
- Flowchart diagrams all events, what should’ve happened
- Ask why?- root causes
- Recommendations and structure
- When assessed and how
It’s the System…Not the People

“Incompetent people are, at most, 1% of the problem. The other 99% are good people trying to do a good job who make very simple mistakes and it’s the processes that set them up to make these mistakes.”

Dr. Lucian Leape
Harvard School of Public Health
Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior.
1. Assessment Question

32% of all medication related malpractice cases involve a patient death, compared with 18% of all other cases

A. True  B. False
2. Assessment Question

According to CRICO, between 2010-2014, Which category of medications caused the most harm?

A. Cardiovascular  
B. Antibiotics  
C. Analgesics  
D. Anticoagulants
3. Assessment Question

The Learned Intermediary Doctrine is between

A. The manufacturer, prescriber and pharmacist
B. The manufacturer, prescriber and patient
C. The prescriber and pharmacist
D. The pharmacist and patient
4. Assessment Question

To be opioid tolerant a patient must have taken

A. 60 mg of oral morphine daily
B. 30 mg of oral oxycodone daily
C. 8 mg of oral HYDROmorphine daily
D. Any of the above for at least a week
5. Assessment Question

Purposefully overriding a high dose alert that results in patient harm is an example of

A. Human error  
B. At-risk behavior  
C. Reckless behavior  
D. It depends, we need more information
Additional Resources


- The ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy [http://www.ismp.org/Survey/NewMssacap/Index.asp](http://www.ismp.org/Survey/NewMssacap/Index.asp)

