Pharmacy Malpractice Trends

ACTIVITY DESCRIPTION
This program provides a synopsis of basic legal principles of pharmacist malpractice, using legal case study summaries that show how the basic principles apply in a contemporary pharmacy practice. Emphasis is placed on traditional liability for order processing errors, as well as expanding liability for errors in an advanced practice role. Suggestions are offered for strategies that can reduce pharmacist and pharmacy exposure to malpractice liability.

TARGET AUDIENCE
The target audience for this activity is pharmacists, pharmacy technicians, and nurses in hospital, community, and retail pharmacy settings.

LEARNING OBJECTIVES
After completing this activity, the pharmacist will be able to:
• Recognize circumstances in which pharmacy error may lead to liability for malpractice
• Identify elements of an effective pharmacist developed system to reduce exposure to malpractice liability
• Identify policies that clearly establishes the pharmacist's standard of care and the steps necessary to meet that standard

After completing this activity, the pharmacy technician will be able to:
• Recognize the elements of a legal case for malpractice based on pharmacy negligence.
• Identify legal case studies that have led to pharmacy liability for malpractice
• Identify the types of errors that most frequently form the basis of a pharmacist malpractice case

ACCREDITATION
Pharmacy
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The Climate of Pharmacy Malpractice

• Order processing errors continue to be the primary cause of malpractice claims against pharmacists/pharmacies
  • Wrong drug/strength/directions/patient
  • These are simple errors that are difficult to prevent

• Intellectual errors are increasing as the cause of malpractice claims
  • Failure to warn the patient
  • Failure to screen & consult with the prescriber
  • Failures in an expanded practice role

• Issues related to liability for malpractice
  • The opioid epidemic
  • Managed care restrictions
  • Tort reform that benefits physicians but not pharmacists/pharmacies
Key Principles

• Respondeat Superior (let the master answer)
  • Pharmacists are generally viewed as sympathetic defendants
  • Finger pointing among defendants spells disaster
• The motion to dismiss/motion for summary judgment
• Physician usually also sued, but not participating in pharmacy arguments—this principle is not as solid now as in the past
• Appellate opinions establish precedent and reflect public perspectives
• Individual pharmacist malpractice insurance may be a good idea

The Pharmacist’s Duty of Care

• Reasonable and prudent under the circumstances
• The concept of duty is often dependent on the relationship between parties and the expectations within that relationship
• A statute or regulation usually does not support a private right of action under the tort of negligence
• The “no duty” defense in pharmacy cases was at one time very effective, but it has become less effective in recent years
Legal Case Study

- Pharmacist dispensed oral hypoglycemic to wrong patient
- Patient had auto accident, allegedly as the result of side effects from hypoglycemia
- Motorist hit by patient sued pharmacy for negligence in dispensing the medication
- “Plaintiffs had no relationship with the defendant.”
- “Does a pharmacist owe a duty to unconnected third parties for the negligent dispensing of medication? The court does not find such a duty here.”

Breach of Duty

- A breach of duty occurs when a pharmacist fails to practice consistent with the standard of care
  - There are actually many standards in pharmacy (no one-size-fits-all standards)
  - The pharmacist must comply with a recognized standard
- “A pharmacist is bound to exercise the skill generally possessed by well-educated pharmacists who are considered competent in their profession, rather than the highest skill and learning, which can be attained only by a few men and women of rare genius, endowments, or opportunities.”
Legal Case Study

• Rx for citalopram. Patient given vial containing both warfarin and citalopram.
• Expert witness says he “assumed the malpractice” based on the error; defendant pharmacy challenges this assumption as unfounded.
• “The fact that [the expert witness] could not state precisely how the pharmacist fell below the standard of care is not controlling here.”

Causation

• Actual cause
  • Applies the “but for” test. But for the negligence of the pharmacist would the patient have been harmed? If yes, then no causation. Patient would have been harmed anyway, despite pharmacist negligence.
  • Often requires medical expert testimony
• Proximate cause.
  • Superseding, intervening, cause
  • The primary test is foreseeability of harm to the patient by the pharmacist at the time the products and services were provided to the patient
Legal Case Study—Actual Cause

- Drug abuser/diverter acquires multiple opioids/benzos from 10 different prescribers and 30 different pharmacies
- Death due to opioid toxicity
- Estate claims pharmacists should have contacted physicians, had discussion with patient, or refused to fill
- “[Deceased] was a drug addict who was filling prescriptions from different doctors at different pharmacies. His actions indicate that he was aware that doctors and pharmacists would not approve of his behavior. Absent more, we cannot logically deduce that had [the pharmacists] intervened, [the deceased] would have stopped abusing drugs and would not have died.”

Legal Case Study—Proximate Cause

- Rx for compounded cream containing ketamine and cyclobenzaprine. Accurately prepared and dispensed.
- Patient died from respiratory depression due to toxic effects of the cream.
- No testimony of dangerously high dosage or improper topical use
- “Every drug has contraindications and possible side effects, but because proximate cause is the standard, an expert needs to point to some facts showing the claimant could prove that, at the time of the breach, it was foreseeable that an adverse effect of the kind actually suffered would materialize in this patient.”
Damages

- **Corrective Justice**
  - Compensation to others for the consequences of negligence we inadvertently committed, either actively or passively
  - Corrects an imbalance caused to those whom we have harmed
  - Experts can attach a dollar value to patient losses

- **Retributive Justice**
  - Punitive damages serve to exact vengeance and to deter future negligence, both specifically and generally
  - Must be evidence of wanton and reckless disregard for the plaintiff’s rights or of morally culpable conduct
  - Intentional malice is usually required

Legal Case Study

- Technician commits order processing error; pharmacist fails to catch error on final check
- Plaintiff asserts that the pharmacy has a “corporate policy of acceptance of errors” because they coach and train those who commit errors
- “While the evidence does demonstrate that defendant emphasized speed when filling prescriptions, the evidence also demonstrates that defendant simultaneously emphasized accuracy.”
- “Negligence, even gross negligence, is inadequate to support a punitive damage award.”
Contributory Negligence

• Patients also have a responsibility to exercise care in the use of medications
• But, patients are not responsible for things they cannot know or appreciate. They are not drug therapy experts.
• Contributory negligence is a complete bar to recovery. This approach varies from state to state.
• In comparative negligence, the jury attributes a percent of fault to each party, and the award to a plaintiff is reduced by the percent of fault attributed to the plaintiff.

Legal Case Study

• Patient orders 2 medication refills from mail order pharmacy. She receives 6 medications for another person, with that other person’s name on them. Patient dies.
• Estate sues pharmacy for negligence.
• “Taking prescription medication that has been prescribed for another person because of failure to read the prescription bottle is carelessly exposing oneself to a danger or risk of which [the patient] knew or should have known.”
• “As a matter of law [the patient] was contributorily negligent and her negligence claim is thus barred.”
Statute of Limitations

• A statute of limitations requires that lawsuits be filed within a prescribed period of time, to prevent delaying litigation until memories have faded and evidence has disappeared.
• Most states recognize a “discovery rule” that starts the of a statute of limitations at the time the harmed party discovered, or could have discovered, the harm (and perhaps who caused it).
• Many states have adopted “tort reform” laws that limit liability for medical malpractice, and these laws may reduce the statute of limitations for health care negligence.

Legal Case Study

• Rx for immediate release dextroamphetamine bid
• Pharmacist dispenses extended release with bid directions
• Error caught by school nurse. Error is corrected and then repeated. Claim is initiated by pharmacy.
• Pharmacy sends to mother a request for access to son’s medical records. Mother conducts online research and discovers potential for harm to her son.
• Court concludes that under discovery rule, the statute of limitations did not start until mother received request for her son’s records.
Case Study: Focus on Patient Education

- Rx for clindamycin. Patient given warning leaflet. Patient returns to pharmacy with questions for the pharmacist about information in the leaflet.
- Pharmacist tells patient that “the warnings on the patient information sheet were applicable to extreme cases and that she should not be ‘paranoid’ and should taken the medication.”
- Patient suffers harm and sues pharmacy
- “We conclude under the circumstances of this case that a trier of fact could determine that defendants breached their duty of ordinary care.”

Learning Points

- Patients have an expectation that pharmacists will provide them with information about safe and effective medication use.
- The printed patient information leaflet is a means to efficiently communicate with patients.
- Concerns expressed by patients should always be taken seriously and never disregarded with flippant comments.
- Patients can be expected to address questions to the person from whom the information was received, but they should be referred to the prescriber if there is any uncertainty about the appropriate response.
Case Study: Focus on Computer Alerts

• Pediatric patient died from acute asthma attack
• Pharmacy records showed that patient had not be refilling her inhaled corticosteroid, yet had been refilling her albuterol rescue inhaler three times more frequently than was appropriate
• “The pharmacy computer system alerted pharmacists that the patient was getting the inhalers at improper intervals.”
• “The risk of her overuse of the medication was not only foreseeable, it was foreseen by the pharmacists. These pharmacists should have known of the dangers associated with the overuse of the inhalers.”

Learning Points

• So-called “alert fatigue” has caused pharmacists to trivialize the alerts provided by computer software.
• However, some alerts inform pharmacists of life-threatening problems.
• Too-early refills is a potential problem that should be given priority; and ways to circumvent 3rd party plan restrictions should be avoided.
• Patient education and prescriber consultation are both effective means of addressing high level alerts. And everything should be documented in notes that can be found later.
Case Study: Focus on Primary Care

• Hospitalized patient was diagnosed with MRSA infection
• Vancomycin was not ordered by the attending physician, “although it would have been appropriately prescribed for him given the nature of his infection.” Patient died.
• Estate sues hospital, alleging malpractice by the attending and by a clinical pharmacy specialist.
• A pharmacist rounded every day with the medical team; had access to full patient records, and was responsible for consults with physicians.
• Court refuses to dismiss claim based on pharmacist malpractice.

Learning Points

• Pharmacists have begun to accept responsibility as clinical specialists within institutional settings. This role will inevitably expand into other settings.
• As responsibilities expand, so will exposure to malpractice liability.
• The role of clinical specialists should be well defined so that courts can appreciate the limits of this position.
• Responsibility should be shared with others. This is not the time to assert individual authority separate from the team.
Summing Up

- Pharmacy malpractice avoidance strategies should focus both on reducing order processing error (the most frequent) and on expanded practice roles (the fastest growing).
- Shared responsibility leads to shared liability, so involve patients, prescribers, and others in drug therapy decisions.
- Most pharmacy malpractice cases are based on relatively straightforward errors that are difficult to prevent. A team effort (continuous quality improvement) may be necessary to effectively reduce exposure to malpractice liability.

Minimizing Pharmacy Malpractice Liability Certificate Program

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