

# Case Presentations in Patient Safety and Ethics

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## Financial Disclosure

- I have no financial conflict of interest to declare

“Dollars for Docs”

- <https://projects.propublica.org/docdollars/>

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## Loyalty Disclosure...Go Beavs!



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## Learning Objectives

After completion of this presentation, pharmacist attendees will be able to;

- Identify ethical dilemmas as they pertain to patient safety issues
- Make rational decisions when faced with productivity vs. patient safety concerns
- Speak to the principle of informed consent
- Elucidate the meaning of “just culture” as relates to patient safety

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## Medication Errors

- Medication Errors-are responsible for the deaths of 7,000-9,000 people annually in the U.S. [1]
- The total cost of looking after patients with medication-associated errors exceeds \$40 billion annually.[1]

[1] Medication Errors Rayhan A. Tariq, Yeveniya Scherbak April 28, 2019.

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## Medication Errors

- In general, medication errors usually occur at one of these points...
  - Ordering/Prescribing
  - Documenting
  - Transcribing
  - Dispensing
  - Administering
  - Monitoring

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## Just Culture

Just culture refers to a values-supportive model of shared accountability. It's a culture that holds organizations accountable for the systems they design and for how they respond to staff behaviors fairly and justly. In turn, staff members are accountable for the quality of their choices and for reporting both their errors and system vulnerabilities (Griffith, 2009).

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## The behaviors we can expect

Human error—inadvertent action; inadvertently doing other than what should have been done; slip, lapse, mistake.

At-risk behavior—behavior that increases risk where risk is not recognized, or is mistakenly believed to be justified.

Reckless behavior—behavioral choice to consciously disregard a substantial and unjustifiable risk.

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## Six Major Elements to Ensure a Culture of Safety

- Move from looking at errors as individual failures to realizing they are caused by system failures
- Move from a punitive environment to a just culture
- Move from secrecy to transparency
- Care must change from being provider-centered (doctor-centered) to being patient-centered
- Move our models of care from reliance on independent, individual performance excellence to interdependent, collaborative, interprofessional teamwork
- Accountability must be universal and reciprocal, not top-down [2]

[2] Lucian Leape Quality of Health Care in America Committee at IOM 2009.

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## Words of Wisdom

- No matter your type of pharmacy - it is your ethical responsibility to have the best process and quality in place to honor the trust your patients have given to you. [3]

[3] Dixie Lelkach-RPh, MBA, FACA PEER Pharmacy Ethics, Education and Resources.

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## Ethics, Law and Liability

- Ethics and law differ in that ethics are social guidelines based on moral principles and values while laws are rules and regulations that have specific penalties and consequences when violated.
- Ethics is “doing the right thing”
- Law is “following the regulations, or else.”
- Liability is “anyone can sue you for any reason.”

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## Four Principles of Bio-Ethics

1. Beneficence
2. Non-Maleficence
3. Patient Autonomy
1. Justice

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## Beneficence

- Beneficence is action that is done for the benefit of others. Beneficent actions can be taken to help prevent or remove harms or to simply improve the situation of others.
- Clinical Applications: Physicians are expected to refrain from causing harm, but they also have an obligation to help their patients.

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## Non-Maleficence (do no harm)

The principle of nonmaleficence states that we should act in ways that do not inflict evil or cause harm to others. In particular, we should not cause avoidable or intentional harm. This includes avoiding even the risk of harm.

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## Patient Autonomy

Autonomy is the “personal rule of the self that is free from both controlling interferences by others and from personal limitations that prevent meaningful choice.” Autonomous individuals act intentionally, with understanding, and without controlling influences.

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## Justice

Justice is a complex ethical principle, with meanings that range from the fair treatment of individuals to the equitable allocation of healthcare dollars and resources. Justice is concerned with the equitable distribution of benefits and burdens to individuals in social institutions, and how the rights of various individuals are realized.

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## Code of Ethics for Pharmacists-preamble

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

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## Case Presentation-I

A pharmacist received a prescription for sulfamethoxazole/trimethoprim 800 mg/160 mg twice daily for 10 days. Before filling the prescription, the pharmacist reviewed his records and saw that the patient had an allergy to sulfa antibiotics, but was not sure about the type or severity of the reaction. The pharmacist called the prescriber, who told the pharmacist that she was aware of the allergy but believed the antibiotic was the patient's best option. The pharmacist made a note to talk with the patient about the allergy.

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## Case Presentation-I

The pharmacist has a responsibility to seek more information about the patient's previous allergic reaction. After obtaining that information, the pharmacist must communicate with the prescriber to ensure that she has the same information. If the prescriber still wants the patient to receive the antibiotic, then the pharmacist has a responsibility to inform the patient of the risks.

As pharmacists, we must both follow prescribers' orders and fully inform patients about their treatment. Informed patients have the right to refuse treatment even if it is in their best interest. Pharmacists need to routinely document patient care, including recommendations, education, and follow-up.

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## Case Presentation-I

Pharmacists have a professional obligation to counsel patients so that they are informed comanagers of their drug therapy.

**Informed consent** is an interactive process with patients through which the pharmacist ensures that they fully understand their medications.

Informed consent requires pharmacists to be knowledgeable about treatment risks and benefits and standards of care.

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## Case Presentation-II

Jerry has been a patient at your pharmacy for approximately two years following a traumatic accident. While unloading steel pipe from a flatbed, the load came loose and crushed Jerry. Jerry fractured his neck and back and had to have his right shoulder replaced. Jerry has been on OxyContin 40 mg tid for the past year. You regularly check the PDMP and he only sees one physician and only utilizes your pharmacy. He has never sought early medication fills and in your conversations, he indicates that he doesn't know how he would be able to function without his medications. He is still in pain but able function somewhat normally. He is also on a pain contract with his physician whom you speak with regularly.

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## Case Presentation-II

Jerry also takes other medications...

Alprazolam .5mg bid prn for anxiety.

Gabapentin 2400 mg daily for neuropathic pain.

Citalopram 40mg daily for depression.

Zolpidem 10mg at bedtime as needed for insomnia.

Miralax daily for constipation.

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## Case Presentation-II

In January, Jerry's physician cut his OxyContin dose to 40 mg bid to meet CDC guidelines and his insurance carriers advice in achieving the recommended daily MME.

In July, his dose was decreased again to oxycodone IR 10 mg up to 4 times a day as needed.

In addition, Jerry is now in behavioral cognitive therapy, is seeing an acupuncturist, has a great new physical therapist and meditates.

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## Case Presentation-II

As a result, Jerry is now working toward functional goals instead of becoming pain free. He is still painful but is learning to deal with it more rationally. As a result,

- He discontinued the alprazolam
- He cut his gabapentin dose
- He is now off of citalopram
- He only rarely takes his zolpidem

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## Case Presentation-II (alternative ending)

Today Jerry is a mess. He lives in his pick up truck and is in constant pain. Jerry concedes he was taking too many opioids but points out it was legal and under a doctor's supervision. Jerry attempted to stick with the reduced doses for six weeks, then decided to visit Old Town in Portland to buy heroin. He said he turned to heroin because he had to have something to deal with his chronic pain. Jerry now misses visits to his physician, sees other doctors and dentists and utilizes multiple pharmacies.

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## Case Presentation-II (alternative ending)

After tapering his opioid dose, Jerry lost hope and couldn't bear living with his chronic pain any longer. On March 17<sup>th</sup>, Jerry committed suicide.

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## Case Presentation-III

The evening pharmacist was behind in the verification queue for the shift, because other staff members were ill or attending a Code Blue response; there was a full patient census. The evening pharmacist has the reputation for verifying the highest numbers of orders during a shift; on a recent shift, the pharmacist verified over 400 individual orders, which is far beyond (>2 SD) other pharmacists. This pharmacist has been counseled about a past history of medication errors; many of them were careless as their root cause was the bypass of accepted safeguards in the department for order review and verification.

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## Case Presentation-III

During the shift report, the evening pharmacist reported to the night pharmacist that they did not review laboratory values for most of the orders verified where this action was required. To quote the evening pharmacist during report, "I was too busy and wanted to get out on time - so I blew it off - no biggie." The following day, the director of pharmacy received 2 complaints from physicians who reported that drug levels were not optimal and should have been adjusted based on laboratory values but were not because of the evening pharmacists' negligence.

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## Case Presentation-IV

You receive a prior authorization request for an 18 month old child (Jessica) for Zolgensma. This medication is a gene therapy medication approved for the often fatal condition of Spinal Muscular Atrophy and costs \$2 million. When Jessica was two days old, she started receiving Spinraza which helped keep her symptoms at bay. While Spinraza helps, she still cannot walk, crawl or eat solid food. Zolgensma may represent a cure. Even with it's high price tag, Zolgensma could be less expensive than years of injections of Spinraza.

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## Case Presentation-IV

The PA request generates significant discussion at the health plan and a full slate of specialty pharmacists, medical directors, the benefit administrator, the priest from mission integration and CEO are brought into the conversation. At one point, the benefit administrator speaks flatly, "I don't know why we're having this conversation, just exclude it from coverage." All other participants are visibly wrestling with the question at hand.

If Jessica is a viable candidate, should this drug be covered?

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## Moral Distress

Moral distress arises when an individual identifies the morally right action required but feels unable to act due to legal or contractual constraints. Moral distress can lead to:

- Burnout
- Professional dissatisfaction
- Pharmacist-Patient disenfranchisement
- Abandoning the profession

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## Resources

- Principles of Biomedical Ethics-Beauchamp and Childress
- ISMP-Institute for Safe Medication Practices-[www.ismp.org](http://www.ismp.org) +
- AHRQ-[www.ahrq.gov](http://www.ahrq.gov)
- Ethics in Pharmacy-A New Definition of Responsibility
  - [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov)

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## Assessment Questions

When facing an ethical dilemma pertaining to patient safety concerns, a pharmacist should;

- (a) Consider the four ethical principles at play.
- (b) Do whatever's expedient to ensure productivity.
- (c) Phone a friend.
- (d) Call the Board of Pharmacy for advice.

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## Assessment Questions

When decisions have to be made regarding productivity vs. patient safety concerns the pharmacist should;

- (a) Get their technicians to work more quickly.
- (b) Err on the side of patient safety.
- (c) Drink more coffee.
- (d) Consider a different career.

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## Assessment Questions

The principle of informed consent means;

- (a) An interactive process with patients through which the pharmacist ensures that they fully understand their medications.
- (b) Something with the “me too” movement.
- (c) Let the patient decide what’s best for them.
- (d) None of the above.

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## Assessment Questions

Describe the meaning of “just culture” as it pertains to patient safety;

- (a) Medication errors are preventable and staff should be reprimanded for making them.
- (b) The Board of Pharmacy should issue a fine for every medication error.
- (c) A values-supportive model of shared accountability.
- (d) Medication errors are acceptable in some cultures.

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# Questions?



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# Thank You!



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