

CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

Pharmacist and Prescriber Responsibilities for Avoiding Prescription Drug Misuse

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Abstract

Pharmacists have the same duty as prescribers to prevent inappropriate use of dangerous drugs. Loperamide, for example, is an over-the-counter medication that has been reported to be potentially misused for euphoric effects. Pharmacists and prescribers alike face challenges in providing optimal care for patients and protecting communities from drug misuse. These challenges include cognitive bias, underdeveloped safety culture, and differing expectations of responsibilities of the other party in ensuring safe prescribing. This commentary explores legal, ethical, and practical considerations for pharmacists and prescribers working together to address uncertainty in drug prescribing.

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Case

Ms D is one of 2 pharmacists at an Indian Health Service (IHS) unit in Oklahoma. Familiarity with community members who recently died by prescription medication overdose has prompted Ms D to focus more on preventing misuse and abuse of prescription medications. She has, for example, recently reviewed the Indian Health Manual's pharmacy section, which outlines standards of practice and the mission to "ensure efficacious, safe, and cost-effective drug therapy."¹ Since her license to practice pharmacy is from the state of Ohio, Ms D also reviewed the Ohio Administrative Code's State Board of Pharmacy section about prescribers' and dispensing pharmacists' "corresponding responsibility"² to properly issue prescriptions to patients.

Ms D is processing a loperamide refill for Mr T, a 32-year-old Cherokee patient with chronic intermittent diarrhea. When viewing Mr T's electronic health record, Ms D notices his history of opioid use disorder. She also sees that Mr T's clinician, Dr O, has refilled the loperamide prescription 4 times over the last 3 months, and there was no documentation of symptom exacerbations during that time. Ms D wonders whether Mr T could be misusing loperamide to try to mimic effects of opioids.³ Ms D calls Dr O to discuss this possibility.

According to Dr O, Mr T's history of substance use disorder is in the distant past. Dr O notes that it is also important for Mr T to have loperamide to manage his symptoms. Ms D is unconvinced, however, and states that dispensing loperamide could contravene Mr T's best interests and violate her duties to this patient as explicated in the Indian Health Manual and Ohio Administrative Code. Exasperated, Dr O reminds Ms D that Mr T has no supplemental insurance, that Mr T does not have access to a hospital or other clinic within 2 hours of his home, and that the IHS pharmacy is his only source for obtaining loperamide.

Ms D and Dr O remain on the telephone line and wonder how to resolve their disagreement about whether it is appropriate to refill Mr T's prescription.

Commentary

In *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine*,⁴ Jonsen, Siegler, and Winslade suggest tackling ethical dilemmas by first looking closely at facts that could help establish agreement about clinical indications for timely, specific interventions. Ms D is probably aware of published reports that persons who abuse opioids have attempted to use loperamide as an opioid substitute for euphoric effects.³ Mr T has a history of **substance use disorder**. It is unclear whether the substance use disorder involved opioids. Although this is a reasonable possibility,⁵ the details of Mr T's substance use disorder history, including whether he is an active user or in recovery, is insufficient to determine the appropriateness of prescribing loperamide. It is also inappropriate to suspect Mr T of prescription misuse on the sole basis of recent overdose deaths in the community (a cognitive bias that will be explored later).

The case as described leaves many reasonable questions unanswered regarding the appropriate use of loperamide by Mr T (see **Supplementary Appendix** Tables 1 and 2). Therefore, Ms D rightly contacted Dr O for clarification. This commentary explores legal, ethical, and practical considerations for pharmacists and prescribers working together to resolve uncertainty in drug prescribing.

Indian Health Service

Which regulatory body—state, federal, or tribal—holds jurisdiction over dispensing at this IHS site? As federally operated pharmacies, each IHS service unit is responsible for developing local policies and procedures that are in accordance with federal law, including US Drug Enforcement Administration (DEA) regulations⁴ and state prescription drug monitoring program reporting.⁶ IHS sites also maintain a pharmacy library that includes current federal and applicable state laws governing the practice of pharmacy.¹ Since IHS pharmacies are federally operated, IHS pharmacists do not need to be licensed in the state where they work. However, IHS pharmacists must comply with their state board regulations in order to maintain their licenses. An opinion from the Arizona Attorney General addressed this issue in the context of a question from the Arizona Board of Nursing and is helpful in explaining how state and federal legal jurisdictions are applied.⁷ If there is ever a discrepancy between federal and state laws, pharmacists are to follow the more restrictive law, regardless of whether it is **federal or state**. Fortunately, federal, IHS, and state regulatory language on corresponding responsibility is consistent (see **Supplementary Appendix** Table 1).

What about tribal jurisdiction over health care? As sovereign nations, federally recognized tribes can exercise their authority to pass laws to protect and promote the health of their citizens.⁸ While jurisdictional issues of tribal, state, and federal laws can

be complicated,⁹ the development of tribal law is an important step in self-determination and tribal political sovereignty. An increasing number of tribes and tribal organizations have also been taking ownership of the design and management of health programs. Since the passage of the Indian Self-Determination and Education Assistance Act of 1975,¹⁰ federally recognized tribes and tribal organizations can assume control of IHS funding to directly develop and manage programs, services, functions, and activities to meet the needs of their tribal communities. A tribe can choose to continue receiving health care services directly from the IHS, to contract with the IHS to administer individual services, or to compact on a nation-to-nation basis with the IHS to control health care programs the IHS would otherwise provide. The decision to move from direct IHS services to contracting or compacting is a tribally driven initiative informed by the tribe's determination of its unique needs and circumstances.

Physician and Pharmacist Responsibilities

In entering discussions of physician and pharmacist responsibilities, all parties must share 3 key understandings: first, that pharmacists have a corresponding responsibility to ensure the medical appropriateness of dispensed medications; second, that all are doing their best for the patient within their capabilities; and third, that clinical judgment will always involve some degree of uncertainty.

Medical appropriateness. Often when those familiar with pharmacy law and ethics topics read the phrase *corresponding responsibility*, they immediately think of the DEA regulation on prescribing that charges pharmacists with the equivalent duty as prescribers to ensure that controlled substances prescriptions are written and dispensed “for a legitimate medical purpose ... in the usual course of ... professional practice.”¹¹ The Department of Justice (DOJ) and the DEA wanted to make it crystal clear that pharmacists have a corollary duty with physicians, dentists, veterinarians, and other practitioners to prevent inappropriate use of dangerous drugs and opioids. This rule helps eliminate an irresponsible defense (ie, “I don’t write prescriptions; I just ‘fill them’”), as implied by Elvis Presley’s pharmacist defense of his dispensing over 5600 controlled substances doses during the 6 months before Presley’s death.^{12,13}

Why should Ms D be worried about any corresponding responsibility with a nonprescription over-the-counter drug, such as noncontrolled loperamide?¹⁴ According to the State of Ohio Board of Pharmacy rule, all prescriptions—not just controlled substances prescriptions—are dispensed under the same standard as federal law.^{2,15} One might reasonably argue that this may be the standard of care expressly^{16,17} or implicitly in all US jurisdictions, since pharmacists are ethically obliged to act in patients’ best interests and “assist individuals in making the best use of medications.”¹⁸

One should note, however, that Dr O and Ms D might feel differently about following the letter of the law. Abood and Burns write in their textbook, *Pharmacy Practice and the Law*:

Pharmacists are highly regulated as health professionals because the slightest misstep in drug distribution or pharmaceutical care could cost a life. As custodians of the nation’s drug supply, pharmacists are subjected to extensive regulation because the products pharmacists control are held to the most exacting standards of any consumer product. Pharmacists study the law because, through the law, society has described what is considered acceptable conduct for pharmacists, and pharmacists who fail to meet this level of acceptability will be held accountable for their failure.¹⁹

Unlike physicians and other health care professionals, pharmacists are trained extensively in the law. In pharmacy school, pharmacists take a pharmacy law course (or some series of required law lectures); they all sit for and must pass a state-specific pharmacy jurisprudence examination as part of the licensure process; and many are required to take a required pharmacy law refresher course periodically as part of their mandatory continuing education requirements for relicensure.²⁰ Regrettably, many of the laws and regulations that govern pharmacy operation and practice appear ridiculously detailed and have little to do with meeting practice obligations to patients. To name a few such regulations: the minimum pharmacy square footage of floor space and uncluttered prescription counter area required per pharmacist available for filling prescriptions, the titles and types of books necessary for a pharmacy reference library, the equipment necessary to compound prescriptions, and unique requirements for a pharmacy operating within a larger mercantile or grocery store.^{21,22,23,24,25}

Patients' best interests. The second shared understanding in interprofessional discussions is that all parties are doing the best they can within their capacity to help the patient. Ms D has not only a legal obligation to understand Dr O's clinical rationale for prescribing loperamide to better ensure compliance with regulations, but also an ethical obligation to provide the best care for the patient. Additional conversation is an opportunity for Ms D to provide Dr O with suggestions for other antidiarrheal substitutes that do not carry the same misuse potential as loperamide. The frequency of loperamide prescriptions for Mr T may have passed under Dr O's radar, especially if more critical patient-driven issues were the focus of visits or if there has been a lack of patient-clinician continuity. Concerns about the risk of drug misuse aside, the loperamide refills may be a clue to an underlying chronic diarrheal condition that has not yet undergone full workup or treatment. When brought to Dr O's attention, this issue can be the means to move care forward for the patient's benefit.

Regarding the financial issues the "exasperated" Dr O advances for prescribing loperamide, one might challenge these as potentially immaterial justifications and caution Dr O and Ms D not to chase them too far down the rabbit hole. As health care professionals, both Dr O and Ms D are ethically obligated to help Mr T compassionately and cost effectively.^{18,26} Both should be making decisions in Mr T's best interests. Without appearing too callous or flippant, one might agree with Ms D that access to care and cost issues should only be taken into consideration once the physician and pharmacist resolve the issue of clinical indications: if loperamide is not the optimal drug at this time for Mr T, other considerations are probably irrelevant.⁴

Pharmacists often see themselves as having little discretion in providing optimal pharmaceutical care to patients. In contrast, physicians, in exercising professional judgement, see themselves as having more options when making decisions in patients' best interests. In reading the facts of this case, one might wonder how much of Ms D's decision making may be driven by a compulsion not to deviate in any way from what she considers to be her legal duty. Should this be the case, Ms D might reflect on the prime question: Is she making decisions out of fear of criticism or sanction for allegedly violating a law or in the patient's best interests?

Uncertainty in clinical judgment. The third shared understanding of pharmacists' and clinicians' job duties is that uncertainty is inherent in clinical decision making. Heuristics—cognitive short cuts used to come to a decision quickly—are common and put professionals at risk for cognitive biases. **Heuristics and cognitive biases** have been

discussed widely in the literature,^{27,28} and some examples are seen in this case. Ms D could be expressing *availability bias*, wherein the probability of an event (eg, recent overdose deaths) might seem higher than it is due to instances being easily recalled. Ms D could also be expressing *representativeness bias* if she bases the likelihood of Mr T's loperamide misuse on how similar Mr T appears to a stereotypical representation of someone who is actively misusing prescriptions, despite her lack of knowledge regarding Mr T's substance use recovery status. And Dr O could be prey to *diagnostic momentum* by continuing an already initiated clinical course of action (eg, refilling Mr T's loperamide prescription) without considering possible reasons for changing the treatment plan. Time constraints, lack of clinical support, or the presence of demands can exacerbate cognitive biases.

Culture of Collegiality and Communication

What should clinicians and teams do to help mitigate cognitive bias? Anti-bias training is a start but does not address how a busy clinic environment can contribute to cognitive bias. Ms D's reaching out to Dr O to ask questions and considering alternatives are 2 strategies listed in Table 1.

Table 1. Possible Responses to Cognitive Bias

- Slow down.
 - Ask questions.
 - Consider alternatives.
 - Use checklists.
 - Solicit peer and committee input to improve practice consistency.
 - Use validated screening tools, such as the National Institute on Drug Abuse's "Clinician's Screening Tool for Drug Use in General Medical Settings."²⁹
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Health care professionals' defensiveness about perceived challenges to their decision making is one barrier to addressing cognitive biases, which can be addressed by cultivating a workplace culture centered on mutual respect,³⁰ transparency, and nonpunitive approaches to learning, wherein the system's vulnerabilities are addressed proactively and prioritized for improvement. This environment is known as a safety culture and is recognized by the Joint Commission as supportive of high-quality health care.³¹ A safety culture is built through facility leadership modeling appropriate behaviors and eradicating intimidating or disruptive behaviors.³² Focusing on the systems, the facts, and the acts, rather than on assumptions about employees' intentions, is vital to building an organizational safety culture.

Suppose Dr O has reasonable answers to Ms D's proffered questions. Ms D should be satisfied that this particular refill is for a legitimate medical purpose prescribed "in the usual course of ... professional practice."¹¹ Careful documentation of this conversation with certification by both Ms D and Dr O further validates for the record that both the **physician and the pharmacist** acted prudently, in the patient's best interests, and according to accepted medical and pharmacy practice standards of care. One should recall that just because the answers are satisfactory at this point does not obligate Ms D to fill or refill any future loperamide prescriptions.

Should Dr O not have reasonable responses to the questions Ms D poses, one might reasonably infer that Ms D—in the proper exercise of her professional judgment—has a valid reason for refusing to refill the loperamide prescription for Mr T.³³ In this case, Mr T would not have a way to obtain loperamide without pharmacist approval. Although loperamide is available for purchase over the counter without prescription, IHS pharmacies are often the sole source of over-the-counter or prescription medications for patients in rural reservation communities. As illustrated in Mr T’s case, this IHS pharmacy is his only viable option to obtain medications due to the vast distance to the next health care facility and his lack of insurance. Further steps Dr O might take if Ms D still refuses to refill the loperamide prescription after a conversation are outlined in Table 2.

Table 2. Steps Dr O Might Take if Ms D Refuses to Refill the Loperamide Prescription

- Dr O might ask to speak with the second pharmacist who works at the Oklahoma Indian Health Service unit. The second pharmacist may not be licensed in the state of Ohio, as is Ms D, and thus may not feel obliged to refuse to refill the loperamide prescription for the same legal reason, although the second pharmacist should use good professional judgment in filling the prescription “for a legitimate medical purpose ... in the usual course of ... professional practice.”¹¹
 - Should Ms D and the second pharmacist who works at the Indian Health Service unit both refuse to refill the prescription, Dr O could talk with their supervisor about the issue.
 - Should Dr O exhaust the chain of command, he could have a conversation with the relevant boards of pharmacy about best practices regarding this problem.
 - If more pharmacists refuse to refill the prescription after hearing Dr O’s explanation of the clinical indications, Dr O might reconsider and plan another course of action.
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Assuming that all pharmacists who would refuse to refill Mr T’s prescription would be acting in good faith and exercising independent professional judgment in the patient’s best interests and that pharmacists’ judgments are supported by a chain-of-command and relevant boards of pharmacy, Dr O’s position would become less tenable because it would appear very likely that the pharmacists are acting reasonably, as any prudent pharmacist should do in similar circumstances, and meeting their ethical and legal standard of care to Mr T.³⁴

Conclusion

Prescription drug misuse is a challenging problem for which both prescribers and pharmacists have legal and ethical obligations to act in patients’ best interests. Pharmacists’ corresponding responsibility includes reviewing all relevant information in order to determine the safety of dispensing a medication—including discussing concerns further with prescribers. Multiple factors impede the ability of health care professionals to provide the best care for patients. Two major factors are inappropriate use of heuristics during periods of stress and time constraints and a lack of workplace safety culture. Cognitive biases can be addressed by restructuring behaviors to allow

deliberate, standardized pharmacy processes that ensure practice consistency and utilize evidence-based tools. Safety culture involves building a workplace culture centered on mutual respect, transparency, and nonpunitive approaches to identifying and fixing system vulnerabilities. Everyone, from health care facility leaders to frontline staff, has an essential part to play in mitigating cognitive bias and building safety culture. In addressing these issues, not only will the health care community fulfill its ethical and legal responsibilities to provide the best care to patients, but we will be one step closer to a more humane and just world.

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