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FROM THE EDITOR

Ethics, Public Health, and Addressing the Opioid Crisis

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Magnitude of the Opioid Crisis

The alleviation of pain is one of the oldest and most central duties charged of physicians. Ailing patients seek health care in the hopes that it will ease their suffering, and clinicians often take great satisfaction when they are able to reduce their patients' discomfort. There is not a single clinician who has not, at some point in their training or practice, been confronted with a patient in pain, prescribed a pain medication, or been touched by a patient whose pain they could not ease. Clinicians wish to ease suffering, but their prescription pads are a source of potentially dangerous and addictive drugs. In the context of the growing opioid crisis, pain management and approaches to opioid prescribing have taken on an entirely new ethical component. Opioid misuse has become one of the gravest and most consequential public health threats facing the United States today.[1] Per the National Institutes of Health, the number of US drug overdose deaths has increased markedly over the past 2 decades, primarily due to the role of opioids.[2,3] In 2018, there were 67 367 drug overdose deaths in the United States—70% of which involved opioids.[4] Between 1999 and 2017, the age-adjusted drug overdose death rate in the United States more than tripled—from 6.1 per 100 000 to 20.7 per 100 000.[5]

Yet these statistics barely scratch the surface of the negative effects of opioid misuse. The impacts of opioid misuse ripple throughout families and communities and have created a new epidemic of despair. In fact, the opioid crisis has reached such a level of concern that, in 2017, the US Department of Health and Human Services (HHS) declared it a nationwide public health emergency in order to authorize the mobilization of resources, institute public health powers, promote multisector responses, and facilitate innovative strategies to combat it.[6] This declaration has been renewed every year since its inception, having most recently been reaffirmed on January 14, 2020.[7] This multiyear state of emergency is not the norm, and it highlights our failures to sufficiently control this crisis. As noted on HHS' public health emergency declarations page, the typical emergency is declared in response to a natural disaster and lasts several months.[8] We as a medical community and a society must take this opioid emergency declaration seriously, paying particular attention to multidisciplinary innovative strategies aimed at prevention. Furthermore, there remains a substantial need for ethics involvement in this crisis—something a public health emergency declaration does not address.

Broad Impact and Engaging Stakeholders

One of the central components of a public health emergency is to promote multisectoral engagement. This strategy is of particular importance for addressing the opioid crisis due to its deep, far-reaching impacts across a broad spectrum of medical and social disciplines. As such, this theme issue strives to engage key stakeholders to promote a diversity of ethical perspectives and to generate understanding among communities of professionals. The importance of this topic and the scope of its impact is evident in the diversity of contributors' perspectives, each of which deserves thoughtful consideration in social, cultural, clinical, and ethical conversations about what we owe individuals, families, and communities affected by pain and our responses to it.

Public Health

Declaring a public health emergency requires that the true urgency underlying the emergency be recognized. It also necessitates that those in health care fields understand the population focus of a public health emergency and engage in population-level thinking. As such, a public health emergency declaration implies an urgent need for clinicians of all kinds to consider their role in responding to the emergency. The declaration should prompt those in health care to answer the call to align their practice with public health strategies and to become more involved in controlling the emergency.

Unfortunately, HHS' 5-point opioid strategy to address the public health emergency noticeably neglects the need for public health interventions and policy.[9] The primary focus remains treatment oriented and responsive. The aggressive marketing strategies of pharmaceutical companies, clinicians' inadequate training to appropriately manage pain, and a failure to sufficiently treat mental health have been identified as primary causal factors underlying the opioid epidemic.[10,11,12] Although these factors are certainly of central importance, they neglect many crucial underlying factors, such as social determinants and policy, that play a role in a person's health trajectory. Therefore, a central question we must consider is this: What role should the government and society play in combatting the opioid epidemic?[13] Public health-focused modalities must be explored and pursued in the context of opioid misuse, and clinicians in all specialties should become more proactive in public health not only in the clinic or hospital but also in their communities.[14]

Ethics

Efforts have been made to increase attention to the ethics of the opioid crisis, particularly in the areas of prescription practices, naloxone availability, and clinician regulations.[15,16,17] However, the ethics of this crisis still have not been sufficiently addressed. Ethics, both as a guide for what ought to be done and a practice, must be central to any and all strategies we use in combatting this public health emergency. Its importance in this matter cannot be understated. Furthermore, the ethical issues inherent in the opioid crisis extend beyond treatment. Several important ethical questions have been brought to public consciousness: What obligations do pharmaceutical companies have to society due to their role in instigating the crisis? And how do we most appropriately address the underlying factors driving substance misuse and addiction? Yet even these questions require much deeper ethical discussion and are by no means conclusively answered. There are many more questions that remain largely unaddressed: What obligations does the state hold to address opioids, both illicit and prescribed? And how ought we to prioritize funding for opioid prevention and treatment initiatives? These are questions that require our thoughtful attention. It is my

sincere hope that you, the reader, will take from this theme issue the need for (1) greater infusion of ethics into our discussions of strategies for addressing opioid misuse and (2) motivating those in health care fields to actively engage in public health regardless of their practicing specialty.

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CASE AND COMMENTARY

Is Nonconsensual Tapering of High-Dose Opioid Therapy Justifiable?

Travis N. Rieder, PhD

Abstract

This case considers a so-called legacy patient, one whose behaviors and symptoms express a legacy of past, aggressive opioid prescribing by a clinician. Some prescribers might feel pressured to taper doses of opioids for such patients, but this article argues that nonconsensual dose reductions for stable opioid therapy patients is impermissible because it both puts a patient at risk and wrongs an individual in a misdirected attempt to ameliorate a systemic wrong. Although perhaps surprising, this argument is supported by current evidence and recommendations for patient-centered pain care.

Case

Dr G is a family medicine physician seeing a new patient, Mr T, whose physician of many years, Dr A, recently retired. Mr T is 58 years old and takes 170 morphine milligram equivalents (MME) of oxycodone by mouth each day to treat chronic pancreatitis pain. Dr G is shocked by this large dose and asks Mr T about it. Mr T explains, "I've been at this dose for a while now. Dr A used to have folks from this drug's company who would visit his clinic, so he knew what he was doing."

Dr G sits and responds, "Well, that might be true, but I can't prescribe that amount. You've grown to tolerate this amount of this drug over time, but that's not good for you; it's not safe. I'm going to help you taper down, to gradually get used to lower doses. We'll make this change together over time."

Mr T looks terrified. "Look, I've run out of pills before. When that happened, I've never been so sick and miserable in my life. I didn't want to live." Becoming exasperated and starting to panic, Mr T insists, "I need to keep doing what's working for me now! Are you saying Dr A has been wrong all this time? You say, 'We'll make this change together over time.' What does that mean? How long will this take?"

Dr G suspects that the opioid therapy is primarily treating the physical dependence caused by the medication rather than the original pain. Based on recent guidelines, she also doesn't think chronic opioid therapy was likely a good strategy for Mr T. She wonders whether to say this explicitly to Mr T and what to do next.

Commentary

In the wake of America's opioid crisis, clinicians across the country are feeling pressured to prescribe fewer opioids, as scholars have claimed repeatedly that they are at least partially to blame for the broader drug overdose epidemic.[1,2,3,4] Guidelines like the one published by the Centers for Disease Control and Prevention (CDC) urge caution when initiating or escalating opioid prescriptions but leave unclear how such reductions are to be achieved.[5] The CDC guideline, however, has been widely misinterpreted as a mandate to deprescribe for existing patients[6]—in particular, for *legacy patients*, so-called because their long-term use of often high-dose opioid therapy is a legacy of past, more aggressive prescribing practices. Although some patients likely achieved this status due to their physicians failing to respect prescribing norms, many did not; long-term opioid therapy was simply seen as acceptable—sometimes even obligatory—during the late 1990s and early 2000s when pain was taken to be the "fifth vital sign" and opioids were sold to clinicians by pharmaceutical companies as safe and effective.[7]

Mr T is likely one such patient, and he represents one of the most difficult challenges of current pain management practice: because he has taken opioids for so long, he is physically dependent on a high dose and scared of his supply being discontinued. Such cases need to be approached with excessive caution. When a patient's physical dependence is induced by past poor prescribing and clinical management, the *ethical structure* of current prescribing decisions changes—and should change. In particular, clinicians must consider both patient autonomy and their obligation not to compound iatrogenic harms to vulnerable patients. I argue in what follows that these considerations suggest that it is impermissible to taper patients like Mr T without their consent.

Morally Relevant Features of Legacy Cases

Physicians in Dr G's position might believe that the only ethically relevant question of the case is whether chronic opioid therapy is evidence-based practice. It is now well accepted that overprescribing contributed to America's opioid crisis,[7] and, as a result, the CDC guideline recommends a cautious approach that closely attends to physicians' past prescribing of opioids for chronic, noncancer pain.[5] This sort of mindset is revealed in Dr G's initial response to the dose: "You've grown to tolerate this amount of this drug over time, but that's not good for you; it's not safe." Physicians like Dr G presumably believe that high-dose opioid therapy carries significant risks and thus that reducing or eliminating opioid use is indicated. Although the evidence is not actually clear on this point,[8] I will assume that Dr G is correct that a reduced dose might be better for Mr T from a clinical standpoint for the sake of exploring whether nonconsensually reducing Mr T's dose is ethically justifiable.

Initiation vs continuation. The most important lesson for responsible opioid prescribing in cases like Mr T's is that the presumption of a duty to taper as following from evidence-based medicine fails to acknowledge the difference between *initiating* patients on opioid therapy and *continuing* patients on opioid therapy.[6] This distinction is morally relevant for at least 2 reasons: first, because long-term opioid therapy patients can have profound physical dependence; and second, because what patients are entitled to can be affected by how they have been treated by the health care system in the past. I'll address each of these points briefly in turn.

Risk-benefit profile. The fact of physical dependence changes the risk-benefit profile of opioid therapy.[8] Mr T fears the withdrawal symptoms that come with discontinuing opioids, and this fear is a perfectly reasonable one: withdrawal can be far more than

unpleasant or painful; it can be an absolute nightmare.[9] And because a patient who has been on chronic opioid therapy might know the symptoms of withdrawal well, the prospect of withdrawal itself can cause significant anxiety. (As Mr T states in the case, "Look, I've run out of pills before. When that happened, I've never been so sick and miserable in my life. I didn't want to live.") Indeed, withdrawal can be so devastating that patients who have their opioid therapy discontinued abruptly or are tapered too quickly have been reported to commit suicide.[10]

Dr G likely believes that she can mitigate some of this suffering with a careful taper, but she cannot promise that tapering will be symptom free, or even that it won't be miserable. What little data we have about tapering in the most ideal circumstances do not provide much reason for optimism. In one study, practiced experts attempted to carefully taper patients to below 90 MME or to transition those unable to taper onto buprenorphine. Despite the resources of a specialty clinic conducting slow, careful tapers, more than a third of the patients dropped out of the study; among those who successfully completed the taper, more than half reported increased pain.[11] In a separate study under essentially ideal conditions, in which patients volunteered for tapering interventions and investigators were national experts on the topic, results were heterogenous. Many patients were able to achieve moderate dose reductions, but others required *increased* doses. Some experienced decreases in pain while others experienced increases in pain.[12] Slow, careful tapers, even for patients with access to far more professional expertise and resources than average patients, do not necessarily make patients more comfortable. Indeed, even ideal tapering regimens can lead to an increase in pain, with no certainty that patients will be able to eventually complete the taper. It is also important to note that the slower the taper—even when offered with the intention of helping mitigate suffering from withdrawal symptoms—the longer (possibly months or years) the withdrawal process is drawn out. This possible prolongation of withdrawal is an important ethical consideration when deciding how to help a patient who has become iatrogenically physically dependent on opioids.

Iatrogenesis. Additionally, legacy patients are owed a certain amount of deference in choosing their treatment as a result of the situation in which the medical community has placed them. In general, we don't think that patients are owed some particular medication or service. Patients aren't allowed to "order" a drug from a physician. Rather, physicians are stewards of potent substances, and it is their job to decide whether it is appropriate to use a medication in any particular case. High-dose legacy patients are different, however, because they've suffered iatrogenic harm from poor prescribing and poor medical management. If Dr G is correct that chronic opioid therapy isn't good for Mr T, then Mr T has already been wronged by being given an inappropriate treatment—perhaps by an unskilled prescriber or perhaps simply because norms concerning prescribing have changed. Now, he's being pushed or required to go through withdrawal in the hope—but with no guarantee—that he won't be in worse pain at the end of the whole ordeal.[12]

In a case like Mr T's, it seems reasonable to say that Mr T's preferences should play a role in decision sharing about treatment. It might well be the case that there is something clinically and ethically wrong about continuing to prescribe high-dose opioids for some patients' chronic, noncancer pain. But there is also something clinically and ethically wrong about forcing patients to endure exacerbated, protracted iatrogenic suffering. There is no morally pure choice here, but ensuring that patients play a central role in sharing decisions with their physician about therapy can mitigate the badness of

the situation; it can allow the exercise of autonomy that has been threatened by patients being put on a medication, long-term, with no plan for when or how to get off.

To be clear, the argument of this section does not justify the conclusion that a physician ought to write whatever prescription a patient wants, nor does it tell us what Dr G ought to do. Rather, it introduces a key distinction (between initiating and continuing opioids) and shows how the presence of physical dependence is ethically relevant for determining the appropriateness of continuing to prescribe opioids. In particular, physical dependence changes the risk-benefit profile of opioid prescribing due to the threat of withdrawal if the prescription is discontinued; and the patient, having already suffered an iatrogenic harm, should be given a voice in determining how best to mitigate that harm. These considerations suggest that there are reasons to continue a prescription even when initiating opioid therapy wasn't appropriate.

Prescribing for Legacy Patients Is Not Always "Misprescribing"

Some prescribers might object that continuing to prescribe opioids for Mr T would be wrong if Dr G believes opioids are no longer treating the original pain. After all, most physicians are now acutely aware of legal and professional risks of prescribing opioids to satisfy a patient's addiction under the guise of pain medicine.[13] What's important to recognize, however, is that Dr G has no evidence that Mr T has an addiction, which is characterized by cravings and compulsive behavior even in the face of adverse consequences, such as job loss, relationship deterioration, or overdose.[14] Rather, Mr T is physically dependent on opioids, and dependence is characterized by withdrawal symptoms when a medication is abruptly discontinued.[14] Dependence does not, by itself, entail addiction.

Although continuing to prescribe to a patient one suspects of suffering from addiction is clearly taken by medicine and the law to be a case of misprescribing, according to the Harrison Act of 1914,[13] there is no clear ethical or legal requirement to discontinue prescribing for a patient physically dependent on opioids. Indeed, there could not be, since dependence forms as a matter of course for many medications, including opioids, benzodiazepines, and selective serotonin reuptake inhibitors. So, how should physicians decide whether a given instance of prescribing constitutes a case of misprescribing? Kelly Dineen has shown that there is virtually no concrete guidance on this topic.[13] In the absence of concrete guidance, physicians must ask in each case whether the benefits of opioid therapy outweigh the risks.[15] Accordingly, physicians must consider in each case not only the risks of chronic opioid therapy but also the risks of deprescribing. Forcibly tapering a patient, even when that patient does not suffer from addiction, can expose him to some harms of addiction. Withdrawal symptoms and pain are not only harms in themselves but also can destabilize a previously stable patient. A patient who is cut off from his source of opioid medication might seek other sources to self-medicate[6] or suffer medical or functional deterioration.[16]

In the public health world, a number of harm reduction strategies are endorsed for curbing opioid overdose. These include interventions like syringe-exchange programs,[17] naloxone distribution,[18] and safe consumption sites.[19] Outside the United States, there is even support for providing persons with opioid use disorder with a safe supply of opioids so that they don't have to turn to markets that offer potentially contaminated sources of heroin.[20] The philosophy behind such interventions is that preventing people from using opioids is not what's important; preventing harms of opioid use—specifically, physical dependence, addiction, and death by overdose—is what's important. Forcibly tapering otherwise stable patients off high-dose, chronic opioid therapy reveals that this

practice might have an effect that is the opposite of what public health is calling for: it may be a *harm expanding* intervention, exposing those who have long received opioid medications variously to worsened pain, withdrawal, social instability amidst untreated dependence, or loss of medical care relationships.[21] Taking such risks into account, continuing to prescribe high-dose opioid therapy for a legacy patient does not clearly constitute ethical or legal misprescribing. In light of both clinical goals for an individual patient and public health goals for communities, the risks of long-term opioid therapy must also be weighed, in each patient's case, against the risks of *not* prescribing.

What Should a Physician Do?

If Dr G is correct that Mr T's current dose is dangerous, then an ideal outcome would be one in which Mr T feels comfortable working with Dr G to slowly taper to a safer opioid dose, while simultaneously receiving multimodal pain therapies to treat his underlying pain. But Mr T does not seem ready for tapering yet, which means that Dr G has more to consider in counseling Mr T and sharing decisions with him.

Dr G is obligated to counsel Mr T about potential clinical and public health benefits of tapering: minimizing or eliminating risks and side effects of opioid use, potentially decreasing his pain over time (if Mr T is experiencing opioid-induced hyperalgesia), and reducing the number of pills in his medicine cabinet that are potentially available for diversion. Dr G's goal should be to establish a supportive relationship with Mr T in which both can agree upon and implement a careful tapering strategy.[22] In the meantime, Dr G should continue prescribing at current levels, while counseling and partnering with Mr T to help him achieve a better quality of life and reduced pain.

We must, however, acknowledge that Mr T might never be convinced that the benefits of tapering outweigh its risks. Were this the case, as I've argued, it would still not be ethically permissible for Dr G to unilaterally taper or discontinue prescribing opioids for Mr T. As time goes on, Dr G could offer alternative strategies: in particular, Dr G might suggest transitioning Mr T to buprenorphine, as this opioid is a safer alternative to oxycodone, thanks to its ceiling effect on respiratory depression.[23] And if, over time, Mr T's pain worsens or he shows symptoms of opioid use disorder, Mr T might no longer be a *stable* legacy patient, and thus the risks of continued opioid prescribing might start to outweigh the benefits, even accounting for the risks of deprescribing. If either of these cases were to occur, Dr G should partner with a pain or addiction specialist to manage Mr T's care and evaluate how to best mitigate emerging risks.

The view that it is ethically impermissible to nonconsensually taper stable legacy patients, even when not tapering means prescribing some form of opioid therapy indefinitely, might surprise some. But this view accords with recommendations offered in the US Department of Health and Human Services' 2019 Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics,[23] which advises clinicians not to taper patients prior to their consent to a plan. This guide suggests monitoring physically dependent patients, mitigating their risk of overdosing by providing overdose education and coprescribing naloxone, and periodically "encourag[ing] movement toward appropriate therapeutic changes."[23] These tasks depend on developing deep familiarity with patients' experience and life history, earning their trust, partnering, and sharing decisions.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

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CASE AND COMMENTARY

Should the Location of a Patient's Home Inform Physicians' Opioid Prescription Practices?

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Abstract

This case-and-commentary examines whether and when prescribers should authorize prescription opioid refills and questions whether and how a patient's living in an area with a high number of overdose deaths should influence that decision. Clinical social work perspectives presented in the commentary inform a multidisciplinary, team-based approach to this decision that is holistic and nondiscriminatory and that prioritizes the ethical value of self-determination.

Case

Mr W is a 51-year-old man who had a successful partial colectomy 5 days ago for severe diverticulitis. He is tolerating by-mouth intake and is passing stools, and his pain levels are becoming more manageable. Dr M, Mr W's surgeon, gives the "go ahead" for Mr W to go home. Ms K, a nurse, instructs Mr W about how to take care of his surgical wound, and he is discharged to his home with oxycodone and acetaminophen for pain and docusate sodium and polyethylene glycol for constipation. A clinic follow-up appointment is scheduled for one week.

During the follow-up appointment, Mr W reports, "I'm feeling better. I used all the pain meds. May I get a refill?" Dr M authorizes a 5-day refill of the oxycodone and refers Mr W to his primary care physician for follow-up.

Dr M later wonders, however, whether she should have authorized a refill for a patient living in an area of the city struggling desperately with regular deaths by opioid overdose.

Commentary

Many prescribers have experienced Dr M's moment of reckoning. Anxiety concerning opioid prescribing—triggered by overdose reports, professional liability, and regulatory limits—suggests that what looks like a simple clinical decision is actually fraught with ethical complexity and uncertainty.[1] The social work perspective is useful to apply to this case and would entail looking at the prescribing decision in the context of personal and environmental factors in the patient's situation. Honoring his right to self-determination

while also identifying possible risk factors and educating him about potential misuse and overdose are essential components of this holistic approach.

What Would a Social Worker Consider?

A better understanding of Mr W needs to draw on biopsychosocial and holistic perspectives often used by clinical social workers. The biopsychosocial model includes social and psychological factors in a patient's situation. Holistic domains have been variously defined, but one holistic framework categorizes behaviors into 4 domains; environmental, psychosocial, physiological, and health related.[2] Also considered are an individual patient's emotional, social, spiritual, and psychological responses to these domains. Because biopsychosocial factors and holistic domains tend not to fit neatly into biomedical models of thinking about a patient's needs and vulnerabilities, they can complement biomedical approaches in disease management and prevention for good patient care.[3]

Incongruence in the patient presentation seems to be the most cogent factor in the prescribing decision, and it is one that requires more exploration to understand. In Mr W's case, considering a possible personal or family history of substance use disorder is warranted, and Dr M should also establish whether the prescription he`s looking to refill is Mr W's first opioid prescription. If it is not, she might closely evaluate whether his more recent opioid prescriptions have been used responsibly. Since Mr W requests a refill after saying he feels better, Dr M might also ask him about this apparent incongruence in a nonjudgmental manner. A clinical social worker would also explore whether anyone in his household uses opioids and for what purpose. Engaging with Mr W and establishing rapport, a social worker could also nonjudgmentally probe into any recreational use of substances by Mr W. Recreational substance use could include illicit or nonprescribed pharmaceuticals and would be a factor to consider in prescribing decisions.

After assessing these empirical dimensions of Mr W's history and present needs, a good care team might try to determine whether it's clinically helpful or ethically appropriate to relate his personal history to demographic data about overdose trends in his community. If Mr W's health record and the state's prescription drug monitoring program reveal that he has had multiple opioid prescriptions in the past or multiple prescribers, Mr W's opioid use patterns could suggest that he is addicted and in need of addiction therapy or is diverting his opioid supply.

Looking at Mr W's case more broadly, Dr M could ask whether he also used up his constipation medicine as directed. (This speaks to a patient's compliance and self-regulation.) Again, given that the patient reported feeling better, what was his reason for asking for more opioids? Was he underreporting his pain? The physician would need more time than a follow-up visit usually allows to get answers to these questions, but these are the questions that need to be asked and answered for Dr M to resolve her concerns about this patient.

Clinician Humility and Patient Autonomy

While a heightened index of suspicion can be helpful in Mr W's case, Dr M should also consider that denying Mr W a refill of his opioid prescription could be unjust to him. As a clinician, she has a duty both to assess Mr W's risk of opioid misuse and to maintain a positive view of the patient and his intentions. All clinical social workers strive to hold a strengths-based view of patients. This means starting an encounter or relationship with

patients based on an assumption that they express their needs genuinely and that we are obligated to respect their right to and capacity for self-determination. The National Association of Social Workers (NASW) code of ethics calls for social workers to "respect and promote the right of clients to self-determination and assist clients in their efforts to identify and clarify their goals."[4,5] How might this tenet be applied in Mr W's case?

Mr W states that his pain has diminished but also expresses a need for continued pain relief and requests a refill on his medication. Educating Mr W about overdose fatalities in his community is important. Does Mr W know that the area in which he lives has a high rate of opioid addiction and overdose due to fentanyl and other opioids? Dr M could ask about his experience of living in that area. Is there a public conversation about the opioid crisis and the overdose problem? But regardless of data showing that an area of a city in which a patient lives has many overdose fatalities, it would be right to question how this data should inform a team's response to a specific patient.

We suggest that Dr M's respecting Mr W's right to self-determination means maintaining the focus on his expressed need, helping him advocate for himself, and offering therapies for pain relief other than opioids. It is also important for her to highlight her concerns for him, given the high rate of opioid overdose fatalities in his community and his critical need to recover from surgery while mitigating his risk for opioid dependence. Using Mr W's responses to her questions about opioid misuse in his community as guiding tool—and accepting that Mr W is telling the truth about his experience—Dr M can decide to treat based on his individual needs, knowing that she has highlighted her concerns about the area in which he lives. Finally, respecting Mr W's self-determination also means that he retains the right to accept or decline Dr M's treatment recommendation.

Nondiscrimination

In order to identify the correct course of treatment, a strong understanding of the patient being treated or prescribed for is more important than where the patient lives. Many communities are suffering greatly from high rates of opioid overdose fatality and opioid use disorder (OUD) associated with both illicit and prescription opioids. Physicians are understandably confronting fears about prescribing. However, a prescriber making pain treatment decisions involving opioids solely based on location opens the door to consciously or unconsciously considering other factors such as race, gender, age, ethnicity, immigration status, or sexual orientation. These factors can lend themselves to bias and discrimination that create health inequities. Studies show that race does have an influence on opioid prescribing; for example, minorities receive lower-quality pain care over the lifespan than whites.[6]

Marginalized groups and individuals have needed people to call out discrimination and oppression, and the field of social work has answered that call. In its pursuit of social justice, the field of social work is uniquely attuned to the many ways people in our society have been mistreated due to discrimination and oppression. The NASW code of ethics ethical standard of discrimination 4.02 states:

> Social workers should not practice, condone, facilitate, or collaborate with any form of discrimination on the basis of race, ethnicity, national origin, color, sex, sexual orientation, gender identity or expression, age, marital status, political belief, religion, immigration status, or mental or physical ability.[4]

The AMA *Code of Medical Ethics* aligns with social work in this regard,[7] as stated in Opinion 9.6.6, Prescribing and Dispensing Drugs and Devices:

> In keeping with physicians' ethical responsibility to hold the patient's interests as paramount, in their role as prescribers and dispensers of drugs and devices, physicians should: a. Prescribe drugs…based solely on medical considerations, patient need, and reasonable expectations of effectiveness for the particular patient.[8]

Pain management is individual, and no one person has the same tolerance level or response to medications as another. Prescribers can only work with the information they are provided with, and not all patients will give an accurate account of their history of medications or substances—over the counter, prescription, or illicit drugs. Unfortunately, the Centers for Disease Control Guideline for Prescribing Opioids for Chronic Pain, published in 2016, does not provide specific guidance on opioid prescribing for acute pain. It states that because chronic pain treatment with opioids can begin with acute pain treatment, physicians should limit initial opioid prescriptions by prescribing "no greater quantity than needed."[9] Physicians are left to interpret this guideline based on their training and experience, while navigating varying regulations and restrictions imposed by states and payers.

Interdisciplinary Teams

In treating pain—and in many other areas of health care—physicians leading an interdisciplinary team with a variety of professionals, including social workers, can help provide better care, reduce costs, and improve health across populations.[10] Social workers play a critical role on health care teams by contributing their skills and expertise in looking at the whole person within the context of that person's psychological and social environment.[11] Social workers know that strong communication and engagement skills are needed to educate patients and help them advocate for their needs.[10,12]

Returning to Mr W, Dr M or a social worker should educate Mr W on specific safeguards, such as safely storing and disposing of opioids and the risk of overdose, and, as previously discussed, on overdose trends in the community. This approach respects the value and worth of patients but allows them to consider their behavior in the context of their environment more critically.

Social workers and other health care specialists can provide not only useful perspectives on patients, but also support and care coordination, especially for pain care.[10] A social worker making follow-up contact with Mr W to do a brief assessment could assist Dr M by either confirming or allaying her concerns. As a part of a care team, social workers can step in and engage the patient in his or her care in ways that may require time and skills that the physician may not have.[13]

Conclusion

Some might easily think that Mr W might not have needed additional opioids or that he only needed a day or two additional supply. Dr M's limiting of the amount of follow-up opioids for Mr W to a 5-day supply was prudent; an even smaller amount would reduce risk even more. Mr W's case is just one patient scenario of many involving opioids and pain, and each one presents its own set of questions for physicians. There are few simple answers when it comes to opioids, but, in general, physicians are no longer approaching opioid prescribing in the same way as in years past. Prescribing opioids thoughtfully, based on a holistic view of patients, with respect for their self-determination; using risk mitigation tools; and utilizing and leaning on the strengths of

other specialists within health care teams can further good pain care as well as help curb the opioid crisis in all our communities.

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CASE AND COMMENTARY

Should "Pain Clearance" Be Routine for Elective Surgery?

Alexandra M. Dunham, MD and Casey Jo Humbyrd, MD

Abstract

For elective surgery, preoperative planning for patients with comorbidities tends to address risk stratification, cardiac clearance, and anticoagulation. This commentary suggests that chronic opioid use should be normalized as a comorbidity requiring "pain clearance" prior to elective surgery. Doing so would likely enhance team communication, optimize patient care, decrease stigma, and facilitate care transitioning and long-term planning.

Case

A 58-year-old construction worker has long-standing pain and arthritis from a complex ankle fracture sustained in his twenties. His pain has been made tolerable by twice-daily oral opioids, which his primary care physician has been prescribing him for the past 10 years. There have never been concerns about his substance use practices or diversion. This patient also takes warfarin anticoagulation daily for atrial fibrillation. His orthopedic surgeon suggests he undergo ankle fusion surgery to improve his function and help remediate pain.

Commentary

When suggesting elective surgery for a patient, a conscientious surgeon will screen for factors that affect anesthetic approach, surgical tactic, or postoperative care. Cardiac history, such as arrhythmia or heart attack; diagnoses such as anemia, uncontrolled diabetes, or sleep apnea; and behaviors, such as smoking, are those for which screening regularly occurs in a surgeon's office. For elective surgery, a health care team has time for medical optimization and care coordination prior to surgery.

When a patient takes warfarin for arrhythmia, the use of a preoperative checklist is triggered[1] to investigate the indication for anticoagulation therapy, verify an appropriate therapeutic target, consider whether anticoagulation suspension or bridge is prudent and who would manage it, and strategize lab follow-up and monitoring. Unless a perioperative plan is fully addressed and dutifully documented, elective surgery simply cannot happen at many institutions. This plan is generally embraced by surgical and anesthesia staff and enforced by administration. After all, risk of a thromboembolic event when interrupting anticoagulation must be weighed against risk of bleeding and

transfusion when continuing anticoagulation, both of which can affect patient outcomes, mortality, and morbidity.[1]

Surgeons have obligations to screen patients for preoperative opioid use and plan for perioperative pain management with rigor, just as they would for other comorbidities. Stigma and bias surrounding substance use marginalize patients with opioid use history and enshroud the patient-physician relationships in unease and ambiguity.[2,3] Formulating opioid use as a routine element of a patient's clinical history, however, normalizes preoperative queries about any patient's opioid use and thus destigmatizes it. Routinizing and normalizing opioid use queries would help physicians execute their duty to approach patients who do have an opioid use history with nonjudgmental regard.[4]

Surgeons' Roles

First, physicians have a duty to learn about a patient's medical history and apply what's relevant in it to that patient's present clinical situation. A surgeon planning an intervention must understand and consider any medical therapy that could influence potential risks and benefits. Opioids, regardless of whether they are prescribed or obtained illicitly, will influence a patient's perioperative management and postoperative recovery. Because opioid use is linked to surgical complications, including infection, delayed healing, higher costs, and poorer outcomes,[5,6,7] a surgeon is obligated to seek all relevant information about a patient's opioid use.

In the wake of the opioid epidemic, there are now many patients taking opioids prior to elective surgery. Preoperative opioid use has been consistently estimated in about one-quarter of patients, with the highest prevalence among orthopedic patients.[5,8] Yet many physicians admit lacking confidence in how to safely prescribe opioids, how to appropriately screen for opioid use, and even how to talk to patients about opioid use.[9] Surgeons do not consistently screen for preoperative opioid use or use prescription drug monitoring programs.[10,11]

We suggest that routine opioid screening would not only be a useful perioperative tool to improve individual patients' perioperative care but also help destigmatize opioid use, making it easier for patients to talk about and easier for care teams to address. For example, when screening reveals that a patient uses or has used opioids, that patient should be indicated for a "pain clearance" protocol, just as patients with a history of cardiac disease are indicated for cardiac clearance. Standardizing screening would also likely help address known biases in opioid prescribing predicated on a patient's race, sex, or class.[12] Routinizing and normalizing opioid use screening could also function as a decision aid, which could be used to educate patients about opioid use and help them make perioperative pain management decisions according to their values.

Collaborative Preoperative Pain Management

In the case, the patient's opioid history and corresponding modifiable risk could be addressed by engaging the expertise of a variety of specialists. At large, tertiary academic health centers, for example, there are abundant opportunities for surgeons to collaborate with colleagues in pain management, regional anesthesia, and behavioral psychiatry. Were the patient in the case screened for opioid use as a routine matter before elective presurgery, his twice-daily oral opioids would be identified as a medication used to manage a chronic condition. Identifying a patient's opioid use history would then trigger a referral to a perioperative pain clinic, overseen by an

anesthesiologist trained in pain management. In a pain clinic setting, a patient's opioid use history would be detailed and confirmed in the patient's health record, urine toxicology screening would be done regularly as a matter of normal routine, and partnership with the patient's prescriber and pain management team would be reliably established. When appropriate, a patient's opioid intake would be modified to fit into a surgical care and long-term pain management plan. Helping the patient form realistic expectations about postsurgical pain reduction would also be part of this plan.

Ankle fusion is generally expected to reliably relieve arthritic pain due to motion in the posttraumatic joint, but fusion surgery would not address extant neuropathic pain. Thus, it can be important to preoperatively prepare a patient to expect to postoperatively be weaned from opioid-based pain medications and instead transition to multimodal and nonpharmaceutical pain management strategies. By leveraging regional anesthesia resources, a plan to minimize intraoperative narcotics can be made and case coverage can be scheduled. Postoperatively, it might be reasonable to wean some patients off opioids completely over an anticipated recovery duration. For other postoperative patients, returning to preoperative baseline levels of opioid use might be reasonable. A surgical preference against using anti-inflammatory medications would also inform multimodal approaches to managing a patient's post-operative pain. In nearly any postoperative situation, a patient's surgeon and pain management clinician each have follow-up obligations to their patient to ensure appropriate recovery progression.

Conclusion

In summary, physicians have obligations to both solicit information about and plan for perioperative care of patients who use opioids. Opioid management can be optimized and destigmatized by physicians treating opioid use as they do other substances (eg, anticoagulants) that can affect a patient's perioperative status and postoperative recovery.

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CASE AND COMMENTARY

Do Physicians Have Collective, Not Just Individual, Obligations to Respond to the Opioid Crisis?

Beth A. Lown, MD and Michael J. Goldberg, MD

Abstract

Evidence-based clinical guidelines could mitigate variations in care for some patients. However, patient and clinician distress can arise when guidelines are misapplied or mandated by processes that are not evidence based, fail to integrate physician expertise and patient preference, or fail to motivate informed, shared decision making. Physicians can choose to collectively advocate at national, state, and local levels for policy changes.

Case

Dr O is an orthopedic surgeon in private practice trying to adapt to a recently passed law restricting opioid prescribing. This law restricts how long physicians may prescribe opioids for acute pain (ie, pain expected to last 3 months or less), prohibiting prescription of more than 5 days' worth of opioids after an initial consultation for acute pain unless the prescription is for postoperative pain relief, which has a 7-day limit.

Dr O is deeply concerned about physicians' roles in the state's opioid problem. Specifically, he is concerned about colleagues who underprescribe clinically indicated opioids, and he is equally concerned about other colleagues who overprescribe opioids and do not manage patients' pain care skillfully or responsibly. Dr O's patients typically require opioid pain relief for more than 7 days after a surgery, so he and other physicians resent being legally required to offer inadequate pain care to many patients.

Dr O and many of his physician colleagues realize, however, that questioning the appropriateness of this new law as public health policy is not enough. He and fellow physicians wonder whether and when they should try to become engaged as a socially and culturally influential group to shape and influence policy decisions that affect their practices and patients.

Commentary

This case raises the following questions: What are physicians' ethical obligations to improve public health and how should they do so? Specifically, what role do physicians have as a profession to address the epidemic of deaths due to opioids? Not specified, but also important, is the question: How should physicians balance their obligations to

individual patients with their obligations to improve the health of the public? One role of professional societies is to improve quality of care by having its members develop clinical practice guidelines, as we discuss below.

Misapplied Guidelines

State laws and regulations for prescribing and reporting that do not allow for the informed and flexible exercise of evidence-based practice and person-centered care might contribute to moral distress among physicians. While few would question the principles of respect for patients' autonomy, beneficence, nonmaleficence, and justice, the question of how these principles apply in individual instances is often open to debate within the medical profession. For example, Dr O believes his patients typically require opioid pain relief for more than 7 days after surgery but is concerned that he is legally required to prescribe opioids for no more than 7 days initially. His conundrum is that, while ethically obligated to act compassionately and in the best interests of his patient, he will be breaking the law if he prescribes what he believes to be adequate pain relief. In North Carolina, which has a 7-day opioid or narcotic initial supply limit for acute postoperative pain, the law specifies: "Upon subsequent consultation for the same pain, practitioners may issue any appropriate renewal, refill, or new prescription for a targeted controlled substance."[1] Nevertheless, several states have passed laws limiting opioid prescriptions for acute pain in opioid-naïve patients.[2] The content of these laws, including permitted duration of opioid therapy and maximum daily morphine milli-equivalents one may prescribe, varies from state to state.[2] The Centers for Disease Control and Prevention (CDC) guideline for opioid prescribing may help mitigate this variation, although the guideline was developed for the treatment of chronic—not acute—pain, as in this case.[3]

Well-intentioned and well-constructed evidence-based guidelines can have unintended consequences, however. Following the issuance of guidelines by the American Pain Society in 1995,[4] the inclusion of assessment of pain as "the fifth vital sign" was linked to reimbursement as a quality metric by the Centers for Medicare and Medicaid Services.[5] Tragically, this step may have contributed to marked increases in opioid prescribing.[5] At the other end of the prescribing spectrum, the opioid guideline that the CDC issued in 2016, which recommended, among other things, optimizing "other therapies and work[ing] with patients to taper opioids to lower dosages or to taper and discontinue opioids" if benefits do not outweigh the harms,[3] may have been applied inflexibly and misapplied to populations outside the scope of the guidelines.[6] Although outpatient opioid prescribing had been declining before the issuance of this guideline, after its publication, prescribers, concerned about their role in the opioid epidemic, began to nonconsensually taper or discontinue patients' opioids.[6]

As a profession, physicians have an obligation to review available evidence and to contribute to the creation of clinical guidelines. Evidence-based practice requires the integration of best available evidence, clinical expertise, and patient preferences.[7] This practice should guide physicians' recommendations and prescribing decisions in pain management and when treating patients who suffer from substance use disorders to help them attain or sustain sobriety. Physicians should advocate for time and reimbursement with employers and payers to have these important, complex conversations. Physicians may also choose to collectively advocate for changes in regulations, policies, and laws in such circumstances.

Physicians' Obligation to Advocate for Public Health

Physicians have an individual and collective obligation to understand the influence of marketing campaigns conducted by pharmaceutical and other companies that benefit financially from physicians' prescriptions and use of their products. But this obligation goes deeper than awareness of such campaigns. US physicians have an obligation to scrutinize their own behaviors. Acceptance of even small gifts from industry, researchers have shown, can add up to large sums of money both over time and from multiple sources. These gifts create powerful incentives to prescribe specific products with sometimes devastating consequences.[8] Aggressive marketing of oxycodone by one major drug company has been implicated in contributing to the opioid epidemic.[9] A recent report noted that this company intentionally marketed more heavily in states with less stringent prescription drug monitoring programs, resulting in significantly more drug overdose deaths in those states even after accounting for regional differences in socioeconomic factors and in supply and demand—an impact that has persisted for 2 decades.[10]

As stated in the American Medical Association's Principles of Medical Ethics, "A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health."[11] This responsibility can be extrapolated to include an individual and collective obligation to keep abreast of changes in knowledge and other relevant information as they occur during the opioid epidemic and to participate in emergency planning and harm mitigation.

The United States is now in the third wave of deaths from opioids. The first wave began in the 1990s, as physicians began to increase opioid prescribing. The second wave began in 2010 with increasing numbers of deaths due to heroin, as patients with substance use disorders turned to illicit drugs. The third wave began in 2013, as illicitly manufactured synthetic opioids flowed into the United States, especially fentanyl sold alone and in combination with other drugs.[12] We may witness a fourth wave of overdose deaths from drugs for which there are currently no antagonists or evidence-based guidelines for treatment; this is a good reason for physicians to advocate for the acceleration of research in this field.

The magnitude of this crisis obliges physicians to advocate for expanded public education and access to medication-assisted treatment (MAT), naloxone, and harm-reduction strategies. When health care expenses, lost earnings, premature deaths, lost productivity, and addiction treatment are considered, the full cost of the opioid crisis was estimated to be $2.5 trillion dollars between 2015 and 2019.[13] Meanwhile, the death toll remains high (69 029 opioid-related deaths between February 2018 and February 2019).[14]

National, State, and Local Options for Action

What are the range of strategies available for physicians to act collectively to improve public health during the epidemic of drug overdoses due to substance use disorders? Nationally, physicians can act collectively in several ways to influence practice and improve public health. They can act through their associations, professional societies, and academies to advocate and lobby for policies that are based on available evidence and consistent with ethical and professional practice and that they believe will improve the health and well-being of the population. For example, health care policies could

address prescribing, access to treatment, and provider reimbursement. Regulatory policies could incentivize treatment over incarceration for substance use disorders.

The American Medical Association convened national, state, specialty, and other organizations to form a broad-based opioid task force to formulate policy recommendations.[15] These recommendations include terminating all payer and pharmacy benefit management requirements for prior authorization to initiate MAT for opioid use disorder and ensuring that MAT is available at the lowest-cost tier to make it accessible and affordable.[15] The task force has also called for access to MAT for incarcerated persons and for their continued care upon their release. Similarly, the task force recommends expanded access to naloxone and funding for research to expand options for evidence-based treatments.[15] In addition, the task force calls on insurers to comply with the 2008 federal Mental Health Parity and Addiction Equity Act[16] to improve access to mental and behavioral health treatment and advocates for patient and public education, particularly for vulnerable populations such as children and pregnant women.[15]

At the state level, physicians can lobby their state medical societies to influence policy. A recent audit of state oversight and opioid prescription monitoring for Medicaid beneficiaries conducted by the US Department of Health and Human Services Office of Inspector General showed that states have implemented a variety of initiatives. These initiatives include state laws, regulations, guidance, and state-specific Medicaid policies for patients with substance use disorders who have been disproportionately affected by the opioid epidemic.[17] Some of the initiatives reported included using data analytics to identify high-prescribing clinicians and users; limits on opioid drug coverage and prior authorization requirements; education, training and feedback for clinicians about their prescribing practices; community outreach and messaging campaigns; and expanded opioid use disorder treatment programs.[17] Other organizations are beginning to identify promising practices, including those aimed at preventing misapplication of the CDC guideline.[18]

Locally, physicians can advocate for policies that will improve pain management, risk assessment, and treatment in their communities by educating themselves, colleagues, and learners and by participating in hospital credentialing and privileging committees that establish and monitor adherence to standards for professional practice.

Physicians can act collectively by advocating for and participating in the establishment of standards for education and practice across the continuum of learning. Organizations that accredit educational institutions and training programs influence professional and practice norms, as do medical education associations and academies. The Association of American Medical Colleges (AAMC) is working with its member institutions to enhance and expand training in the management of pain and substance use disorders.[19] Excellent resources are available to clinician educators from the US Department of Health and Human Services and elsewhere to inform curricula, research, and policy.[20,21] The AAMC is also promoting awareness of the Opioid Workforce Act of 2019, introduced to expand graduate medical education slots for qualifying hospitals with approved residency programs in addiction medicine, addiction psychiatry, and pain medicine.[22] The Accreditation Council on Graduate Medical Education has joined the National Academy of Medicine's newly formed Action Collaborative on Countering the US Opioid Epidemic, a private-public partnership aimed at coordinating and accelerating efforts to stem the tide of the opioid epidemic.[23]

Summary

In summary, physicians have obligations to individual patients and to the public's health, and they have many opportunities to contribute to the enhancement of both. The obligations include contributing to or keeping abreast of evidence and best practice guidelines as they evolve; demonstrating compassion, respect, and clinical judgment when prescribing and tapering opioids; and acknowledging and addressing conflicts of interest when they influence individual and collective professional behavior. Physicians can also contribute collectively to the improvement of public health at the national, state, and local levels through their professional and educational organizations.

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The case to which this commentary is a response was developed by the editorial staff.

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CASE AND COMMENTARY

What Does Good Pharmacist-Physician Pain Management Collaboration Look Like?

Kyle Bryan, PharmD and Thomas E. Menighan, MBA

Abstract

Physicians and pharmacists have critical roles in addressing the current opioid epidemic and ensuring appropriate care for patients with pain. Both physicians and pharmacists have responsibilities to ensure that opioids are prescribed and dispensed for legitimate medical purposes and to meet legal requirements. Health care systems have implemented policies to curb opioid prescribing and dispensing, but many of these policies place additional pressures on clinicians and can cause friction between physicians and pharmacists. Cases discussed in this article highlight 5 optimal physician and pharmacist behaviors that can help foster better collaboration between these clinicians, improve management strategies, and improve care of patients with pain.

Multiple Opioid Prescribers

Case. KT is a 33-year-old man who enters a pharmacy with a history of chronic back pain. He hands the pharmacy technician 2 prescriptions: one for oxycodone extended release (ER) 40 mg, 1 tablet every 12 hours; and one for oxycodone 5 mg, 1 tablet every 4 to 6 hours as needed for pain. As the pharmacist is reviewing the prescriptions, she sees the patient has recently been taking hydrocodone/acetaminophen 10 mg/325 mg, 1 tablet every 4 to 6 hours as needed for pain, and that these new prescriptions are from a different physician who practices in a nearby state. Concerned about the significant increase in opioid dosage and the potential presence of multiple prescribers, the pharmacist calls the office of the physician who wrote the new prescriptions and asks to speak with the physician. After a brief hold, the physician answers the phone and asks the pharmacist in a noticeably defensive tone, "Why are you questioning me? What do you know about this patient?" The pharmacist begins to explain her concerns about the patient's dosage, but the physician interjects and states that she should fill the prescriptions as they were written. The pharmacist then tries to discuss the potential concurrent opioid prescriptions from 2 different prescribers and verify the increase in dosage. The physician reiterates that the pharmacist should fill the prescriptions as written. At this point, the pharmacist states that she won't be able to fill the prescription without verification that the physician is aware of the other prescriber and the past use of a lower dosage prescription opioid. The physician quickly provides the needed information, confirming that the patient has been instructed to take the long-acting ER

dosage consistently, discontinue hydrocodone-acetaminophen, and hold off on the short-acting opioid for a week to adjust to the higher ER dose and take that medication only as needed. The physician ends the call by telling the pharmacist, "You don't have the knowledge, so you shouldn't attempt to practice medicine."

Commentary. A patient has obtained opioid prescriptions from 2 different physicians, with a significant increase in dose and associated risk. Pharmacists, like physicians and other health care professionals, are committed to optimizing patient outcomes and ensuring patient safety. Pharmacists have a professional responsibility to comprehensively review a patient's medication profile and to review all possible safety concerns in a patient's medication regimen while also considering current evidence-based pain management and geriatrics guidelines. In addition to their professional practice responsibilities, pharmacists must also meet legal obligations, including Drug Enforcement Administration (DEA) requirements for controlled substances. DEA rules mandate that both physicians and pharmacists have responsibilities to ensure that controlled substance prescriptions are written for a legitimate medical purpose.[1] Certain factors, such as prescriptions from different states and multiple prescribers, can be red flags for potential opioid use disorder.

Community pharmacists often have the benefit of access to information about patients' medications prescribed by multiple physicians and can comprehensively evaluate medication regimens for safety and other potential therapeutic problems. What they often lack is access to important information such as diagnoses and prescribers' goals of therapy. Significant concerns about a patient's medication(s) might require the pharmacist to contact the prescriber to discuss the concerns, verify information, and provide recommendations. In addition, a patient's health plan might also require that pharmacists verify information with the physician's office in order to adjudicate the prescription claim. Increasingly, pharmacists are required to include a diagnosis code with the prescription claim or verify that the prescriber was contacted to discuss high opioid dosages. Physicians and pharmacists are under tremendous time pressure, and calls are not made lightly. Some questions can be addressed by office staff, but others are most effectively resolved by a direct conversation between the prescribing physician and the pharmacist.

Effective, comprehensive chronic pain management often necessitates multidisciplinary coordination and a multimodal approach to care.[2] More generally, interprofessional collaboration is key to high-quality, patient-centered care.[3] The Table details selected behaviors that can facilitate improved physician-pharmacist collaboration and the resultant management of patients with pain.[3] In all cases, the patient is best served when pharmacists and physicians communicate in an effective, efficient, and professional manner, without bias, and with a patient-centered focus that facilitates collaboration and active engagement in finding solutions and resolving conflict. Clinicians also have a professional responsibility to understand and appreciate the roles and responsibilities of others in promoting the best care.

Table. Desired Behaviors of Clinicians for Optimal Collaboration in Pain Management

- Communicate respectfully, openly, and without bias, with a patient-centered focus.
- Establish rapport and build trusting relationships.
- Embrace and appreciate the roles and responsibilities of other health care professionals.
- Show empathetic behaviors for the patient and other health care professionals that include avoidance of stigma.
- Actively engage in finding solutions and resolving conflict.

Source: Interprofessional Education Collaborative[3] and Owen JA, Skelton, JB, Miller WA, Moon JY, and Romanelli F (unpublished data, 2020).

Additional information from the prescriber will often assist the pharmacist in (1) discussing with the patient how to take the medication(s); (2) providing education on topics such as side effects, drug interactions, risks and benefits, and storage and disposal; (3) monitoring patient experience with medication(s) and medication adherence; (4) identifying and mitigating risks, ensuring that prescriptions are legitimate, and ensuring that unintended duplication of therapy from multiple prescribers is addressed; and (5) improving coordination of medications among clinicians. Without this information, the pharmacist in this case could be faced with the ethical and legal dilemma of deciding whether to fill prescriptions that could be unsafe for KT, while recognizing KT's need for effective pain management.

Transition of Care

Case. CR is a 70-year-old woman who enters the pharmacy with all of her medication bottles and a set of discharge orders from her most recent visit to the hospital after undergoing orthopedic surgery. CR asks the pharmacist for help in sorting everything out and states she is worried about taking too many medications. Looking at the orders, the pharmacist notes that several medications from CR's home regimen have been discontinued and helps CR go through her medications to clarify which ones she should stop taking. After reviewing CR's remaining medications, the pharmacist notes that the discharging clinician has retained her home medications of tramadol 50 mg, 1 to 2 tablets every 8 hours as needed for pain; and cyclobenzaprine 10 mg, 1 tablet every 8 hours as needed for muscle spasms. Additionally, the hospitalist added to CR's regimen oxycodone 10 mg, 1 tablet every 4 to 6 hours as needed for pain; and zolpidem 10 mg, 1 tablet at bedtime for sleep. The pharmacist contacts the hospitalist to explore possible changes in therapy, recognizing the patient's interests in decreasing the number of medications she takes and noting safety concerns for a patient of CR's age taking concurrent opioids and hypnotics, due to the increased risk of overt central nervous system (CNS) depression and falls.[4]

The physician who comes on the line is familiar with the pharmacist and greets her warmly. She states that a nurse colleague took the medication history and verified that the patient had been taking all these medications regularly. The pharmacist explains that the cyclobenzaprine and zolpidem prescribed are on the American Geriatrics Society BEERS Criteria®, a list of medications that are potentially inappropriate to use in the elderly and therefore should be avoided in most instances.[4] The physician agrees with the pharmacist that the zolpidem warrants caution and gives a verbal order to

change the zolpidem to 5 mg 1 tablet by mouth at bedtime for sleep, with a plan to discontinue in 10 days. While CR's pain is too severe to go without opioid analgesics, the physician agrees with the pharmacist that she does not need both tramadol and oxycodone. Together, they decide to advise CR to use the oxycodone for a short period of time for severe pain and to discontinue tramadol while taking the oxycodone. The pharmacist asks the physician about the cyclobenzaprine, stating concern about the patient continuing it with the opioid and zolpidem because of the risks associated with CR's regimen containing 3 CNS depressants. The physician informs the pharmacist that the patient expressed a strong desire to stay on the cyclobenzaprine. The pharmacist contacts the patient's primary care clinician to discuss the changes in therapy, including a plan to wean her off the cyclobenzaprine and reduce her fall risk.

Commentary. This case presents a very common scenario in community pharmacy in which problems arise for patients in transitions of care from hospital discharge to home. Patients often have questions regarding discharge orders, and community pharmacists often have limited information available except what is written on the discharge prescription orders. Adding to the complexity of the situation is the fact that open lines of communication between pharmacists and physicians can be lacking, with messages often having to be relayed through several intermediaries. There are often multiple clinicians whose input is needed in order to effectively coordinate care, involving many practice settings across the health care system.

The 5 behaviors detailed in the Table were optimally exhibited in this case. Good rapport and trust were exemplified by the physician and pharmacist, and both clinicians placed the patient at the center of care. The physician and pharmacist both expressed empathy for the patient and understood the complexities of navigating the health system. They actively collaborated to promote optimal outcomes for the patient. Once again, recognizing time constraints, the pharmacist succinctly and effectively detailed the problems and provided recommendations for moving forward. Care was improved by both clinicians sharing information about the patient, and a readmission might have been prevented.

In care transitions and common practice situations, collaboration between physicians and pharmacists is paramount to ensuring the best possible care. Transitions of care are among the most vulnerable points for patients, given the complexities of their having multiple clinicians and needing to navigate new, existing, and discontinued medications. There is also need for better mechanisms to collect medication histories[5] and better methods to coordinate care. Pharmacists often find that patients begin taking discharge medications while simultaneously taking medications they had at home prior to discharge.[6,7] Emphasizing behaviors that reinforce empathy for the patient, together with appropriate communication, collaboration, and respect for the roles of all parties involved, is critical for addressing and resolving potential safety problems and optimizing patients' medication regimens.

Conclusion

Effective management of chronic pain often requires a multidisciplinary, multimodal approach. These cases highlight 5 behaviors that can improve care, avoid untoward events, and facilitate collaboration among physicians, pharmacists, and other clinicians: (1) communicating respectfully, openly, without bias, and in a patient-centered manner; (2) establishing rapport and building trusting relationships; (3) embracing and appreciating the roles and responsibilities of other health care professionals; (4)

showing empathy for the patient and other health care professionals and avoiding stigma; and (5) actively engaging in finding solutions and resolving conflict. Incorporating these behaviors into daily practice can foster a coordinated, patient-centered approach to care and optimize patient outcomes.

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MEDICAL EDUCATION

What Clinicians and Health Professions Students Should Learn About How Pharmaceutical Marketing Influences Opioid Prescribing and Patient Outcomes

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Abstract

Marketing drugs and devices to clinicians affects their prescribing behaviors, drives up health care costs, and increases risk of harm to patients. This article canvasses what clinicians and health professions students should know about undue influence of drug and device marketing on their practices. It also considers policy changes that would better protect patients and better situate clinicians to care for patients and communities in ways that are ethical, safe, and effective.

Introduction

This article discusses 4 major impacts of pharmaceutical detailing or lobbying on health care: (a) an increase in opioid prescribing and a rejection of proposed care by insurers, (b) an increase in the cost of care, (c) a discrepancy between disclosure policies and practices, and (d) harms to patients. Changes in policy are imperative to protect patients and lower the cost of care and might include continued enforcement of transparency in disclosure, consideration of new payment models that disincentivize prescription of costlier drugs when other alternatives exist, and the instantiation of independent bodies to review and evaluate evidence of deviations in practice driven by outside influence.

Industry Influence on Prescribing Behavior

There is evidence that industry payments influence prescribing behavior. A study of 2444 Massachusetts physicians found that 36.8% have received industry payments and, among these, the prescription rate of brand-name statin drugs was 22.8% compared with 17.8% among those not receiving payments.[1] Given the increased cost of brand-name drugs compared to generic products, this 5% differential represents many thousands of dollars in payments received. The study furthermore found a 0.1% increase in brand-name statin prescribing for each $1000 in payments received.

The prescription of opioids is similarly driven by drug payments. A 3-year study of more than 860 000 physicians fulfilling Medicare Part D prescriptions found that those who received opioid-specific industry payments prescribed 8784 daily doses of opioids per year more than those not receiving payments.[2] Among those approximately 63 000

physicians who received payments in this study, an additional 50 daily doses of opioid prescribed was attributable to a 1% increase in payment.

Measures to reduce the influence of payments on prescribing practice have been promising. One study examined the effect of detailing policies regulating salesperson gifts and access to physicians on prescribing behavior by comparing the prescribing behavior of approximately 2000 physicians in 19 targeted academic medical centers to that of 25 000 control physicians for a 10-to-36-month period prior to the implementation of a detailing policy and then for 12 to 36 months afterward.[3] Institutional implementation of a formal detailing policy resulted in a relative 8.7% decrease (an absolute decrease from 19.3% to 17.63%) in market share of detailed drugs vs a 5.6% relative increase (an absolute increase from 14.2% to 15.06%) in market share of nondetailed drugs. Across the board, it appears that those medical centers that have implemented the strictest policies with concomitant means of enforcement have had the greatest impact on reducing opioid prescribing.[4]

Industry Drives Increased Costs

DeJong and Dudley addressed the concern that financial interests of drug companies are driving up market prices to the point at which significant financial hardship to patients may occur. They described this trend as a "financial toxicity" that "can weigh on them [patients] as much as any symptom":

> Pharmaceutical companies… interests may conflict with those of patients…. Drug costs are revenue to manufacturers but out-of-pocket expenses to most patients, many of whom are increasingly struggling to afford their care…. Cost-related medication nonadherence … is likely to worsen as the market share of health plans with large deductibles increases.[4]

Chen and Vargas-Bustamante similarly speak of the existence of a fundamental conflict between the cost-effectiveness criteria used by public and private insurers in patient treatment and the financial profit goals valued by both pharmaceutical and medical device companies.[5] Although there has been a large increase in prescriptions of both branded and generic opioids,[6] it is the detailing of branded drugs that has largely driven cost increases.

Guideline Influence and Disclosure Agreement

The Sunshine Act was implemented in 2013 in the United States and requires that all transfers of monetary value to physicians and teaching hospitals in excess of $10 be disclosed by US drug and device manufacturers.[7] The American College of Cardiology (ACC) and the American Heart Association (AHA) have published a set of clear guidelines[8] to help physicians maintain appropriate ethical relationships in the context of their dealings with industry. The guidelines specifically state that, because clinical practice directives affect a large portion of the population, no relevant financial relationships with industry are permissible among committee members writing the guidelines.

One investigation showed that overall agreement regarding disclosures over a 4-year period was poor between pharmaceutical companies and the authors of the ACC and AHA guidelines, with companies failing to match author disclosures at a rate of 71.6% and authors failing to match company disclosures at a rate of 54.7%.[9] However, the study authors conceded it was unclear whether this lack of agreement was due to failure of disclosure or errors in reporting.

Another investigation examined 125 National Comprehensive Cancer Network guideline authors and found that 86% reported at least one significant financial conflict of interest, with 84% of guideline authors receiving general payments averaging slightly in excess of $10 000.[7] Thirty-nine percent of all authors accepted general payments in the absence of research payments.[7] Such research payments—received by 47% of authors and averaging approximately $236 000— although ostensibly serving the function of advancing both science and patient care, are not completely without concern:

> While these [research] payments support investigation and are often paid to the physician's institution, physicians accrue other, indirect benefits by procuring outside research funding. Therefore, research payments as well as general payments have the potential to create conflicts of interest.[7]

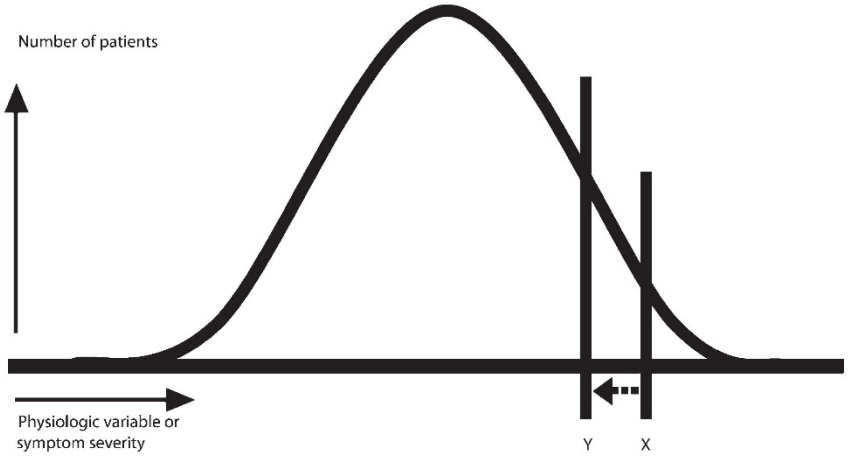
Detailing and Patient Harm

Recent studies have demonstrated an association not only between pharmaceutical marketing and increase in prescriptions, but also between marketing and patient harm. A $2^1/_2$-year survey found that 434 754 payments of nearly $40 million in nonresearch opioid marketing were made to 67 507 US physicians between 2013 and 2015.[10] Opioid overdose mortality was associated with marketing, with the strongest mediating effects of marketing based on the number of physicians receiving payments rather than the dollars per capita spent.[10]

The pharmaceutical industry reportedly spends some $19 billion per year "establishing and maintaining" relationships with physicians, one consequence of which might be the promotion of certain drugs with lower therapeutic potential compared to those that might be more cost-effective.[5] Although some have claimed that randomized controlled trials (RCTs) are necessary to demonstrate harm as a function of physician-industry relationships, Goldberg argues, based on the precautionary principle, that a large amount of uncertainty about the causal relationship between an intervention and its effect does not invalidate justification for public health measures intended to protect patients from harm.[11] Justifying the need for measures designed to protect the public health from damaging agents, Goldberg states: "If the justification for intervening in the name of public health rests on the production of causal evidence via RCTs, the vast majority of public health actions past and present are unjustified."[11]

Traditional evidence-based practice of medicine is predicated upon providing benefit to the highest number of patients while simultaneously maintaining the lowest risk. The benefit-risk ratio is maximized by treating patients with the worst symptoms and highest risk from a disease and thus with the most to gain from a drug or intervention and the least to lose by adverse reactions. Brody and Light examined the inverse benefit law, which states that "the ratio of benefits to harms among patients taking new drugs tends to vary inversely with how extensively the drugs are marketed."[12] Because new drugs are only recommended for a small subpopulation above the evidence-based threshold (the area to the right of the vertical line X in the Figure), the marketing strategies of drug companies attempt to increase the number of people for whom the drug is recommended (the area to the right of the vertical line Y in the Figure). The result of this leftward shift of the vertical line in the Figure is to simultaneously increase a drug's market share and create a larger population at risk of adverse drug reactions to the right of the vertical line by raising the number needed to treat for one patient to benefit from a given drug or intervention.[12]

Figure. Distribution of Disease or Risk Factors Within a Population



Note. X indicates an evidence-based threshold for beginning drug therapy (portion of population eligible to receive a drug indicated by area under the curve to the right of X). Y indicates an industry-marketing-based threshold for beginning drug therapy (portion of population eligible to receive a drug indicated by area under the curve to the right of Y). The "left shift" from X to Y reduces overall drug efficacy by administering the drug to patients at lower risk or with less severe symptoms, thereby raising the number needed to treat, and exposes many more people to the risk of adverse drug reactions.

Source: Brody H, Light D. The inverse benefit law: how drug marketing undermines patient safety and public health. *Am J Public Health*. 2011;101(3):399-404.[12] Reprinted by permission of the American Public Health Association.

Need for Policy Change

There are several interventions that might serve to change physicians' prescribing behaviors and provide an increased margin of safety and cost control for patients at risk. Practices such as full transparency in disclosure of physician-industry relationships, measures aimed to disincentivize prescription of costly brand-name drugs when generic equivalents are equally effective, and the creation of independent bodies to review and adjudicate conflicts of interest would all serve to alleviate some of the difficulties described above. The institution of mandatory-access prescription drug monitoring programs (PDMPs), or electronic database registries using both physician and pharmacy data to track controlled-substance prescriptions, has been found to be significantly negatively associated with receipt of opioid-related payments to physicians.[2] DeJong and Dudley have also suggested the need for separate groups without conflicts of interest to provide product education in an effort to increase transparency.[4]

Other solutions that have been proposed include a Centers for Medicare and Medicaid Services (CMS) "one-stop shop" website with complete clinician-industry relationship information,[13] "coordinated cases" whereby insurers develop formulary lists with reasonable copayments after negotiation with the pharmaceutical industry,[5] an increase in regulations to limit industry advertisement,[5] restriction of guideline writing to groups demonstrably free of industry influence,[12] and setting up clinical trials independently funded and designed with a primary emphasis on safety and efficacy.[12]

Conclusions

Relationships between physicians and industry present a delicate and often difficult dilemma. Supporters argue for the educational value of such relationships to physicians and, for those engaged in research, important funding to carry out studies. The associated effect of these relationships, however, is often problematic. Undue influence

on prescribing behavior with a concomitant increase in costs has been demonstrated. Particular attention needs to be paid to these relationships—particularly in the case of clinical practice guideline committee writing members—due to their wide-ranging downstream effects. There exists a need for stronger, enforceable guidelines and restrictions to prevent the harmful effects on patients that might ultimately result when these relationships are not well defined and limited.

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STATE OF THE ART AND SCIENCE

American College of Preventive Medicine Statement on Prioritizing Prevention in Opioid Research

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Abstract

Research is the foundation of evidence-based health care that motivates innovations in clinical interventions and public health. Prior and current research on opioid use has focused mainly on individual patient-physician relationships, opioid use disorder and treatment, and overdose responses. This article recommends 3 priorities for future research and investigates why, from clinical and ethical standpoints, future research should be directed toward building the capacity and increasing the effectiveness of population-based programs and improving prevention strategies.

Prevention as a Priority

Many factors contribute to deciding which health knowledge gaps are most worth filling, how research topics are selected, and how research funding is allocated. Overall, however, research priorities are products of social, cultural, and community values. Prior and current research on opioid use has focused mainly on individual patient-physician relationships, opioid use disorder and treatment, and overdose responses. We suggest that it is now time to prioritize research focused on building the capacity and increasing the effectiveness of population-based programs that reduce opioid-related harms. We recommend 3 areas of future focus in shifting opioid research toward prevention: (1) understanding the roles of social determinants in opioid misuse, opioid use disorder, and other opioid-related harms (henceforth "opioid misuse"); (2) improving prevention policy and program implementation; and (3) investigating and implementing risk mitigation and harm reduction approaches.

Social Determinants of Opioid Misuse

Inequities in the distribution of societal benefits and resources are intimately tied to nearly all aspects of health—hence the term *social determinants of health*.[1,2] The phrase usually addresses issues related to socioeconomic conditions, education and job opportunities, housing, neighborhood conditions, crime, social norms and attitudes, and race and gender, among others.[3] Research has suggested associations between certain social determinants and the later development of opioid misuse.[4,5] However, the

relationship between social determinants and opioid misuse has been less well studied than the relationship between social determinants and other health issues.

Social determinants likely play a role in whether someone both develops opioid use disorder and enters remission and recovery. The Substance Abuse and Mental Health Services Administration (SAMHSA) identifies 4 dimensions that support recovery: health, home, purpose, and community.[6] Thus, it is a natural progression to pursue research on how social determinants influence risk or protection so as to better predict, identify, and prevent opioid misuse. For example, if we shifted efforts and funding from incarceration towards housing and job training, would outcomes be different? The boundless potential for public good and well-being that might be generated through addressing social determinants need only be explored, and there is an ethical impetus to do so.

We offer 2 ethical arguments for research on the relationship between social determinants and opioid misuse. First, distributive justice and equality of opportunity are highly relevant when discussing social determinants and how they relate to health. Many communities with high rates of opioid misuse are systematically disadvantaged by a maldistribution of resources apart from medical care (eg, housing, nutritious food, safe recreational areas) that can be influenced by social policies and that shape health in powerful ways.[7] As a matter of equity, there is a deep ethical imperative to study such factors in relation to opioids, particularly in these chronically and pervasively disadvantaged populations. Ultimately, justice-based approaches to opioid research aim to ensure a more equitable allocation and dedication of resources to disadvantaged populations to enable individuals to achieve some baseline level of capability, thereby promoting a healthy society.[8]

Second, we consider the likelihood that understanding and addressing the relationship between social determinants and opioid misuse will create beneficial effects across multiple domains of health. Social determinants significantly influence the life trajectories of individuals and populations over a wide variety of health considerations and across multiple domains of well-being.[9] For example, opioid misuse has been linked to the recent epidemic of despair.[10,11,12] The spread of opioid misuse (ie, cross-generationally and within communities) via shared traumas or normalized experiences of opioid use could be interrupted by addressing the shared social determinants in these contexts. Ameliorating one outcome (ie, opioid misuse) of social determinants would achieve positive effects across multiple domains of well-being, thereby offering a more powerful ethical argument to prioritize research endeavors in this area.[13] Establishing an improved understanding of the relationship between social determinants and opioid misuse would further strengthen the case for policymakers and public health officials to implement strategies to address social determinants in communities to improve their overall health and well-being.

Prevention Programs and Policies

Primary, secondary, and tertiary prevention strategies are all critical in addressing the opioid crisis. Primary prevention focuses on preventing the initial development of disease; secondary prevention attempts to identify preclinical disease; and tertiary prevention seeks to reduce the impact of disease.[14] Current efforts are largely focused on tertiary prevention strategies (ie, addiction treatment and prevention of opioid overdose deaths). As an ethical imperative, we argue for increasing research in the areas of primary prevention (ie, preventing opioid misuse and the development of opioid use disorder) and secondary prevention (ie, early identification of opioid use disorder

and reducing preclinical opioid-related harms) and for broadening the research focus in tertiary prevention to include a more comprehensive array of programming. In addition, primary and secondary prevention programs must be expanded beyond school-based programming and reducing opioid prescribing. They must include family strengthening programs, assisted housing opportunities, job training and placement programs, improvements in mental health services, and programs that capitalize on other known risk factors for the development of opioid misuse and opioid use disorder. Reducing rates of adverse childhood events is likely to reduce the incidence of opioid and other substance use disorders[15,16]; yet, if we do not establish these associations or develop interventions, we allow unnecessary incursions of risk throughout populations. During the early years of the opioid crisis, much attention focused on interventions that were known to have short-term impact on opioid-related mortality, such as medications for opioid use disorder and naloxone distribution.[17,18] This work must continue, but it is unreasonable and unethical not to simultaneously address upstream factors to circumvent the unnecessary accumulation of harms.

If we truly wish to combat the opioid crisis, we should consider implementing policies employed internationally to test their effectiveness in US populations (ie, benchmarking foreign policies). Utilizing evidence-based public health tools is both the most effective and the most ethical practice to ensure that we are using scarce resources most appropriately. Policies at local, state, and federal levels also set the tone for how we address opioid misuse and those who suffer from it. Some argue that the state has certain ethical responsibilities to promote the health and well-being of its citizens and to proactively set that tone.[19] Policy is the language through which the state defines its values and conveys its priorities for bettering society. In order for the state to fulfill these responsibilities through policy for opioids, it requires sufficient evidence to support policies that address opioid misuse.

Risk Mitigation and Harm Reduction

Risk mitigation and harm reduction include both secondary and tertiary prevention methodologies. Examples include naloxone distribution programs,[20,21] syringe service programs,[22,23] overdose prevention sites (ie, safe consumption sites),[24,25] and efforts that support safer drug supply (such as drug testing[26,27] or heroin-assisted treatment[28,29]). Several harm reduction strategies have strong evidence in support of their effectiveness for reducing morbidity and mortality related to opioids, while others have not been sufficiently evaluated (in some cases, because implementing such programs is currently illegal in the United States).[30] In addition to directly improving the health of individuals, risk mitigation and harm reduction strategies hold promise for breaking interfamilial, intergenerational, and community patterns of opioid misuse.[31]

Unfortunately, risk mitigation and harm reduction programs and participants in such programs face significant cultural, political, and social stigma. Opposition to these programs stems from the philosophy that punitive measures (eg, criminalization and incarceration) will better control drug use than more supportive medical models used in the management of other chronic conditions. Evidence focused on these modalities might identify more effective harm reduction techniques and shift social norms and beliefs, enabling better alignment of policy with epidemiologic evidence. Incremental gains in these areas could mirror condom distribution during the height of the HIV/AIDS epidemic, which not only reduced HIV transmission but also helped to change many Americans' perceptions about public health interventions regarding sexual health.[32] In addition, some promising practices (eg overdose prevention sites, decriminalization of

drug use, and heroin assisted treatment) remain illegal in the United States but could offer important lifesaving services to many.[30,33]

Several ethical and participatory questions arise from risk mitigation implementation research. In the context of opioid use, public health researchers should continue controverting misguided moralistic views of addiction by addressing opioid use disorder as the chronic condition it is (in contrast to opioid misuse, which could be occasional or sporadic) and strive to implement evidence-based programming to reduce morbidity and mortality. Without public health officials and clinicians engaging with the public to foment a shift in social attitudes from blaming users of opioids to acceptance of opioid misuse as a medical and public health issue, these critical strategies will remain sidelined though they are desperately needed. The perpetuation of harms that otherwise could be avoided by utilizing risk mitigation strategies creates an ethical impetus to engage in social dialogue regarding opioid misuse and its management.

Conclusions

It is clear we must shift our focus regarding opioid research. If we are to better control the opioid epidemic, we must generate a greatly improved evidence basis in 3 critical areas: social determinants; prevention embedded in programs, policies, and strategies; and better utilization of proven risk mitigation and harm reduction strategies. Policymakers, clinicians, and public health officials have an epistemological responsibility—which is an ethical responsibility when health and well-being are at stake—to ensure that decisions affecting the health of populations are well informed. If they choose to implement unproven strategies or ignore more effective strategies because of misguided moralistic views, they are wasting resources and making an unethical choice in a resource-constrained environment. If, however, limited research funds continue to be allocated only to treatment, the evidence for primary and secondary prevention will never be sufficiently developed to drive policy and practice change. Providing policymakers with data-supported legislative strategies, imparting to clinicians the confidence to employ established interventions, and informing public health officials of empirically supported population-based programs and research is an ethical imperative.

In the face of historical mores and pharmaceutical industry trends that favor pharmacological treatment interventions over prevention methodologies, a paradigm shift toward more deliberate and deserved attention to and funding for prevention strategies is desperately needed. Even in recent conferences dedicated to addressing the gaps in opioid research, there has been no mention of any of the research domains raised in this article.[34] A call for prevention-based strategies is not only needed but also ethically justified.

Each of the 3 research domains discussed here are critical to future prevention and control strategies in addressing the opioid epidemic. Greater research focus must be placed not only on public health and prevention efforts broadly, but also on complex societal issues such as opioid misuse.[35,36] This focus stems from the overarching ethical primacy of preventing harms before they arise and the idea that the pursuit of public health promotes equity in multiple dimensions of well-being. By failing to devote more research efforts to prevention-oriented pursuits, we will remain trapped in a reactionary role, struggling to treat new and existing cases rather than preventing them at their onset.

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POLICY FORUM: PEER-REVIEWED ARTICLE

Revisiting the WHO Analgesic Ladder for Surgical Management of Pain

Laura Stone McGuire, MD and Konstantin Slavin, MD

Abstract

The opioid epidemic challenges current attitudes toward pain management and necessitates the reexamination of the World Health Organization (WHO) 3-step analgesic ladder, introduced in 1986 for cancer pain management. Surgical treatment of pain is a logical extension of the original guideline, which is often absent in conversations with patients about treatment options for their pain and consequentially underutilized. However, with concerns growing regarding opioid use, a shift in the stepwise approach of the WHO analgesic ladder in an age of developing technology and surgical offerings could have profound implications for patients and public health. Surgical interventions potentially provide a long-term, cost-effective management strategy to reduce opioid use. This review canvasses surgical options, highlights literature on failed back surgery syndrome and spinal cord stimulation and reconsiders the current ladder approach to pain management.

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Introduction

Presented in 1986, the World Health Organization (WHO) analgesic ladder provided a framework for the stepwise medical management of cancer-related pain.[1] This 3-step ladder begins with nonopioid analgesics with or without nonpharmacological approaches for mild pain, continues with weak opioid medications (eg, codeine) with or without nonopioid analgesics and adjuvants for mild-to-moderate pain, and progresses to strong opioids (eg, oxycodone) with or without nonopioid analgesics and adjuvants for moderate-to-severe pain.[1] The American Pain Society's identification of pain as the "fifth vital sign" in 1995 portended the increased importance of not only adequate treatment of pain in patients but also education of health care professionals.[2,3] Eventually, a modified version of the 3-step ladder placed interventional pain management as a fourth step.[4,5] Development of this algorithmic approach aimed to control refractory or

intractable pain in both an efficient and a safe manner, providing a rational and balanced method to maximize pain relief while minimizing side effects and risks.

However, the opioid epidemic challenges current attitudes toward pain management and necessitates the reexamination of the WHO analgesic ladder. One issue relates to the perceived priority of medical as opposed to surgical intervention for pain relief due to high risk of surgery and low risk of medications. Within the current interpretation of the ladder, it would be inappropriate to bypass a step and to use pain-relieving interventions, such as surgery, without trying opioids first.[4] Although initially designed for cancer-related pain, the analgesic ladder now serves many pain types, including neuropathic pain, which often proves refractory to opioid-based management.[6] Thus, in the experience of the authors, most patients initially presenting to a neurosurgeon for evaluation for possible surgical intervention have been managed with opioid medications for extended periods.

Practical Considerations in Surgical Management of Pain

Surgery for pain differs from many conventional operations, neurosurgical and others, aimed at elimination of the source of pain—such as, for example, appendectomy, spinal decompression, carpal tunnel release, or joint replacement. Instead, it is aimed at the pain-processing (nociceptive) system and includes destructive procedures (open or percutaneous ablations and transections), electrical neuromodulation (via cortical, deep-brain, spinal, and peripheral neurostimulation), and chemical neuromodulation (with implantable drug delivery systems). Neurodestruction interrupts the pain-transmitting pathways by removing a peripheral nerve (neurectomy) or dorsal root ganglion (ganglionectomy), removing a sympathetic ganglion or cutting a nerve chain (sympathectomy), severing spinal or cranial nerve roots (rhizotomy), lesioning spinothalamic tracts or the dorsal root entry zone (DREZ) within the spinal cord (cordotomy, DREZ myelotomy), or severing nerve tracts in the pain-processing centers of the brain (tractotomy, thalamotomy, cingulotomy). Electrical neuromodulation relieves pain either by directly suppressing pain transmission (with a complete but reversible conductance block, as in cases of high-frequency peripheral nerve stimulation) or by activating inhibitory mechanisms (through production of paresthesias or through paresthesia-free paradigms, as in cases of spinal cord stimulation) via electrical stimulation of the peripheral nerves, dorsal root ganglia, dorsal columns of the spinal cord, deep cerebral structures (thalamic nuclei and periaqueductal and periventricular gray matter) or via electrical stimulation of the motor cortex using implantable electrodes that are usually connected to internal pulse generators or externally powered receivers. Chemical neuromodulation is based on continuous delivery of various medications (analgesics, local anesthetics, ion channel blockers, adrenergic agonists, or various combinations thereof) via implanted catheters, pumps, and ports.

Each modality has advantages and disadvantages. Neuromodulation, both chemical and electrical, tends to be reversible, adjustable, testable, and nondestructive. It also provides patients with real or perceived ability to control the treatment using dedicated remote controllers. Benefits might not be immediate, however, and expensive implantable hardware and multiple adjustments are usually required for long-term success.[7] Neurodestruction, on the other hand, tends to bear more risk, as the procedural results are neither reversible nor adjustable. However, the advantages include immediate pain relief and relatively low cost in comparison to neuromodulation techniques, as there is no requirement for expensive implants and no subsequent adjustments. Due to the inherent plasticity of the nervous system, some of the

destructive interventions are associated with a higher rate of pain relapse in the long-term and have been traditionally reserved for patients with shorter life expectancy.[8,9,10]

Each of these interventions has been used for decades. Due to cumulative surgical experience and advances in imaging techniques, the safety of surgery for pain has significantly improved. Percutaneous cordotomy with computed tomography (CT) guidance is safer than the open cordotomy of the 1950s.[10,11,12,13,14] Magnetic resonance imaging (MRI) guidance, together with intraoperative neurophysiological testing, increases accuracy of deep-brain stimulation targeting to a fraction of a millimeter.[15] Advancement from a single-contact electrode to 32-contact electrodes provides countless options for stimulation paradigms in cases of spinal cord stimulation. Thus, the prior argument that risk of surgery outweighed risk of opioid prescription, which previously predominated in the avoidance of surgical intervention for pain, no longer holds completely true, at least for neuromodulation.

Impact of Surgical Management of Pain

Given the scope of the opioid crisis, the potential impact of surgical intervention for pain is far-reaching, extending from patient-level to systems-level outcomes. Of the pain interventions available, perhaps the most studied to date is spinal cord stimulation (SCS), particularly in patients with chronic low-back pain or failed back surgery syndrome (FBSS). The long-term success rate following conventional SCS is as high as 74%,[16] and, in a retrospective study, 69% of the 130 patients with FBSS who were treated and continued with SCS during an average 6-year follow-up reported substantial improvement of symptoms.[17] Additional prospective studies have shown that traditional and 10-kHz SCS also can reduce reliance on opioids for management of pain,[18,19] and systematic reviews and meta-analyses have similarly reported stable or reduced medication use in patients treated with SCS.[20,21,22] For example, a recent meta-analysis of 63 studies found a 58% average level of pain relief at 24 months postoperatively.[23] Importantly, retrospective studies have found patient outcomes following SCS to be time dependent, with earlier intervention linked to better symptom relief.[16,24,25] These findings suggest that the stepwise approach of the analgesic ladder could play a role in delaying referral to neurosurgical evaluation.

From a public health perspective, the use of SCS in the treatment of FBSS is cost effective, as it is one of the conditions most commonly treated with surgical intervention for pain management. FBSS may occur in 5% to 40% of all patients who undergo lumbosacral spine surgery for back pain,[26,27] contributing to the estimated $19.8 billion in indirect costs of back pain.[28] Despite evidence of the clinical efficacy and low complication rates of SCS,[29] SCS remains largely underused: an analysis of 16 455 patients with FBSS found that only 2.4% underwent SCS implantation,[30] and a later study of 122 827 FBSS patients identified 4.3% who underwent SCS.[31] The same study found that SCS implantation results in a short-term increase in costs at 1 year but significantly decreased annual cumulative costs at 9-year follow-up.[31] Furthermore, SCS for patients with FBSS has been shown to be cost-effective for all payers (commercial insurance, Medicare, and Medicaid) beginning at 2 years and extending through 9 years.[32] Additional studies have demonstrated the cost effectiveness of SCS not only in FBSS[30,33] but also in other indicated pathologies, such as chronic back and limb pain, complex regional pain syndrome, peripheral arterial disease, and refractory angina pectoris.[34,35,36] In a value-based health care economy, using interventions to provide the most value and benefit to the patient while incurring the least expense over time is essential.

Ethical Considerations and Paradigm Shift

Despite advances, surgical treatments remain a final step in pain management, typically after all other approaches fail.[37] With concerns growing regarding complications of opioid use in an age of developing technology and surgical offerings, a paradigm shift in pain management away from the WHO analgesic ladder toward earlier surgical intervention could have profound implications for patients and public health. Over time, surgical procedures have become more precise, less invasive, and better understood and recognized by both patients and their physicians. The ethical dilemma of beneficence vs nonmaleficence is not limited to weighing the advantages and risks of surgery alone. The risks of surgery *avoidance* should also be considered, given that medical ("conservative") treatments can cause tolerance, dependence, or clinical side effects, as seen with most analgesic regimens, opioid or otherwise. The possibility of long-term pain relief and associated increase in functionality and improvement in quality of life justifies surgery as an earlier treatment option, perhaps before opioids are introduced.

Paramount to good pain management, however, is a discussion with the patient about operative management of pain as part of a spectrum of available treatments and a multimodal approach to pain control. Establishing an institutional multidisciplinary team, which could include interested primary care practitioners, pain specialists, neurosurgeons, and ethicists, with regular conferences on the comprehensive management plans of patients with pain syndromes could facilitate reliance on a multimodal approach rather than on the standard stepwise ladder. In a broader sense, it would be important to have clinical ethicists provide input on (1) the value and consequences of choosing surgery vs nonsurgical options for pain management, (2) the risk of delay in offering surgery due to concerns about surgical complications vs the risk of initiating or continuing medical treatment, and (3) the value of introducing various alternative management strategies early with the patient's involvement in decision-making process. Ultimately, providing an individualized treatment plan for patients and their pain control is critical,[38] and, in adherence to Beauchamp and Childress' concept of respect for patient autonomy,[39] patients have a right to choose their treatments and should be presented with objective pros and cons of each treatment approach, including surgery for pain, especially when considering the initiation of opioid medications.

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POLICY FORUM

Ethical Imperatives to Overcome Stigma Against People With Substance Use Disorders

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Abstract

Responding to the public health crisis in the United States resulting from untreated opioid use disorder (OUD) requires expanding delivery of effective treatments, including medications, and eliminating stigma against people with OUD and people seeking OUD treatment. Stigma discourages people with substance use disorders from seeking care and compromises the care they receive when they do seek it. Stigma against both medication treatments for OUD and harm-reduction approaches like syringe services programs has created additional barriers to these strategies' acceptance and use. It is ethically incumbent upon everyone in medicine and health care to recognize addiction not as a moral failing but as a treatable disease.

Opioid Use Disorder as a Public Health Crisis

The United States is in the midst of a public health crisis arising from untreated opioid use disorder (OUD) that is currently claiming 130 lives every day.[1] Despite the existence of effective, potentially lifesaving treatment, far too few of the approximately 2 million people in the United States with OUD receive appropriate care.[2] Thus, one of the cornerstones of current federal efforts to reverse the opioid crisis is greatly expanding the delivery of effective treatments, including medications for OUD (MOUD),[3] while at the same time supporting the development of new therapeutics for OUD and overdoses.[4]

A major obstacle to these efforts is overwhelming stigma against people with OUD and other substance use disorders (SUDs).[5] Stigma stymies progress across the entire trajectory of prevention, treatment, and recovery. In caring for people with SUDs, health care professionals can unintentionally contribute to or perpetuate stigma. People with drug or alcohol use disorders—more than 20 million Americans[2]—are far too often judged, mistreated, and untreated by the very people who aim to help them and who, by regarding SUD not as a chronic illness but as a moral weakness, justify withholding care.[6]

Stigma Against People With SUD

Addiction is a medical disorder characterized by profound alterations in brain circuitry subjected to repeated substance exposure.[7] More common in people with genetic,

environmental, or developmental risk factors, these alterations affect reward processing, which is necessary to motivate and prioritize behaviors; executive function, which is necessary for self-regulation; and mood, which is necessary for well-being.[8] Although progress has been made in understanding the root causes of addiction, many health care workers continue to endorse stigmatizing views of people with SUDs.[9]

The stigma of an addiction and the risks of losing a job or child custody can keep people with SUDs from seeking treatment.[5] Without systematic screening, fear of stigma can lead to addiction going unidentified, since people are reluctant to reveal their substance use to their physicians.[10]And since nobody wants to think of themselves as being an "addict"—a label that is implicitly shaming and judging—people whose lives literally depend on treatment might not even acknowledge to themselves or their loved ones that they have a problem.

The obstacles to overcoming stigmatizing attitudes toward people with SUDs are great. People with SUDs might violate social norms in a way that alienates them even from their families and friends. They might lie or steal to support their drug problem[11] and behave violently when undergoing withdrawal[12] or while experiencing a drug-induced psychotic episode.[13] As a result, people with SUDs can be judged harshly. Recognizing these obstacles, addressing stigma is an integral part of the 5-point strategy of the US Department of Health and Human Services (HHS) for addressing the opioid crisis. HHS, with which the authors are affiliated, is addressing stigma at multiple touchpoints—for instance, by encouraging drug courts as an alternative to incarceration and by identifying special challenges and solutions for people living in rural communities.[14]

Stigma Against SUD Treatment

For decades, the addiction treatment system in the United States has been largely separate from the rest of health care, and this reality both stems from and feeds stigma. Although MOUD is now recognized as the gold standard in the treatment of OUD,[15] opioid treatment programs, which have offered methadone to people with OUD for decades, remain the only source of this effective medication.[16] Unfortunately, they are often viewed by communities as potential settings of drug-related crime. The "not-in-my-backyard" problem is an example of stigma that continues to present a challenge not only to opioid treatment programs but also to other facilities trying to serve those with OUD. HSS' current efforts to integrate behavioral health and primary care services are focused on increasing access to SUD treatment, especially in underserved and hard-hit communities.[17]

One way to promote integrated care is by addressing barriers to coordination. Regulations established to protect patient privacy—most notably, the Health Insurance Portability and Accountability Act (HIPAA) and the Code of Federal Regulations provisions for preserving confidentiality of records of patients with substance use disorders (42 CFR Part 2)—have had the unintended consequence of impeding appropriate data integration across care settings, prompting revisions to the latter.[18] The Center of Excellence for Integrated Health Solutions, funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and operated by the National Council for Behavioral Health, is a resource to assist clinicians in accessing the data they need to tailor treatment interventions while preserving patients' privacy.[19]

The approval in 2002 of a partial opioid agonist, buprenorphine, was a major step forward toward greater integration of addiction treatment with the rest of health care by

allowing for the medication treatment of addiction in primary care.[20] Buprenorphine can be prescribed by any waivered physician, physician assistant, or nurse practitioner and is available in an increasing number of misuse-resistant and extended-release formulations (implants, depot injections).[16] Unfortunately, dose and duration limits imposed by insurers sometimes limit patient access.[21] Extended-release naltrexone, an opioid antagonist that prevents opioids from activating receptors in the brain, requires only a once-a-month injection. It also can be prescribed by any qualified clinician, as it has no misuse liability and is not a scheduled substance.[16] Every person with OUD is unique and their care—including choice of medication—should be tailored accordingly.

In 2019, the National Academies of Sciences, Engineering, and Medicine issued a report on MOUD. Its conclusion was powerfully worded, stating that buprenorphine, methadone, and naltrexone save lives and are effective in reducing illicit opioid use, reducing relapse, protecting from overdoses, promoting treatment engagement, reducing criminal involvement, and improving functioning.[16] Moreover, these effects are evident in every subpopulation with OUD.[16] Thus, we must recommit to addressing the barriers to treatment, including stigma and the shortage of clinicians capable of providing MOUD.[16] SAMHSA has taken up this important challenge to train and empower more clinicians to prescribe MOUD.[22] In parallel, the National Institutes of Health (NIH), through the NIH HEAL (Helping to End Addiction Long-term℠) Initiative, is supporting ongoing research to develop models of care and optimal ways to implement them.[4]

Understanding of the critical role of medications in treating OUD has been slow to permeate not only health care but also justice settings. As many as 65% of inmates have a SUD, but evidence-based treatment while incarcerated remains hard to come by.[23] Although there are certainly practical barriers, lack of treatment also stems from the false belief that the use of agonists or partial agonists just substitutes one addiction for another.[24] This misconception persists, despite existing evidence that providing MOUD to incarcerated people with OUD can have a multitude of benefits, including lower risk of overdose upon release.[25,26]

Furthermore, harm reduction measures such as syringe services programs (SSPs), which provide clean needles, HIV testing, and other services to people who inject drugs, have been shown to improve outcomes and do not encourage or increase drug use.[27] For this reason, the Office of the Assistant Secretary for Health, the Office of the Surgeon General, and the Centers for Disease Control and Prevention have publicly supported comprehensive SSPs as a way to prevent the spread of infectious disease and connect people to care.[28]

Alleviating Stigma

Research shows that alleviating stigma related to behavioral health conditions, including SUDs, is challenging.[29] Public education and improving literacy about the medical (rather than the moral) basis of mental illness might lessen the perception of blame and increase care seeking, although it is not clear whether these measures reduce stigmatizing attitudes. The most effective interventions for reducing stigma are those that increase contact between the affected population and the wider population.[29] The more people directly relate to those with mental illness or addiction, the less likely it is that they will moralize, stigmatize, and discriminate against these individuals.

Widespread availability of treatment for SUDs in primary care and other health care settings like emergency departments will help reduce stigma around SUD by countering

the assumption that it is a moral failing. HHS is leading unique initiatives that expand access to quality SUD treatment. States have been granted the flexibility to design demonstrations that improve access to high-quality, clinically appropriate treatment for Medicaid beneficiaries with SUD.[30] Medicare coverage for OUD treatment services furnished by opioid treatment programs has now expanded.[31] Through these advances, HHS is supporting the delivery of treatment and recovery services and thereby stigma reduction.

To increase access to care, we encourage physicians in various specialties, as well as nurse practitioners and physician assistants, to receive training in recognizing addiction and, when appropriate, referring patients to treatment or initiating treatment themselves. This training should qualify health professionals to become waivered prescribers of buprenorphine when possible.

Finally, to reduce stigma, health system policies must also ensure that all personnel preserve the dignity of patients with SUDs, beginning with communication standards that avoid stigmatizing language.[32,33] Procedures should also be instituted to legally and financially protect those seeking and receiving appropriate SUD treatment, such as enforcing parity laws that require insurance companies to cover evidence-based substance use counseling and medications to the same extent that they cover treatments for any other chronic disease.

History repeatedly shows that progress is made in addressing a public health crisis when the condition is brought out of the shadows. It is ethically incumbent upon medical professionals and everyone across the health care system, including insurers, to treat people with SUDs with the same dignity and respect given to any other patient group. Making headway against the current opioid crisis depends on an attitudinal shift away from blame, shame, and stigma and toward respect and compassion.

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POLICY FORUM

Addressing Obstacles to Evidence-Informed Pain Care

AMA Pain Care Task Force

Abstract

Pain is a universal human experience and the most common reason patients seek health care. This article describes barriers to effective, high-quality, evidence-informed pain care. Based on the clinical literature and pain specialists' survey results, the AMA Pain Care Task Force suggests strategies that clinicians can use to offer good pain care to patients. The task force also canvasses key policy-level concerns that situate clinicians in micro- and macro-level complexities related to payers, workforce and training demands, legal and regulatory questions, research, stigma, and patients' beliefs and expectations.

Framing the Issue

The costs of pain-related health care utilization and lost productivity are estimated to be $560 to $635 billion per year in the United States.[1,2] Personal costs to patients with persistent pain are almost incalculable due to their significant impact on patients' emotional, functional, and financial health and social life. Everyone, at some point in their life, looks to their physician for relief from pain. From Hippocrates[3] to the American Medical Association (AMA) *Code of Medical Ethics*,[4] physicians have been charged to care for patients in pain, even if they have an incurable disease. Treatment of pain has been described as a "moral imperative" for the medical and scientific communities.[5]

A mandate in the Patient Protection and Affordable Care Act of 2010, together with widespread recognition that there was a need for better understanding of the science and complexity of pain, led to development of a series of government reports and action plans, including a 2011 report by the Institute of Medicine (IOM; now the National Academy of Medicine), *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, as well as a follow-up action plan in 2016 by the US Department of Health and Human Services (HHS), "The National Pain Strategy" (NPS).[5,6] NPS recommendations called for reducing barriers to all modalities for treating pain and for reducing pain stigma.[6] The action plan also noted that existing chronic pain prevention and treatment knowledge could be used more effectively.[6] In 2019, the HHS Pain Management Best Practices Inter-Agency Task Force report was released.[7] The HHS task force performed a comprehensive and up-to-date review of a wide range of pharmacological and nonpharmacological therapies and, on this basis,

identified gaps in knowledge and made recommendations for research and policy on pain treatment to help create a national approach to pain management.[7]

Experts recommend that policymakers at all levels proceed with caution, balance, and deep understanding of the complexity of pain management in the formulation of effective policy.[8] Many complex and compounding barriers exist that directly and indirectly affect the practice and delivery of pain care. Payer coverage and administrative practices, physician training and education issues, research and evidence utilization, and stigma are among the barriers identified. Additionally, patient expectations concerning pain management, disparities in pain care, and confusion about opioids and opioid-related laws and regulations have created significant barriers to physicians' provision of optimal pain care.

Payer Administrative and Reimbursement Barriers

Administrative practices and payment structures put in place by payers create some of the most significant barriers for physicians seeking to provide pain care. Prior authorization requirements by payers are particularly burdensome for physicians and their staff. In fact, 92% of pain specialists surveyed in 2019 by the American Board of Pain Medicine reported that they were required to submit a prior authorization for nonopioid pain care, which delayed patient treatment, and 66% hired additional staff to process the additional workload.[9] Treatments shown to provide benefit for chronic pain but commonly subject to prior authorization include manual manipulation (ie, occupational or physical therapy), nonopioid prescription pain medications or treatments, and pain creams and patches.[9] Another barrier is "fail first," whereby payers cover the least costly medication or treatment first instead of what was recommended by the patient's clinician. Variation in benefit plans means that pain services and medications are covered for some but not others.[10]

Payer coverage models vary widely and increase the complexity of prescribing treatment and the difficulty of accessing care. For example, there is clear evidence that integrated, multidisciplinary, and multimodal care results in better overall outcomes for chronic pain and is more cost-effective in the long-term than opioid therapy alone.[8,11,12] Nevertheless, coverage of and payment for this type of pain care is inadequate.[8] Benefit plans that don't support multidisciplinary, multimodal, and collaborative care for pain are out of step with many clinical practices, current and emerging evidence, and the needs of patients with complex pain. The AMA endorses the HSS Pain Management Best Practices Inter-Agency Task Force recommendations that payers remove barriers of inadequate coverage and inadequate reimbursement of treatments for chronic pain.[13]

Physician Workforce and Training

According to the IOM Report, in 2011 there were "strong indications that pain receives insufficient attention in virtually all phases of medical education,"[5] and many physicians were still unprepared to provide high-quality pain care.[10] A study published in 2011 showed that almost 80% of US medical schools required courses on pain but that the curriculum was "limited, variable and fragmentary."[14] In 2013, an interprofessional committee developed core competencies for pain, which recognized that pain care goes beyond knowledge of anatomy to integration of knowledge with skills in preventing, assessing, and treating pain, sometimes as part of a multimodal team.[15] Enhancing the pain management curriculum in medical education is increasingly being seen as a priority.[15,16,17]

Enhancing education for practicing physicians about pain and related areas is also increasingly a priority. As of 2018, efforts by the AMA and state and specialty societies have dramatically increased opportunities for health care professionals to complete continuing medical education and to access other resources related to pain care, opioid prescribing, substance use disorders, and other topics on pain management and the nation's opioid epidemic.[18]

Allied health care clinicians such as physician assistants and advanced practice nurses are often involved in a patient's treatment program, and these practitioners play an increasing role in pain care (eg, assessment, prescribing, follow-up). However, these clinicians frequently lack specific training in pain management. There are few formalized training programs on pain for nonphysician clinicians, and many such clinicians only have on-the-job training in pain management.[19]

Research and Utilization of Evidence

Pain is a challenging topic to investigate. Although evidence of effective treatment for pain currently exists, pain cannot always be objectively measured.[20] Additionally, to address the social, emotional, and functional factors involved in pain, researchers need to use different theoretical models, such as the biopsychosocial model, in studying pain assessment and treatment.[6] Furthermore, clinicians need evidence of the safety, cost, usability, and effectiveness of a treatment when developing an individualized care plan.[6] For example, out-of-pocket costs and travel required for treatments may not be feasible for some patients.

Physicians', payers', and policymakers' acceptance of existing evidence on the efficacy of integrative and complementary therapies is essential to providing high-quality care.[6] Therapies such as acupuncture, bodywork, meditation, biofeedback, and guided imagery have been shown to help some chronic pain patients reduce their need for medications and experience significant decreases in pain but are rarely covered by payers.[21] The HHS pain report states: "As novel and proven treatment options emerge to improve acute pain and specific chronic pain conditions, they should be rapidly incorporated,"[7] but this uptake is impossible when payers don't acknowledge the growing evidence base and clinical efficacy of these treatments.[6,22]

Stigma

Patients reporting pain have sometimes been disbelieved, dismissed, or seen as "drug seeking" for wanting to continue opioid analgesic therapy that has provided relief and maintained or improved function.[5] Acknowledgement of the presence and impact of this stigma on patient care for chronic pain is crucial.[23] Patients seeking care should be treated with compassion and dignity without dismissing the need for careful management of opioid therapy.

Stigmatizing of medications used for opioid use disorder has resulted in barriers for pain and opioid management. Co-prescribing naloxone with opioid medication is an accepted and encouraged practice for risk mitigation and can provide lifesaving overdose reversal. However, it is not always in stock in pharmacies[24] and misperceptions about naloxone are common.[25] Pharmacists in one study described being reticent to offer naloxone out of fear they would be viewed as accusing the patient of being a drug "abuser" and out of discomfort with how to discretely dispense it.[26] Prescribing buprenorphine for pain, which does not require a federal waiver, is not commonplace and in some states is prohibited.[27] These restrictions make this useful medication

difficult to appropriately prescribe. For some patients, buprenorphine is an effective option for pain that provides less risk for respiratory depression than full agonist opioids,[28] but insurance companies may not cover it or may approve it only if prescribed for treatment of opioid use disorder.[29] General association of these medications with opioid use disorder is most likely creating stigma-related barriers to their widespread use.

We also must acknowledge health disparities in pain care, as in all aspects of health care, as a form of stigma. Racial and other biases, language differences, gender, economic disparities, and other factors create real barriers to care. Evidence has shown that minorities, those with lower income, and non-native English speakers with chronic pain are less likely than others to receive analgesic medications. Research also shows that African Americans are likely to have their pain intensity underestimated by primary care clinicians, and pharmacies located in minority areas are less likely to carry adequate stocks of analgesic medications.[30,31,32]

Opioid Prescribing and the Centers for Disease Control and Prevention Guidelines

Unfortunately, one effort to decrease opioid-related harms has had the unintended consequence of encouraging rigid limits on opioid prescribing and of some patients' opioids being involuntarily discontinued or reduced inappropriately. In 2016, the Centers for Disease Control and Prevention (CDC) published a Guideline for Prescribing Opioids for Chronic Pain with the intent of providing voluntary prescribing guidelines to primary care physicians.[33] Among the recommendations were limiting opioid prescribing by day and dose thresholds. Even prior to the guideline release, the AMA raised concerns about possible unintended consequences of the CDC recommendations on chronic pain patients who had been effectively managed on long-term opioids that exceeded the voluntary dosage threshold.[34]

Following release of the CDC guideline, states, federal agencies, pharmacies, pharmacy benefit managers, and payers implemented regulations and restrictions on opioid prescribing and dispensing, and the voluntary dosage guidelines soon became rigid limitations in many areas of policy, practice, and regulation.[35] Although the CDC may have intended its guideline to be instructional, voluntary, and mainly applied to primary care practices, patients who have benefited from high-dose opioid therapy have been harmed due to some physicians assuming they must decrease opioid therapy for patients across the board to fit within the guideline's 90 MME daily threshold limit.[33] Unintended consequences, such as limiting access to opioid therapy for cancer, surgery,[35] and hospice patients, have been reported as a result of dispensing and coverage limits put in place by pharmacies and payers after the 2016 CDC guideline was released. Some patients have been forced to suddenly taper to lower doses or discontinue therapy, causing withdrawal and other physical problems.[35,36] While the CDC guideline is commonly seen as one of the factors leading to the nation's 22% decrease in opioid prescribing between 2013 and 2017,[37] there seems to be no indication that patients' access to nonopioid pain care has increased or that pain care outcomes have improved.

In 2019, the CDC acknowledged these concerns and clarified that the intent of the guideline was not to support sudden tapering or "cutting off" opioids for patients who are simply physically dependent on high-dose or long-term opioids when doing so would result in severe withdrawal symptoms or psychological distress.[38] In welcoming the clarification, then AMA President-elect Patrice Harris, MD, stated: "The guidelines have

been treated as hard and fast rules, leaving physicians unable to offer the best care for their patients."[37]

Legal Issues and Opioid Prescribing

Although decisions concerning opioid treatment and any other form of pain therapy should be made between physician and patient, physicians' fear of liability when prescribing opioids for pain has increased.[39] Because many state regulations have set hard limits on dosage and duration of opioid analgesic therapy,[35] some physicians have reported fears of sanction from state medical boards, increased scrutiny from the Drug Enforcement Administration (DEA), or being labeled a "high prescriber" by insurance companies or pharmacies when prescribing either long-term opioid therapy or, in some instances, any opioids for a patient with pain.[39] Being labeled a "high prescriber" is deeply concerning for palliative care and pain specialists, who generally prescribe higher levels of opioids for longer durations. DEA raids and possible criminal charges, being known as a high-prescriber on lists compiled by pharmacy chains, warning notifications from the US Attorney's office, and medical board sanctions are some of the consequences that a physician can encounter.[40] These efforts can successfully target seriously unethical and excessive prescribers, but these prescribers are relatively few in number. A family physician in a small community who supplies most of the community's pain care could be labeled a "high prescriber" and suffer consequences inappropriately. The AMA advocates that physicians should not be subject to professional discipline, loss of board certification or clinical privileges, criminal or civil liability, or other penalties solely for prescribing opioids at a quantitative level above voluntary thresholds when indicated.[40,41]

Patient Expectations

Managing expectations for pain treatment and the resulting pain relief can be challenging for physicians and patients. Paramount for successful treatment is applying a collaborative approach with shared decision making and realistic goal setting. The idea of "acceptable" pain in some chronic pain situations has also been shown to be a realistic alternative to the idea of complete pain extinction.[42] The focus can be on maximizing the safety and effectiveness of treatment as well as on progress on functional goals and quality-of-life improvements.[43]

Conclusion

The IOM report on pain asserts that cultural transformation is necessary to better prevent, assess, and treat pain of all types.[5] The barriers described are significant and, when compounded, make patient care complex and difficult. Acknowledgment of systemic barriers in the delivery of evidence-informed pain care in the United States is needed, and actions to remove those barriers is urged. Payer coverage, reimbursement, and administrative practices that interfere with accessing a variety of effective treatment options need to be removed. Expanding their knowledge and skills in addressing pain should continue to be a high priority for physicians. Pain assessment and treatment that applies the best available evidence and accepted standards of care should be individualized and physician driven. Dismantling pain-related stigma is essential. When indicated, physicians should prescribe opioids safely and in the best interests of patients. Policymakers must work with the medical community to remove arbitrary prescribing limits that have caused uncertainty and fear for patients and physicians. Until barriers to effective pain care are removed, the transformation necessary to provide effective and evidence-informed pain care will not be realized.

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AMA Pain Care Task Force (PCTF) was convened in 2018 and is made up of representatives from 20 federation member associations. This broad-based group of clinicians and experts is working collaboratively to improve pain care for patients by identifying actionable opportunities to improve medical education related to pain care, highlighting barriers to providing evidence-based pain care, and offering principles of pain care for physicians, payers, and policymakers. Dr S. Bobby Mukkamala is the current chair-elect of the AMA Board of Trustees as well as the chair of the PCTF.

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POLICY FORUM

Advocacy and Action to End the Opioid Epidemic by the AMA Opioid Task Force

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Abstract

Members of the AMA Opioid Task Force include the American Medical Association, the American Osteopathic Association, 25 specialty and state medical societies, and the American Dental Association. In 2015, the task force issued 6 recommendations focused on specific actions to help reverse the nation's opioid epidemic. Clinicians have demonstrated progress in each of these areas, and, while much work remains, making good policy will be key to motivating continued progress. Recommendations adopted in 2019 focus on tangible actions policymakers can take to help end the epidemic. This article offers an overview of task force recommendations.

Professional Responsibility in Opioid Epidemic Responses

The American Medical Association (AMA) Opioid Task Force convened in 2014 to coordinate organized medicine's response to the growing national epidemic of opioid-related overdose deaths and to amplify effective solutions and best practices. Members of the task force include the American Medical Association, the American Osteopathic Association, 25 specialty and state medical societies, and the American Dental Association.[1]

The task force first recognized that to reverse this epidemic in the United States, clinicians must take tangible steps that have a measurable impact on improving patients' access to evidence-based care and reducing opioid-related harm. These steps include emphasizing the need for judicious prescribing when clinically appropriate; integrating prescription drug monitoring programs (PDMPs) to track controlled substance prescriptions statewide and provide timely information about prescribing and patient behaviors; making appropriate referrals and promoting access to care for patients with substance use disorders; and other steps needed to reduce opioid-related harm. The task force issued 6 recommendations focused on the following specific actions that physicians can take:[1]

1. Register for and use state PDMPs;
2. Make sure to have "education and training on effective, evidence-based treatment" for substance use disorder and pain;

3. "Support … comprehensive care for patients in pain and those with substance use disorder";
4. Reduce stigma by providing comprehensive care to patients with pain and patients with substance use disorder, who deserve compassion, not judgment;
5. "Expand access to naloxone in the community and through co-prescribing"; and
6. Encourage "safe storage and disposal of opioids and all medications."

Recommendations' Influence

Since issuing these recommendations, the AMA has released 3 annual reports on actions clinicians have taken.[2,3,4] The most recent AMA Opioid Task Force progress report found that clinicians are taking action,[4] and some reports suggest that prescription opioid-related mortality might be leveling off.[5] Yet, the number of deaths from heroin and illicitly manufactured fentanyl and fentanyl analogs are at historic levels.[6,7,8] Key findings include the following:

- *Decrease in opioid prescribing*. Opioid prescriptions decreased 33% between 2013 and 2018, including a 12.4% decrease between 2017 and 2018.[9]
- *Increase in PDMP use*. Clinicians utilized state PDMPs more than 460 million times in 2018—an increase of 167 million queries from 2017 and 390 million queries from 2014.[10]
- *Increase in education resource use*. Health care professionals completed continuing education (CE) courses and accessed and reviewed education and training resources—including those devoted to opioid prescribing, pain management, opioid use and substance use disorder treatment, and related topics—more than 700 000 times in 2018, which represents an increase of 150 000 from 2017, according to an AMA survey and responses from 51 state and specialty society representatives (unpublished data, 2019). Additionally, the AMA Ed Hub™ hosts a content page devoted exclusively to opioids and pain management, which has a comprehensive list of CE activities sorted by topic.[11]
- *Increase in number of physicians certified to treat opioid use disorder*. More than 85 000 physicians and a growing number of nurse practitioners and physician assistants are now certified to treat patients in-office with buprenorphine. This is an increase of more than 28 000 from 2016.[12] Because of advocacy by the AMA and state and specialty societies, more than 15 states have supported legislation to remove prior authorization for medications to treat opioid use disorder.[13]
- *Increase in naloxone coprescribing*. Nearly 600 000 naloxone prescriptions were dispensed in 2018. This is a more than fourfold increase from 136 000 dispensed in 2016.[9]

Although clinicians must follow the 6 Task Force recommendations in order for these positive trends to continue, continuation of these trends alone will not end the opioid epidemic in the United States. With more people dying each year, government and organizational policy is needed to protect patients' access to evidence-based care for pain and opioid use disorder.

Policy Innovations Needed

In 2019, new task force recommendations were issued that call on policymakers and all relevant stakeholders to eliminate barriers to evidence-based treatment by taking the following steps[14]:

1. Remove prior authorization, step therapy (ie, fail-first processes requiring patients to try one or more medications specified by the insurance company, typically generic or lower-cost medicines), and "other inappropriate administrative burdens or barriers" that deny care or delay access to medications for addiction treatment for opioid use disorder approved by the US Food and Drug Administration.
2. "Support assessment, referral and treatment for co-occurring mental health disorders as well as enforce state and federal laws that require insurance parity for mental health and substance use disorders."
3. "Remove administrative and other barriers to comprehensive, multimodal, multidisciplinary pain care and rehabilitation programs."
4. "Support maternal and child health by increasing access to evidence-based treatment, preserving families and ensuring that policies are nonpunitive."
5. Support civil and criminal justice system reforms "that help ensure access to high quality, evidence-based care for opioid use disorder," including medications for addiction treatment.

In response to these recommendations, all 50 states and the District of Columbia have adopted policies to increase access to naloxone.[15] A few states, such as Pennsylvania and Colorado, have also stepped up enforcement of mental health and substance use disorder parity requirements.[15] At the federal level, Medicare has established new monthly payments for office-based opioid use disorder treatment and weekly payments for opioid treatment programs.[16] A federal task force has also recommended sweeping changes to improve pain management policies and practices.[17]

Next Steps

Clinical- and policy-level improvements have been critical to saving lives, but more must be done to end the overdose epidemic in the United States. All barriers to and delays in receiving treatment must be eliminated. Payers, pharmacy benefit managers, and pharmacy chains must revise policies and practices that restrict patients' access to opioid therapy or evidence-based care for pain or substance use disorders. Clinicians must continue to demonstrate leadership to make critical progress in eliminating overdose deaths. The AMA Opioid Task Force recommendations and a recent national roadmap report published by the AMA and Manatt Health[15] are in alignment regarding policies and practices that can motivate desperately needed improvements to patient and community health outcomes.

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POLICY FORUM

How Structural Violence, Prohibition, and Stigma Have Paralyzed North American Responses to Opioid Overdose

Mark Tyndall, MD, ScD and Zoë Dodd, MES

Abstract

As of 2020, North America is now into the fifth year of an unprecedented increase in drug overdose deaths driven by a toxic, unpredictable, and unregulated drug supply. While the genesis and drivers of and response to the opioid overdose crisis have wide regional variations, structural violence, prohibitions against illicit drug use, and stigma consistently play a central role. The criminalization of users of illicit drugs has led directly not only to users' incarceration, but also to their marginalization and isolation and to violence, entrenched poverty, and a vicious cycle of trauma. This policy has created an environment wherein any initiatives to prevent and reverse overdoses have been severely restricted. While a war on drugs and the people who use them has been widely criticized as destructive and unwinnable, the criminal policies that support the war on drugs have not changed even in response to this unprecedented crisis.

Context of the Opioid Overdose Epidemic

The opioid overdose epidemic claimed more than 134 000 lives in the United States and more than 12 000 lives in Canada between 2016 and 2018.[1,2] In the United States, overdose deaths contribute more to reduction in life expectancy than chronic lower respiratory diseases, Alzheimer's, or flu, and, in British Columbia, Canada, overdose deaths contribute to a decrease in life expectancy among those of lower socioeconomic status.[3,4] Although much of the media focus has been on prescription opioids, the majority of overdoses result from illicit drugs containing synthetic opioids with unpredictable potency.[5] People buying these drugs run the constant risk of using toxic drugs and overdosing. The primary narrative that has emerged in the media and that dominates the public discourse has been to target those most affected,[6] including the people who use drugs, the communities that have been hardest hit by the crisis, and, more recently, the pharmaceutical companies that manufacture prescription opioids.[7] However, the criminal policies that support the war on drugs have not changed even in response to this unprecedented crisis. The criminalization of users of illicit drugs has led directly not only to users' incarceration, but also to their marginalization and isolation and to violence, entrenched poverty, and a vicious cycle of trauma.

Response Paralysis

At all levels, and by any measure, the response to such a massive and ongoing loss of life has been inadequate, as it has focused on prescribing and its downstream effects. Nearly all 50 states have prescription drug monitoring programs (ie, databases that track controlled substance prescriptions) that provide health or law enforcement authorities with access to clinical data on prescribing patterns.[8] The Centers for Disease Control and Prevention has focused specifically on monitoring trends, enhancing data collection, partnering with health systems to treat addiction and with community organizations and first responders to prevent overdoses, and increasing public awareness about opioid use risk.[9] In British Columbia, Canada, a public health emergency was declared in April 2016 that resulted in expanding treatment options, scaling up naloxone programs, and opening up new safe injection sites across the province.[10] Although these initiatives have saved lives, there has been little movement on drug policy reform or on dealing with the contaminated illicit drug supply.[11]

The failure to act more decisively can only be explained by the entrenched discrimination and stigma against people who use drugs. In fact, laws, such as the harsh criminal penalties associated with drug possession and sales,[12,13] along with cultural norms and institutional polices, "encode" stigma, thereby reducing public support for policies to rectify the opioid overdose crisis.[14] Criminalization puts the responsibility and blame for opioid use firmly on the individuals at risk. Basically, the underlying assumption is that if people are willing to use drugs that are prohibited and toxic, then it is their own fault. Making something illegal means that policymakers can deny people the most basic harm-reduction interventions or treatment options without fear of backlash.

In general, harm-reduction strategies remain controversial throughout North America despite overwhelming evidence that these interventions are pragmatic, effective, and necessary. Needle and syringe exchanges to reduce the transmission of HIV and other blood borne infections, methadone and other opioid substitution therapies to reduce illicit drug use, and supervised injection sites to connect people with services and eliminate overdoses[15,16] are all evidence-based interventions. Yet, in response to the opioid overdose crisis, many jurisdictions have blocked community-led harm-reduction interventions and pursued even stricter enforcement measures.[17] The ongoing battle to open a supervised injection site in Philadelphia is a case in point.[18]

In any other epidemic, such as an infectious outbreak, we would not even consider criminal enforcement as a response. Saving lives would be the priority. Our first response should be to provide a nontoxic, regulated alternative.[19] In the case of the illegal opioid market, it is clear that removing the toxic product is just not possible, which should leave no alternative but to provide safer options in the form of a regulated opioid program. In Vancouver, 2 studies demonstrated that providing a safer injectable opioid in the form of heroin[20] or hydromorphone[21] was feasible and effective. Scaling up the Vancouver program has proved to be difficult, however, despite evidence of its efficacy.[22] Programs with lower barriers to participation that use low-cost hydromorphone pills are currently being piloted in Canada.[22]

Structural Violence

The barriers to reducing opioid-related harms are a manifestation of structural violence. The term *structural violence* was first introduced by Johan Galtung, a Norwegian sociologist who was a leader in peace and conflict studies. He defined structural

violence as "violence [that] is built into the structure and [that] shows up as unequal power and consequently as unequal life chances" and as "predicated on social injustice."[23] Paul Farmer used structural violence to help explain the HIV epidemic in Haiti.

"Structural violence" is one way of describing social arrangements that put individuals and populations in harm's way. The arrangements are structural because they are embedded in the political and economic organization of our social world; they are violent because they cause injury to people.[24]

In the opioid overdose crisis, it is not just the drugs that are causing harm but the social arrangements (ie, criminalization of drug use, isolation, and homelessness) that have created such a dangerous environment for people. It is notable that these structures are largely arbitrary, ideological, and unchallenged.

Much of the structural violence experienced by drug users is built upon and perpetuated by prohibition and law enforcement. The basic tenet of enforcement is based on a belief that punishing people for drug use will be a deterrent to further use and serve as an example to people who might consider using drugs in the future. This approach has clearly been ineffective, as illicit drug use continues to rise, the illegal market becomes more unpredictable, and more people end up in the criminal justice system for drug-related offences.[25,26] The increase in opioid overdose deaths is a tragic but predictable outcome of this failed strategy.

Ethical Responses

At the core of the response to the current opioid overdose crisis is the unspoken discrimination against and willful neglect of many of society's most vulnerable people. The opioid overdose crisis has exposed the tragic reality of how little we can do when the dominant response to illicit drug use is based on prohibition and criminal enforcement rather than on a broader sociomedical approach.

We don't often think of personal drug use as a human rights issue, but, arguably, it is one. In 2016, Human Rights Watch and the American Civil Liberties Union released a report on the criminalization of drug use in the United States, the summary of which concluded that "enforcement of drug possession laws causes extensive and unjustifiable harm to individuals and communities across the country."[27] The people impacted by the criminalization of drug use are poorly organized and often hidden, as drug use is illegal and highly stigmatized. People using drugs face numerous barriers with regard to employment, housing, food security, and health care, while spending much of their time in the criminal justice system.[28] Despite these barriers, drug user groups can be a critical force for change, and there are good examples of how people using drugs have changed drug policy. The Supreme Court of Canada's decision to keep open InSite, North America's first legally sanctioned supervised injection site, was largely due to the advocacy of drug users in Vancouver.[29]

If personal drug use is a human right, then addressing drug use and addiction will require a much broader approach. The best interventions proposed and practiced in the medical community will always be limited within the confines of a system in which drugs are illegal and the people using them must turn to sources that are entirely unregulated and often toxic. An ethical response to the opioid overdose crisis must include providing a strong social support system, breaking down stigma and discrimination, improving

access to addiction treatment, and promoting harm- reduction interventions. Physicians and physician groups can play a major role in all of these areas by including social support in their treatment plans, actively breaking down stigma by treating patients with respect, offering evidence-based addiction treatment, and promoting harm reduction. These interventions could greatly improve health care outcomes and reduce opioid overdose deaths. In addition, physicians should be at the forefront of challenging drug laws and a criminal justice system that inflicts so much harm on patients and their families. If we do not recognize and address the drivers of drug use, challenge destructive drug policies, and tear down the pillars of structural violence, we will not see real change.

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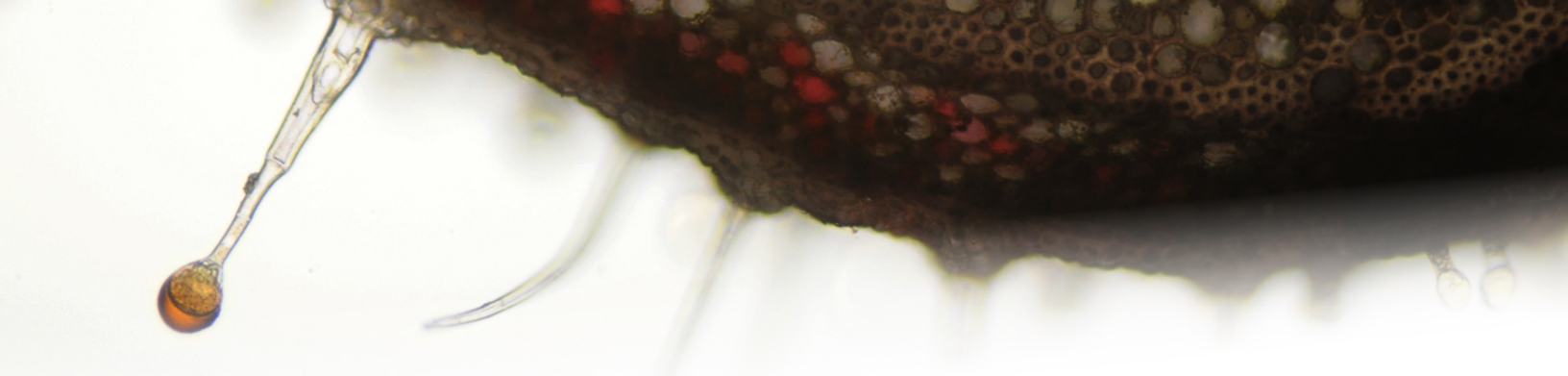

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HISTORY OF MEDICINE

Opioids' Long Shadow

Marcia Meldrum, PhD

Abstract

2020 is not the only time the world has seen opioids ruining the lives of thousands. This article discusses 3 historical episodes in which the need to relieve pain was challenged by the need to prevent and control opioid addiction: the era of iatrogenic addiction in the early 20th century before and after the passage of the Harrison Act of 1914; the shift in attitudes toward and treatment of pain from the 1950s to the 1970s; and the current opioid epidemic, fueled by opioid overprescription and overuse, from the late 1990s to the present. These episodes illustrate the tensions between pain relief and risk reduction and between clinical practice guidelines and modern corporate health care, as well as the stigmatization of chronic illness in American culture and society.

A Catastrophic Toll

The opioid epidemic of the 2000s has destroyed the lives of many Americans and their families. The National Institute on Drug Abuse (NIDA) estimated that 128 overdose deaths occurred each day in 2018.[1] The Centers for Disease Control and Prevention (CDC) reported an increase in suspected opioid overdoses in the United States of 30% overall and 70% in the Midwest from July 2016 through September 2017.[2] NIDA traces these tragic events to the misleading message spread by manufacturers of opioids in the late 1990s, ie, that patients suffering from severe or chronic pain would not become addicted to prescription opioids.[1] This message proved to be false for many; patients became dependent on the prescription drugs and moved on to cheaper and readily available illicit drugs, including heroin and fentanyl.[1] A subset of physicians, some motivated by a desire to help chronic pain patients, others by financial gain, exacerbated the problem by overprescribing; many of those who received opioid prescriptions then diverted some or all of their prescribed supply. The results have been catastrophic: in 2018 alone, 47 600 people died from opioid overdoses and an estimated 2 million were regularly abusing opioids[3]; the problem is still growing.[4] Yet a systematic review reports that fewer than 30% of patients for whom opioid analgesics are prescribed misuse them and that only 8% to 12% "develop an opioid use disorder."[1]

Despite addiction risks, opioids remain the most inexpensive and available therapy for chronic pain. The CDC estimates that, in 2016, 20% of US adults (50 million) suffered from chronic pain, and 8% of US adults (19.6 million) had high-impact chronic pain, with

higher prevalence of both among women, older adults, and adults living in poverty, among other groups.[5] Chronic pain is an epidemic that not only destroys lives but also costs the United States "an estimated $560 billion each year in direct medical costs, lost productivity, and disability programs."[5] The suffering caused by chronic pain helps explain why, even as numbers of opioid overdoses and deaths continued to rise, opioid prescriptions per capita increased 7.3% from 2007 to 2012.[6]

Each one of those prescriptions represented a clinical and ethical choice, perhaps often a difficult one for physicians and patients, who must weigh the risks of drug dependence and its potential effects on health and productivity against the costs of pain in suffering, loss of mobility, functioning, and quality of life. But the dilemma is not a new one. This article considers some historical, cultural, and social factors that have shaped opioid use to treat pain in the United States.

Morphinism and Its Influence on Medicine

The use of morphine for pain became increasingly common in late 19th-century America, where it was readily available without prescription, and often led to *morphinism*, or addiction, in habitual users. As the 19th-century physician, George Wood, wrote: a general practitioner "[i]n his own therapeutic observation … witnesses frequent disturbances of the functions from its [opium's] medicinal employment."[7] While physicians valued morphine as an analgesic in their practices, they were often criticized and accused of quackery by colleagues, patients, and observers for encouraging its use and thus fostering addiction.[8] Eugene O'Neill vividly dramatized this attitude in *Long Day's Journey Into Night* (set in 1912), when the son of a woman addicted to morphine shouts furiously at his father, "If you'd spent money for a decent doctor when she was so sick after I was born, she'd never have known morphine existed! Instead you put her in the hands of a hotel quack who wouldn't admit his ignorance and took the easiest way out."[9] Medical apprehension over morphinism became more acute after heroin, initially introduced as a safe alternative for pain treatment, quickly became a street drug and was recognized as more highly addictive.[10,11] An alarming *New York Times* report on heroin and morphine addiction in 1913 stated pointedly that "twenty-three percent of the medical profession … were now victims of the morphine habit" and recommended prohibition of the drugs: "The loss to medicine, whatever it might be … would be worthwhile in view of the possible benefits."[12]

Legal Roots of Stigma in the Harrison Act

The Harrison Act of 1914 prohibited the sale of opioids without a registered physician's signed prescription; its passage was not initially opposed by the American Medical Association,[13] perhaps in part because physicians hoped it would relieve them from being charged with causing iatrogenic addiction. The act specifically exempted physicians' use of morphine when "personally attend[ing]" a patient and appeared to leave physicians unfettered to maintain or treat users of opioids.[14] However, the Treasury Department charged with the law's enforcement determined that maintaining chronic opioid use was not legitimate medical practice. In the 1920s, Treasury agents prosecuted physicians and closed city and state clinics that attempted to treat those who were addicted.[13] The Supreme Court backed the Treasury Department's position in a series of decisions, ruling, for example, in *Webb et al v United States* (1919) that "to call such an order for the use of morphine [for maintenance] a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required."[15]

Need for Pain Relief: Behavioral or Medical Disorder?

Lawrence Kolb's studies of the 1920s portrayed most opioid addicts as psychologically and morally deficient,[16] which supported the legislative and judicial precedents that users of opioids should not be considered patients with a medical disorder.[17] The medical literature of the following half-century suggests that many physicians excluded those who were addicted from their practices and reserved opioid prescriptions for the comfort of patients with terminal illnesses or for the short-term relief of patients experiencing postinjury or postoperative pain. These informal but well-understood guidelines that developed in practice—days of life remaining, dosage amounts, and intervals—sought to navigate the clinically and ethically precarious terrain between the relief of suffering and the avoidance of addiction.[18] For example, as surgeon Warren Cole wrote in 1956:

> We must appreciate that severe constant pain will destroy the morale of the sturdiest individual. On many occasions the terminal phase progresses so rapidly that there is not enough time, between onset of the severe pain and death, for addiction to become very important.... But since it is ... impossible to predict duration of life with cancer, we are often loathe to give liberal amounts of narcotics because the drug addiction itself may become a hideous spectacle.[19]

Nurse Ada Jacox described, in 1977, how the prescription decisions played out on hospital wards and stigmatized patients asking nurses for pain relief:

> They show this concern [about addiction] by withholding medication because it is still 'one-half to three-fourths of an hour early' before the four-hour interval between dosages expires.... Instead of evaluating the effectiveness of the current dosage and frequency, the battle goes on repeatedly with the patient complaining of pain two or three hours before the medication is given and the nurse insisting that the patient must wait. The patient becomes more irritable and anxious as his pain increases; meanwhile, the nurse becomes impatient and begins to believe that the patient ... is addicted to his medication. The drama is absurd.[20]

Attitudes toward opioid pain relief underwent a culturally complex change in the late 1960s as a result of increases in drug use and addiction among middle-class users of opioids and Vietnam veterans, coupled with the availability of a new opioid addiction treatment, methadone maintenance. These developments gradually led to the recognition of addiction as a medical disorder, although moral stigma still attached to users with low incomes and to people of color.[17]

The Pain Field and Advocates of Opioid Therapy

In the 1970s, the formation of the pain management field focused attention on the undertreatment of chronic pain and on respect for a patient's self-report: "Pain is what the patient says it is."[21] Pain management advocates, such as John Bonica, championed multidisciplinary pain clinics, which offered modalities such as cognitive behavioral therapy and physical therapy. But such programs were expensive, time intensive, often not covered by insurance, and considered by many to place an unfair burden on patients to adjust their lifestyles.[22,23] In the 1980s, cancer pain specialists, such as Russell Portenoy and Kathleen Foley, supported long-term opioid therapy—first for cancer pain and then for severe chronic pain patients—coupled with "the intensive involvement" of the physician, as the more ethical choice to enable the patient to regain meaningful quality of life. Portenoy and Foley suggested that opioid use need not lead to addiction and stigma for pain patients;[24,25] not all pain management specialists agreed.[26]

Genesis and Spread of the Epidemic

In the late 1990s, some pharmaceutical manufacturers converted this ethical choice into a marketing strategy. They separated chronic opioid therapy from medical "intensive involvement" and aggressively encouraged opioid prescription for those with moderate pain, as well as for chronic pain patients who overused the drugs and became addicted.[17] Although CDC and pain society guidelines attempted to remap the clinically and ethically precarious terrain of opioid prescription, incorporating their recommendations into actual practice often involved time-consuming procedures that were difficult to integrate into corporate health care practices.[27] As the epidemic grew, Drug Enforcement Administration regulation and state monitoring of opioid prescriptions burgeoned in response.[28] While regulatory sanctioning was enhanced, social stigma was tempered by compassion, as many people struggled to help family members and friends who were overusing and at risk for death by overdose.[4] The practice decisions today of physicians treating a patient with pain or a patient at risk for opioid use disorder have been framed by a century of history.

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ART OF MEDICINE

What Artists and Museum Educators Can Teach Us About Combatting the Opioid Epidemic

Emily Alesandrini, MA

Abstract

Art world superstar Jean-Michel Basquiat painted the electrically vibrant, sketchy skull, *Untitled*, before dying of a heroin overdose at age 27. The painting's imagery and its creator's substance use struggles call to mind the victims of the current opioid epidemic. Large donations from the Sackler family, patrons of numerous museums and arts institutions, have prompted questions about art world affiliation and accountability. Largely in response to protests staged by activists such as artist Nan Goldin, numerous museums have renounced Sackler funding. What more can arts organizations consider doing amidst the crisis? The Currier Museum of Art in New Hampshire offers community support and suggests a framework for museums' roles in healing.

Memento Mori

Jean-Michel Basquiat's *Untitled* (1982) depicts an electrically vibrant, sketchy, and disfigured skull with a gaping mouth, bared teeth, and eyes bulging amid layers of frenetic marks against a toxic blue background. Now in the collection of Yusaku Maezawa, the large work in acrylic, spray paint, and oil stick on canvas measures $72\frac{1}{8}$ x $68\frac{1}{8}$ inches.[1] The skull's face, demonstrative of rage or despair, is both visually abrasive and perversely stimulating in its display of color and emotion. Arguably, the work serves as a *memento mori*—a painted reminder of mortality and the transience of human life. In the history of Western painting, *memento mori* appear in the forms of expiring hourglasses, overripe fruit, or extinguished candles. The skull is the most frequently used symbol in this genre.[2]

Almost serving as a *memento mori* himself, Basquiat died of a heroin overdose in 1988 at the age of 27.[3] When viewed today through the lens of addiction, the artist's work *Untitled* takes on new meaning. Against a backdrop of declining life expectancy and growing numbers of deaths by opioid overdose, *Untitled* resonates powerfully and poignantly with contemporary social realities of the opioid crisis.

Protesting Opioid-Based Arts Funding

Sackler family companies continue to profit from selling opioids, such as oxycodone, and opioid addiction treatments, such as naloxone.[4] International arts patronage from the

Sackler family has prompted questions about financial accountability within arts institutions throughout the United States and abroad. Artist Nan Goldin is a recovered opioid use disorder patient who founded the Prescription Addiction Intervention Now Sackler organization (PAIN Sackler) to raise awareness about Sackler influence on the arts and to demand that public institutions both remove Sackler insignia from their premises and refuse future Sackler funding.[5] PAIN Sackler and other advocacy groups call upon the Sackler family to devote their $13 billion fortune (as of 2016)[6] to rehabilitating patients.

In March 2018, demonstrators led by PAIN Sackler members gathered near the famed Egyptian Temple of Dendur in the Sackler Wing at the Metropolitan Museum of Art in New York City, throwing prescription pill bottles into the reflecting pool and unfurling banners that read "Fund rehab."[7] In February 2019, PAIN Sackler activists protested at the Solomon R. Guggenheim Museum in New York City, staging a performed "die-in" with fake prescription slips raining through the rotunda.[8] In response to these efforts and increased media attention, the National Portrait Gallery in London, the Tate Modern in London, and the Metropolitan and Guggenheim in New York City all publicly renounced Sackler funding in 2019.[9]

Goldin is not alone in utilizing her creative practice and platform as a means of protest. Sculptor Domenic Esposito has repeatedly and surreptitiously placed a 10-ft, 800-lb metal sculpture of a bent heroin spoon outside Sackler companies headquartered in Connecticut and Rhode Island, the Massachusetts State House, and the Department of Health and Human Services in Washington, DC.[10] For the last 12 years, artist Jeffrey Stockbridge photographed those whom he calls "abandoned people" of the opioid crisis in Philadelphia. Exploring the city's poorest neighborhoods, Stockbridge's documentary-style photography highlights the humanity and vulnerability of his subjects.[11]

The Art of Hope

Arts institutions are joining artists and those affected by the crisis in this public engagement. In Manchester, New Hampshire, the state with the highest number of fentanyl deaths per capita in the United States in 2018,[12] the Currier Museum of Art has founded The Art of Hope program as a resource for those affected by substance use disorders. Museum educators use artworks in the institution's collection for art projects and discussions about self-care, shame, and strategies for resilience and recovery. Lynn Thomson, the museum's manager of family and community engagement, explained how the program began with a focus on responding to the question: What is Manchester dealing with now, and what does the community need?[12] In the Currier program, participants are invited to reflect on paintings that depict, for example, a shipwreck in a storm, which can help catalyze conversations about addiction and the role of social support in recovery.

What else can arts organizations be doing to support families and communities affected by addiction? Expanding the Currier program to other institutions and incorporating addiction treatment information, art therapy, and other sources of support into public programming could be a start. Artworks like Basquiat's *Untitled* can help catalyze conversations about the pain, loss, and healing of those affected by substance use disorders. Perhaps the *memento mori*, in addition to reminding viewers of life's fragility, can also galvanize health care and arts organizations' clinical and policy-level initiatives to save lives.

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ART OF MEDICINE

Breath Is Life

Kajal Patel

Abstract
This painting memorializes the lives of people who died in the COVID-19 pandemic and people who have died from police brutality.

Figure. *Power of Breath*

Media
Acrylic on canvas.

As a child, I used to pick dandelions that had transitioned from flower to seed, close my eyes tight, and blow on them to disperse them and to make a wish. Little did I know then that one breath of dispersed dandelion seeds was toxic to plants in the rest of the garden. The novel coronavirus humbles us, taking our breath away in more ways than one; dandelions in this painting are represented as transforming into white seeds flowing through a space in which they transform into novel coronavirus, SARS-CoV-2, proteins settling in shades of teal.

In a pandemic year further toxified by the murder of George Floyd at the hands of Minneapolis police officers, we recall his last words: "I can't breathe."[1] May his last breath, and the last breaths of all whose lives have been lost in the first half of 2020, be memorialized.

Words are made of breath. We can use our breath to spread weeds or flowers; we can choose to spread kindness, hope, and compassion.

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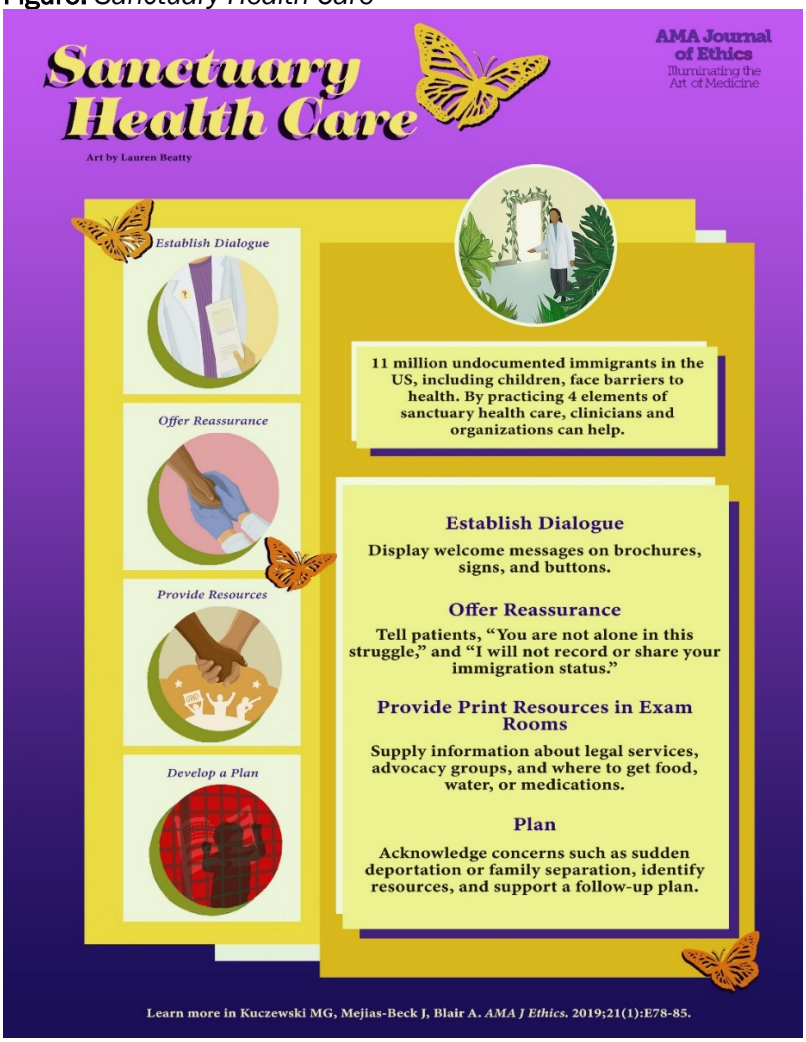
ART OF MEDICINE

Sanctuary Health Care

Lauren Beatty

Abstract
Eleven million undocumented immigrants in the United States, including children, face barriers to health. By practicing 4 elements of sanctuary health care, clinicians and organizations can help.

Figure. *Sanctuary Health Care*



Lauren Beatty is a summer intern at the American Medical Association in Chicago, Illinois, and a student at the School of the Art Institute of Chicago.

Editor's Note

This visual is freely available to all online and as a PDF for digital and print circulation in any clinical or teaching setting.

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VIEWPOINT

How FDA Failures Contributed to the Opioid Crisis

Andrew Kolodny, MD

Abstract

Over the past 25 years, pharmaceutical companies deceptively promoted opioid use in ways that were often neither safe nor effective, contributing to unprecedented increases in prescribing, opioid use disorder, and deaths by overdose. This article explores regulatory mistakes made by the US Food and Drug Administration (FDA) in approving and labeling new analgesics. By understanding and correcting these mistakes, future public health crises caused by improper pharmaceutical marketing might be prevented.

Introduction

In the United States, opioid use disorder (OUD) and opioid overdose were once rare. But over the past 25 years, the number of Americans suffering from OUD increased exponentially and in parallel with an unprecedented increase in opioid prescribing.[1] Today, OUD is common, especially in patients with chronic pain treated with opioid analgesics,[1] and opioid overdose is the leading cause of accidental death.[2]

The high prevalence of OUD has led to an array of health and social problems. The United States has seen record high rates of neonatal opioid withdrawal syndrome, more children entering foster care,[3] rising heroin and fentanyl use,[4] outbreaks of injection-related infectious diseases,[5] and a decline in workforce participation in areas with relatively high rates of opioid prescribing.[6] The Centers for Disease Control and Prevention (CDC) has aptly described the crisis as the "worst drug overdose epidemic in [US] history."[1]

Using the term *epidemic* to describe the sharp increase in OUD and overdose deaths is appropriate. But we should recognize that, unlike communicable disease outbreaks, the opioid crisis was not caused by a pathogen. As a federal judge presiding over hundreds of county and state cases against opioid manufacturers and distributors recently found: "It is accurate to describe the opioid epidemic as a man-made plague, 20 years in the making."[7]

Much of the responsibility for the opioid crisis rests with the pharmaceutical industry's promotion of aggressive opioid prescribing. Indeed, in a first-of-its-kind trial against opioid manufacturers, a state court in Oklahoma last year found that the "exponentially

increasing rates of addiction," "overdose deaths," and babies born exposed to opioids were caused by "false, misleading, and dangerous marketing campaigns" for opioid medications.[8] But the fact that opioid manufacturers disseminated false claims regarding the risks and benefits of opioids for the past 25 years points to a dereliction of duty by the US Food and Drug Administration (FDA)—the federal agency charged with regulating pharmaceutical companies.

Regulatory Failures

The FDA's regulatory failures with respect to opioids have not gone unnoticed. In 2017, the President's Commission on Combatting Drug Addiction and the Opioid Crisis found that the opioid crisis was caused in part by "inadequate oversight by the Food and Drug Administration," and the National Academy of Sciences (NAS) publicly called on the FDA to overhaul its opioid policies.[9,10] Last year, a former FDA Commissioner rebuked the agency he had previously led, saying on the television program *60 Minutes* that the FDA was wrong to allow promotion of opioid use for chronic pain.[11]

Despite this mounting criticism, FDA policies for approving and labeling opioids remain largely unchanged. The FDA has not undertaken a root cause analysis of its regulatory errors that contributed to this public health catastrophe, let alone instituted any major reforms.[11] To the contrary, the agency has adopted a defensive posture and sought to shift blame. For example, in response to a critical letter from Senator Maggie Hassan of New Hampshire, the FDA's top official at the Center for Drug Evaluation and Research since 1994 offered a blanket defense of the FDA's handling of opioids, claiming that the agency has properly enforced the Food, Drug, and Cosmetic Act.[12]

This article does not attempt to provide a full accounting of the FDA's role in the opioid crisis. Nor is such an accounting possible without full participation of the FDA and its official oversight bodies. Rather, this article focuses on just a few policy failures that contributed to the opioid crisis. Until these past mistakes are understood and corrected, the United States will remain vulnerable to health crises caused by inadequate regulation of pharmaceutical companies. In the following discussion, I detail FDA failures to regulate false marketing claims by opioid manufacturers and to require adequate and well-controlled clinical trials for opioids and its poor management of conflicts of interest between FDA staff and industry. Understanding how and why the FDA allowed improper marketing of opioids can help us better address the current crisis and improve regulation of pharmaceutical companies in the future.

Failure to Properly Enforce Marketing Regulations

The Food, Drug, and Cosmetic Act requires drug manufacturers to demonstrate that their products are both safe and effective before they are marketed.[13] The benefits of a drug must outweigh potential risks for specific indications listed on an FDA-approved label.[13] Although prescribing medication for unapproved uses is common and sometimes appropriate, drug makers are prohibited from promoting off-label uses without premarket review by the FDA.[13]

The FDA did not properly enforce the Food, Drug, and Cosmetic Act when it approved Purdue Pharma's new drug application for extended-release (ER) oxycodone in 1995. Had it done so, ER oxycodone's label would have had a narrow indication for the specific conditions for which the benefits of ER oxycodone outweigh the risks, such as relief from severe pain from a life-limiting illness. Instead, the label on ER oxycodone featured a

broad indication,[14] allowing Purdue to promote the drug's use for common conditions for which opioids are more likely to harm than help, such as low-back pain and fibromyalgia.

As Purdue earned billions of dollars from sales of oxycodone, other drug companies took note.[15] They introduced their own opioids and joined Purdue in funding a brilliant, multifaceted campaign that changed the culture of opioid prescribing in the United States. Clinicians who previously understood that opioids are addictive, that development of tolerance results in dose escalation, and that dependence would make discontinuation difficult began hearing from spokesmen for opioid manufacturers that addiction was rare and that long-term use was safe and effective.[1,6,7,8,9,10,11,12,13,15] Risks were minimized, benefits were exaggerated, and opioid prescribing surged.

In 2002, faced with evidence that opioid prescribing had risen beyond levels that could be clinically warranted, the FDA convened an advisory committee meeting of 10 outside experts and asked if the broad indication on opioid labels should be narrowed to prohibit marketing for common chronic pain conditions.[16] Eight of these experts had financial ties to pharmaceutical companies, including Purdue,[16] and advised the FDA against narrowing the indication.[17] An opportunity to reign in overprescribing early in the crisis was lost, and, by 2013, enough opioids were prescribed to provide every adult in the country with a full pill bottle.[18]

Failure to Obtain Evidence of Long-term Safety and Effectiveness

Marketing opioids as safe for long-term use is at odds with a growing body of medical literature, dating from the 1950s,[19] which demonstrates serious dose-dependent risks, including addiction, respiratory depression, neuroendocrine dysfunction, and other medical problems.[20] Even in safety trials for opioid drugs approved by the FDA, serious adverse events—including respiratory depression, death, and drug diversion—are common.[21,22] And, despite evidence that as many as 41% of patients on long-term opioids meet the *Diagnostic and Statistical Manual of Mental Disorders* fifth edition (*DSM-5*) criteria for OUD,[23] drug companies are not required to assess clinical trial subjects for development of OUD at the conclusion of a study.

The Food, Drug, and Cosmetic Act requires "adequate and well-controlled studies" before products can be approved and promoted as safe and effective.[13] The FDA generally requires at least 2 randomized controlled trials demonstrating clear efficacy for a proposed indication.[24] Yet it approved extended release oxycodone based on only one adequate and well-controlled study, a 2-week clinical trial in osteoarthritis patients.[25]

FDA failure to obtain adequate evidence of effectiveness was not limited to oxycodone. Over the past 25 years, despite mounting evidence that a surge in opioid consumption was resulting in adverse public health consequences, the FDA continued to approve new opioid formulations for chronic pain based on efficacy trials utilizing a controversial methodology called enriched enrollment randomized withdrawal (EERW).[26] Since its 2006 approval of oxymorphone, the FDA has relied on EERW as evidence of opioid efficacy for chronic pain.[27] EERW trials differ from traditional double-blind, randomized, controlled studies. In an EERW trial, prior to randomization for a double-blind phase, all subjects are made physiologically dependent on the opioid in a 4- to 6-week open-label phase. Then only the patients who tolerated the opioid and found it helpful during the open-label phase are randomized to remain on the opioid or switch to a placebo.

Critics of EERW have correctly described this methodology as "cooking the books" for 2 reasons.[28] First, because only patients who tolerated the opioid and found it helpful are allowed to proceed to randomization, the study is not representative of the general population, and the results cannot be generalized to clinical practice. Second, because daily use of opioids causes physiological dependence, efficacy results are skewed in favor of the subjects who remain on the opioid. This is because opioid-dependent subjects who are switched to placebo experience opioid withdrawal symptoms, including increased sensitivity to pain. Moreover, switching opioid-dependent subjects to placebo renders the study not truly double-blind.

The FDA's decision to rely on EERW trial methodology is a consequence of the agency's close ties to industry. In fact, the FDA's decision to use EERW for analgesics was based on discussions at private meetings between FDA officials and pharmaceutical company executives hosted by an organization called Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).[29] Drug companies paid up to $35 000 each for the opportunity to attend IMMPACT meetings and interact with FDA staff.[29] Yet, despite the uproar that followed public disclosure of the IMMPACT meetings, the FDA continues to rely on EERW trials as evidence that opioids are effective for chronic pain.[26]

Failure to Manage Conflicts of Interest

The FDA has never been held to account for its improper handling of the opioid crisis. But the FDA's conduct is all the more troubling in light of the close relationship between the agency officials responsible for opioid oversight and opioid manufacturers. For example, the 2 principal FDA reviewers who originally approved Purdue's oxycodone application both took positions at Purdue after leaving the agency.[11] Over the past 20 years, several other FDA staff involved in opioid approvals also left the FDA to work for opioid makers. Last January, the head of the FDA's analgesic division retired from the FDA to start her own consulting business, which promises drug makers "help" to "successfully and efficiently bring your products to market" with "more than 30 years of experience at the FDA."[30] To be clear, the revolving door between the FDA and the pharmaceutical industry is not limited to opioids. A 2018 study found that 11 of 16 FDA medical reviewers involved in approving 28 products now work for the companies whose products they regulated.[31] Without appropriate limits on employment after leaving the FDA, staff might be tempted to put the interests of future employers, whose favor they wish to gain, ahead of public health.

Oversight Recommendations

While fewer clinicians are initiating long-term opioids, overprescribing is still a problem. According to a recently published report, more than 2.9 million people initiated opioid use in December 2017.[32] The FDA's continued approval of new opioids exacerbates this problem. Each time a branded opioid hits the market, the company, eager for return on its investment, is given an incentive and, in essence, a license to promote aggressive prescribing. The FDA's continued approval of new opioids pits the financial interests of drug companies against city, state, and federal efforts to discourage initiation of long-term opioids.

To finally end the opioid crisis, the FDA must enforce the Food, Drug, and Cosmetic Act, and it must act on recommendations from the NAS for an overhaul of its opioid approval and removal policies. The broad indication on opioid labels must be narrowed, and an explicit warning against long-term use and high-dose prescribing should be added. The label should reinforce, rather than contradict, guidance from the CDC, the Department

of Veterans Affairs, the Agency for Healthcare Research and Quality, and other public health agencies that are calling for more cautious prescribing.[18,33,34]

Oversight bodies within the Executive Branch and Congress should conduct a long-overdue examination of the FDA's role in the opioid crisis. Past mistakes must be corrected, and preventative measures, such as rules to stop the revolving door, must be put in place to ensure that public health is consistently prioritized ahead of industry interests. Understanding why our regulatory systems failed to prevent a man-made epidemic is a critical step toward abating the opioid crisis and preventing future public health catastrophes.

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Dr Kolodny has served, and continues to serve, as an expert witness on behalf of states and counties in litigation against opioid manufacturers and distributors. He is also the executive director of Physicians for Responsible Opioid Prescribing.

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