

REVIEW ARTICLE

Ethical Considerations in Prescribing or Withholding Opioids for Chronic Pain

Katie E. Smeltzer, MS, OMS IV, Gautam J Desai, DO, FACOFP, & Britt Johnson, MA, PhD, JD

Kansas City University of Medicine and Biosciences College of Osteopathic Medicine

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Abstract: Pain is among the most common reasons that patients seek help from their physicians in the United States: it is estimated that chronic pain results in up to \$635 billion per year in health care costs and lost productivity.

The management of chronic pain is complex and can be problematic for many clinicians, as pain is a subjective complaint. It may present out of proportion to the severity of a patient's injury, or it can present without any objective findings at all. Based on past experiences, some clinicians may be overly restrictive in their prescribing of opioids, which may prevent some patients with legitimate pain from receiving appropriate therapy.

As the number of people suffering from chronic pain has risen over the past few decades, so has the number of opioid prescriptions, and this has not come without consequences. Opioid dependence and addiction has increased, and poor opioid prescribing practices and opioid diversion has resulted in the non-medical use of pain relievers by an estimated 25 million people from 2002-2011.

Despite the prevalence of patients that suffer from chronic pain, very few physicians are formally trained in pain management. A reasonable ethical approach for all physicians is to seek guidance from the 4 basic bioethical principles – beneficence, non-maleficence, justice and autonomy – in order to identify the ethical challenges of employing opioids in the management of chronic pain.

INTRODUCTION

Pain is among the most common reasons that patients seek help from their physicians in the United States, which is not surprising considering that approximately 25 million Americans suffer from acute pain.¹ An additional 100 million individuals in the United States suffer from chronic pain, and it is estimated that chronic pain results in up to \$635 billion per year in health care costs and lost productivity.²

The management of chronic pain is complex and can be problematic for many clinicians. Pain, especially in a chronic setting, is a subjective complaint. It may present out of proportion to the severity of a patient's injury, or it can present without any objective findings at all. Because of this, a physician must rely solely on the patient's narrative to assess pain and its impact on the patient's ability to have a meaningful and productive life. Based on past experiences, some clinicians may be overly restrictive in their prescribing of opioids, which may prevent some patients with legitimate pain from receiving appropriate therapy. For many reasons, physicians may

be hesitant to prescribe medications with potential for misuse or because of fear of side effects or not having received proper education.³

When initial measures of pain management, such as non-steroidal anti-inflammatory agents or calcium channel ligands like gabapentin, fail, many physicians turn to opioid analgesics to provide pain relief for their patients. Consequently, as the number of people suffering from chronic pain has risen over the past few decades, so has the number of opioid prescriptions. In 2013, over 240 million prescriptions for opioid analgesics were dispensed in the United States.⁴ This has not come without consequences. The number of medical emergencies related to legally prescribed opioids increased 183% between 2004 – 2011, and there were almost 17,000 deaths due to prescription opioid overdose in 2010.⁵ Opioid dependence and substance use disorders have increased, and poor opioid prescribing practices and diversion have resulted in the nonmedical use of pain relievers by an estimated 25 million people from 2002-2011.

Despite the prevalence of patients that suffer from chronic pain, very few physicians are formally trained in pain management. A reasonable ethical approach for all physicians is to seek guidance from the 4 basic bioethical principles – beneficence, non-maleficence, justice and autonomy – in order to identify the ethical challenges of employing opioids in the management of chronic pain.

CORRESPONDENCE:

Gautam J. Desai, DO, FACOFP | gdesai@kcumb.edu

ETHICAL CONSIDERATIONS

Beneficence

The principle of beneficence states that a physician should seek to help patients by implementing clinical therapies that benefit the health of the patient. Physicians are committed to helping patients, and pain relief is no exception. The effects of opioids are well known to physicians. These medications provide analgesia by binding to mu opioid receptors in parts of the brain that regulate pain perception.⁶ Opioid analgesics are capable of providing the immediate relief of pain, which has an obvious benefit in an acute setting. However, data is lacking for the effectiveness of long-term opioid therapy in treating chronic pain. While there is a growing body of evidence that opioids are effective in improving pain and allowing patients to return to a meaningful, productive life,¹ there have been no well-designed studies published of treatment regimens lasting longer than 16 weeks.⁷

- A physician may be inclined to provide opioid prescriptions to a patient after careful, thorough, and proper evaluation of the benefits such medication may provide the patient. Non-pharmacological therapies which have been proven to be safe and effective in the management of chronic pain, such as osteopathic manipulative treatment (OMT), acupuncture, physical therapy, etc, should be considered as options as well.
- If a physician has not received training, or feels unqualified to personally prescribe opioids for patients, he or she should help the patient by referring the patient to specialist for management of the chronic pain.

Non-maleficence

The principle of non-maleficence requires that physicians do not intentionally cause harm to their patients, and most physicians will recognize this principle in the familiar maxim *primum non nocere*: "Above all, do no harm."⁸ This principle is of particular concern to physicians considering the use of opioids for chronic pain, due to the risks and dangers of prescription opioid medications.

The same mu receptors that are responsible for the analgesic effects of opioids are also responsible for their addictive properties and dangerous side effects. Physicians must balance treating a patient's pain, avoiding substance use disorder, and addressing tolerance to the medication. While developing a substance use disorder is a possibility when using opioid drugs, tolerance and physical dependence are inevitable. Physicians should understand that a patient who has become tolerant to their current opioid dose might demonstrate behaviors indistinguishable from drug-seeking behaviors of those with substance use disorders. Physicians must carefully screen for substance use disorder, and ensure that patients in legitimate need of increases or modifications of their opioid therapy are not being undertreated.

- As part of avoiding patient harm, physicians must be sure to avoid causing dangerous side effects through judicious evaluation of the patient, as well as consideration of other medications and therapies, which may help the patient with less risk than opioid therapy. The prescriber should consider indications for the use of opioids, and not freely prescribe for all types of patient pain.

- In August 2016, as a response to the nation's prescription opioid crisis, for the first time, the United States Surgeon General sent a direct mailing to over 2 million clinicians in the United States asking for their help in addressing this issue. The mailing included a pocket card, which contains guidelines from the Centers for Disease Control and Prevention for prescribing opioids (*Figure 1, page 28*).
- The best way to treat substance use disorder is to prevent it in the first place.

Justice

The principle of justice requires that like patients be treated alike. This requires physicians provide similar care, regardless of physical location (of doctor or patient) or personal bias. Previous studies suggest that patients who access pharmacies in minority areas are more likely to find that the pharmacy does not carry a sufficient supply of opioids for the treatment of their pain, in contrast to pharmacies in primarily Caucasian neighborhoods. This creates a medication desert, where patients with legitimate pain are unable to obtain relief due to reasons beyond their control. Physicians should work with the patient to make sure the patient is able to access their medications, and if the patient is having difficulty, the clinician should attempt to assist the patient to find out which pharmacy will have the medications.^{9,10}

Physicians should be aware of their own potential for bias in the treatment of their patients. Black patients have been shown in the past to be less likely to receive opioids than white patients, after controlling for other factors. By keeping in mind the osteopathic philosophy of treating each patient as a whole, and taking the time to properly assess each patient's unique situation, physicians may be able to mitigate this bias.¹¹

Autonomy

The principle of autonomy illustrates the right of patients to make educated decisions in regards to their own healthcare.¹¹ This has become a prevalent aspect of medical ethics, as the relationship between doctor and patient has shifted to a combined decision-making model.¹³ However, the physician and patient may have differences in opinion for the patient's treatment plan. Consider the scenario of a new patient who has been taking opioids for years for chronic, nonmalignant low back pain. The physician may advise the patient that the physician does not prescribe opioids for chronic nonmalignant pain. The patient perspective may be that the patient's previous prescriber gave the patient an effective therapy, and they wish to stay on that rather than try another modality. Without clear communication of treatment goals, expectations, and a willingness to be open, neither party may leave the encounter happy. Both sides may have conflict and difficulty in coming to an agreement on the best treatment.

CONSIDERATIONS FOR THE OSTEOPATHIC PHYSICIAN

Although the 4 basic principles of bioethics serve as a framework for identifying the ethical issues regarding the use of prescription opioids in chronic pain, there is no universal method for decision-making when conflicts among these principles arise.¹⁴ Osteopathic physicians might then turn to the principles and philosophy of

FIGURE 1:

TURN THE TIDE

PRESCRIBING OPIOIDS FOR CHRONIC PAIN

ADAPTED FROM CDC GUIDELINE
Opioids can provide short-term benefits for moderate to severe pain. Scientific evidence is lacking for the benefits to treat chronic pain.

IN GENERAL, DO NOT PRESCRIBE OPIOIDS AS THE FIRST-LINE TREATMENT FOR CHRONIC PAIN (for adults 18+ with chronic pain > 3 months excluding active cancer, palliative, or end-of-life care).

BEFORE PRESCRIBING

1 ASSESS PAIN & FUNCTION
Use a validated pain scale. Example: PEG scale where the score = average 3 individual question scores (30% improvement from baseline is clinically meaningful).
Q1: What number from 0 – 10 best describes your PAIN in the past week? (0 = "no pain", 10 = "worst you can imagine")
Q2: What number from 0 – 10 describes how, during the past week, pain has interfered with your ENJOYMENT OF LIFE? (0 = "not at all", 10 = "complete interference")
Q3: What number from 0 – 10 describes how, during the past week, pain has interfered with your GENERAL ACTIVITY? (0 = "not at all", 10 = "complete interference")

2 CONSIDER IF NON-OPIOID THERAPIES ARE APPROPRIATE
Such as: NSAIDs, TCAs, SNRIs, anti-convulsants, exercise or physical therapy, cognitive behavioral therapy.

3 TALK TO PATIENTS ABOUT TREATMENT PLAN

- Set realistic goals for pain and function based on diagnosis.
- Discuss benefits, side effects, and risks (e.g., addiction, overdose).
- Set criteria for stopping or continuing opioid. Set criteria for regular progress assessment.
- Check patient understanding about treatment plan.

4 EVALUATE RISK OF HARM OR MISUSE. CHECK:

- Know risk factors: illegal drug use; prescription drug use for nonmedical reasons; history of substance use disorder or overdose; mental health conditions; sleep-disordered breathing.
- Urine drug screen to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.
- Medication interactions. AVOID CONCURRENT OPIOID AND BENZODIAZEPINE USE WHENEVER POSSIBLE.
- Prescription drug monitoring program data (if available) for opioids or benzodiazepines from other sources.

WHEN YOU PRESCRIBE

START LOW AND GO SLOW. IN GENERAL:

- Start with immediate-release (IR) opioids at the lowest dose for the shortest therapeutic duration. IR opioids are recommended over ER/LA products when starting opioids.
- If prescribing ≥ 50 MME/day, increase follow-up frequency, consider offering naloxone for overdose risk.
- Avoid ≥ 90 MME/day, consider specialist to support management of higher doses.
- For acute pain: prescribe < 3 day supply; more than 7 days will rarely be required.
- Counsel patients about safe storage and disposal of unused opioids.

See below for MME comparisons. For MME conversion factors and calculator, go to TurnTheTideRx.org/treatment.

<p>50 MORPHINE MILLIGRAM EQUIVALENTS (MME)/DAY:</p> <ul style="list-style-type: none"> • 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300) • 33 mg of oxycodone (~2 tablets of oxycodone sustained-release 15mg) 	<p>90 MORPHINE MILLIGRAM EQUIVALENTS (MME)/DAY:</p> <ul style="list-style-type: none"> • 90 mg of hydrocodone (18 tablets of hydrocodone/acetaminophen 5/300) • 60 mg of oxycodone (4 tablets of oxycodone sustained-release 15mg)
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AFTER INITIATION OF OPIOID THERAPY

ASSESS, TAILOR & TAPER

- Reassess benefits/risks within 1-4 weeks after initial assessment.
- Assess pain and function and compare results to baseline. Schedule reassessment at regular intervals (≤ 3 months).
- Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.
- If over-sedation or overdose risk, then taper. Example taper plan: 10% decrease in original dose per week or month. Consider psychosocial support.
- Tailor taper rates individually to patients and monitor for withdrawal symptoms.

TREATING OVERDOSE & ADDICTION

- Screen for opioid use disorder (e.g., difficulty controlling use; see DSM-5 criteria). If yes, treat with medication-assisted treatment (MAT). MAT combines behavioral therapy with medications like methadone, buprenorphine, and naltrexone. Refer to findtreatment.samhsa.gov. Additional resources at TurnTheTideRx.org/treatment and www.hhs.gov/opioids.
- Learn about medication-assisted treatment (MAT) and apply to be a MAT provider at www.samhsa.gov/medication-assisted-treatment.
- Consider offering naloxone if high risk for overdose: history of overdose or substance use disorder, higher opioid dosage (≥ 50 MME/day), concurrent benzodiazepine use.

ADDITIONAL RESOURCES

CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN: www.cdc.gov/drugoverdose/prescribing/guideline.html

SAMHSA POCKET GUIDE FOR MEDICATION-ASSISTED TREATMENT (MAT): store.samhsa.gov/MATGuide

NIDAMED: www.drugabuse.gov/nidamed-medical-health-professionals

ENROLL IN MEDICARE: go.cms.gov/peccs
Most prescribers will be required to enroll or validly opt out of Medicare for their prescriptions for Medicare patients to be covered. Delay may prevent patient access to medications.

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osteopathy to guide them in making decisions related to prescribing opioids for chronic pain, especially the two principles listed below:

- Emphasis on prevention
- Treating the patient as a whole

Some patients seek out osteopathic family physicians due to their past experiences with DO's who provided care for the whole family, as well as performed OMT. Past studies have demonstrated that OMT is efficacious in the treatment of pain and improving functional status.^{15,16}

Prevention of future problems is also an ideal way to avoid the need for narcotics. Patients should be encouraged to maintain healthy lifestyles, with attention to a balanced diet and regular physical activity, starting at a young age.

Studies have shown that depression and pain are intricately linked, with patients suffering from depression experiencing less pain reduction in treatment studies compared to patients without depression.¹⁷ Patients being assessed for pain should be asked about signs and symptoms of mood disorders, both of which are crucial in the biopsychosocial model of pain, as well as any stressors in the workplace or at home. Physicians should learn how pain affects each aspect of the patient's life such as the patient's work, finances, relationships, and spiritual practices, and strive to set realistic goals for improvements in pain and its adverse effects.

For those patients who do have chronic pain, consideration should be given to non-pharmaceutical modalities, such as OMT, acupuncture, physical therapy, and other modalities – either discretely, or in conjunction with medications. Osteopathic physicians should work with patients, and the patients' families, to set clear goals and expectations. Together, physician and patient should create a pain contract that includes not only the expectations the physician has of the patient regarding medication use and participation in non-pharmaceutical treatment options, but also the patient's expectations of the physician's commitment to managing the patient's pain. Both parties should sign and keep a copy of this contract, which clearly states these expectations.

CONCLUSION

All physicians have a moral obligation to assist patients in need – patients suffering from chronic pain included. While the care and associated policy restraints differ for a patient suffering from sickle cell anemia pain when compared to a patient needing an emergency appendectomy, both patients have medical needs to be addressed. It is the job of the physician to work with the patient in order to understand the symptoms and underlying causes. Just as with any illness, a physician must educate the patient regarding the condition and the available intervention options, while carefully weighing the risks and benefits of all those options. Together, the patient and the provider create a treatment plan.

Chronic pain responds best to a multidisciplinary approach. Fortunately, osteopathic physicians are uniquely qualified to address chronic pain for their patients. Prevention of pain, thorough assessment of a patient's physical, social, and mental health, knowledge and use of OMT (in addition to other adjunctive therapies),

and the focus on treating the whole patient are all core elements of practicing medicine as an osteopathic physician. These skills and approaches will be beneficial to both physician and patient when facing issues of chronic pain.

Further, if opioids are in fact needed, the medication can effectively be used while respecting the obligations of both parties to prevent misuse and diversion of opiates.

REFERENCES:

1. Rasor J, Harris G. Using Opioids for Patients with Moderate to Severe Pain. *The Journal of the American Osteopathic Association*. September 2007;107 (9): E54-E510.
2. Debono DJ, Hoeksema L, Hobbs R. Caring for Patients With Chronic Pain: Pearls and Pitfalls. *The Journal of the American Osteopathic Association*. August 2013;113 (8): 620-627.
3. Jamison RN, Sheehan KA, Scanlan E, Matthews M, Ross EL. Beliefs and Attitudes about Opioid Prescribing and Chronic Pain Management: Survey of Primary Care Providers. *Journal of Opioid Management*. Nov-Dec 2014;10 (6): 375-82.
4. Dart RC, Surratt, Cicero T, et al. Trends in Opioid Analgesic Abuse and Mortality in the United States. *The New England Journal of Medicine*. January 2015;372 (3):241-248.
5. Dart RC, Surratt, Cicero T, et al. Trends in Opioid Analgesic Abuse and Mortality in the United States. *The New England Journal of Medicine*. January 2015;372 (3): 241-248.
6. Volkow ND, McLellan T. Opioid Abuse in Chronic Pain - Misconceptions and Mitigation Strategies. *The New England Journal of Medicine*. March 2016;374 (13): 1253-1263.
7. Cohen MJ, Jangro WC. A Clinical Ethics Approach to Opioid Treatment of Chronic Noncancer Pain. *AMA Journal of Ethics*. June 2015;17 (6): 521-529.
8. Beauchamp TL, Walters L, eds. *Contemporary Issues in Bioethics*. Fifth ed. Belmont: Wadsworth Publishing Company.
9. Green CR, Ndao-Brumblay SK, West B, Washington T. Differences in Prescription Opioid Analgesic Availability: Comparing Minority and White Pharmacies across Michigan. *The Journal of Pain*. October 2005;6 (10): 689-699.
10. Morrison RS, Wallenstein S, Natale DK, Senzel RS, Huang LL. "We Don't Carry That" -- Failure of Pharmacies in Predominantly Nonwhite Neighborhoods to Stock Opioid Analgesics. *The New England Journal of Medicine*. April 2000;342: 1023-1026.
11. Burgess DJ, Nelson DB, Gravely A, et al. Racial Differences in Prescription of Opioid Analgesics for Chronic Noncancer Pain in a National Sample of Veterans. *The Journal of Pain*. April 2014;15 (4): 447-455.
12. Gillon R. Medical Ethics: Four Principles Plus Attention to Scope. *BMJ*. July 1994;309.
13. Ballantyne JC, Fleisher L. Ethical Issues in Opioid Prescribing for Chronic Pain. *PAIN*. 2010;148: 365-367.
14. Gillon R. Defending the Four Principles Approach as a Good Basis for Good Medical Practice and therefore Good for Medicine. *Journal of Medical Ethics*. 2015;41: 111 - 116.
15. Task Force on the Low Back Pain Clinical Practice Guidelines. American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients with Low Back Pain. *The Journal of the American Osteopathic Association*. August 2016;116(8): 536-549.
16. Franke H, Franke JD, Fryer G. Osteopathic Manipulative Treatment for Nonspecific Low Back Pain: A Systematic Review and Meta-analysis. *BMC Musculoskeletal Disorders*. August 2014;15: 286.
17. Licciardone JC, Gatchel , Aryal S. Recovery From Chronic Low Back Pain after Osteopathic Manipulative Treatment: A Randomized Controlled Trial. *The Journal of the American Osteopathic Association*. March 2016;116(3):144-155.