Controlling pain and reducing misuse of opioids

Ethical considerations

Jaro Kotalik MD MA FRCPC

Abstract

Objective To help family physicians achieve an ethical balance in their opioid prescribing practices.

Quality of evidence MEDLINE was searched for English-language articles published between 1985 and 2011. Most available evidence was level III.

Main message It is essential to follow practice guidelines when prescribing opioids, except when another course of action is demonstrably justified. In addition, when considering the appropriateness of an opioid prescription, with its many ethical implications, the decision can be usefully guided by the application of the ethical principles of beneficence, nonmaleficence, respect for autonomy, and justice. As well, it is essential to keep current about legal and regulatory changes and provincial electronic registries of opioid prescriptions.

Conclusion Physicians need to ensure that their patients' pain is properly assessed and managed. Reaching optimal pain control might necessitate prescribing opioids. But the obligation to provide pain relief needs to be balanced with an equally important responsibility not to expose patients to risk of addiction and not to create opportunities for drug diversion, trafficking, and the addiction of others. Basic ethical principles can provide a framework to help physicians make ethically appropriate decisions about opioid prescribing.

Relief of pain is one of the fundamental obligations of medical professionals. During the past few decades, pain control, even if it is not always optimal, has improved considerably. As new, long-acting opioids were developed, physicians adopted the practice of more generous prescribing, not only for acute but also for chronic pain. Unfortunately, the misuse of prescription opioids has become what the College of Physicians and Surgeons of Ontario recently called a "public health crisis."[1] A recent telephone survey indicated that 0.5% of Canadians were taking these drugs without medical indication,[2] but estimates based partially on US data and other methodology suggested that 1% to 3% of our population belonged in this category.[3] The individual and societal consequences of opioid misuse and abuse are serious. A study done at the Centre for Addiction and Mental Health in Toronto, Ont, identified a considerable rise in the number of individuals seeking treatment for prescription opioid addiction.[4] Some First Nations communities found addiction problems to be so severe that they declared "a state of crisis."[5] In Ontario, the annual number of deaths involving oxycodone increased 5-fold between 1991 and 2004. This trend corresponds to the 850% increase in oxycodone prescriptions. An analysis of about 1000 deaths from overdose in Ontario indicated that 56% of these individuals received opioid prescriptions within 4 weeks before death, suggesting that drug prescribing might be implicated in these deaths, perhaps associated with misuse (whether intentional or accidental), diversion, or addiction.[6] A recent study concluded that "opioid-related deaths are concentrated among patients treated by physicians who prescribe opioids frequently."[7] Similar observations were made in the United States,[8] so this is not a uniquely Canadian problem.

Physicians alone cannot reverse the situation. This serious social and health problem has to be addressed using a variety of measures. However, physicians need to play their role in this effort, both as individuals and as a self-governing organized profession. The obvious starting point for individual practitioners is to reflect on their prescribing practices and adjust them whenever possible

KEY POINTS Opioids are the optimal treatment for some patients' pain, yet their widespread misuse and abuse causes serious problems. Many family physicians struggle to achieve an ethical balance in their opioid prescribing practices. Various guidelines and practice tools are now available. These are helpful, but require physicians to take into account moral values, interests, rights, and responsibilities, and hence to engage in ethical analysis. The basic ethical principles of beneficence, nonmaleficence, respect for autonomy, and justice can help physicians to make decisions about opioid prescribing.

This article has been peer reviewed.
Can Fam Physician 2012;58:381-5

This article is eligible for Mainpro-M1 credits.
To earn credits, go to www.cfp.ca and click on the Mainpro link.

La traduction en français de cet article se trouve à www.cfp.ca dans la table des matières du numéro d'avril 2012 à la page e190.

in order to reduce opioid-related harms without leaving patients with poorly treated or untreated pain.

If prescription opioids are creating serious problems, can a physician in primary practice respond to the situation by simply avoiding prescribing opioids entirely? Some emergency departments and walk-in clinics, overwhelmed by demands for opioids, made such a decision. I hear from some of my colleagues that, as this decision becomes known in the community, the pressure from drug seekers diminishes. But the effects of such problematic policies have not been studied. For a number of reasons, total avoidance of prescribing opioids is not an ethical option for most physicians. Many argue that pain relief is a fundamental human right.[9] The Canadian Pain Coalition reminded us recently that at least 1 in 5 adults lives with chronic pain.[10] Serious consequences of untreated chronic pain include loss of function and productivity, economic losses, and increased risk of depression and suicide.[11] Failure to properly control pain, for which opioids might be required, can represent substandard care and can even lead to accusations of negligence.

Ethical approach to prescribing

Consequently, most clinicians cannot avoid the arduous and complicated task of determining the appropriateness of an opioid prescription in each individual case of uncontrolled pain and in every encounter with such patients. The basic ethical obligation is to acquire current knowledge, skills, and tools to assist in making these decisions. Some useful material is contained in Health Canada's Abuse and Diversion of Controlled Substances: A Guide for Health Professionals.[12] The recently released Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain[13] provides more detailed tools for this decision making. It is essential to become familiar with the Canadian guideline and to follow the recommendations, unless you have a persuasive reason in a particular case to decide differently. However, the guideline does not cover management of acute pain or cancer pain, and its application for chronic pain is not straightforward. Even if additional practice tools are used, a considerable space is left for judgments about needs and interests, risks and benefits, and fairness and responsibility. In other words, there are ethical decisions to be made and ethical concerns to be addressed at each step of providing pain control with opioids.[14]

Various ethical frameworks can be used to help make ethical decisions. The approach taken in this paper to prescribing opioids from an ethical perspective is to seek direction from each of the 4 basic bioethical principles. For the past 30 years, these principles have proven their value.[15] The principles of beneficence and nonmaleficence are grounded in the traditional Hippocratic ethic, and are accepted as guides for action by health care providers. Of more recent origin are the principles of justice and respect for autonomy, which are linked to a drive for social justice and human rights. Each of these principles can guide our decision making about opioid prescribing.

Quality of evidence

MEDLINE was searched for English-language articles published between 1985 and 2011. Most available evidence was level III.

Main message

Principle of beneficence. This principle specifies that a health care professional should provide net benefit to the patient. It might seem to be the easiest principle to apply because physicians are usually familiar with the benefits of opioid therapy, as they are well documented in literature. However, some physicians have to overcome their lack of training in caring for patients with chronic noncancer pain,[16] or their possible aversion to prescribing opioids at all. Even with experience, empathy for a patient's suffering, and an open mind, it is not simple to estimate the benefits that a particular patient can obtain from opioids. The problem, as we all know, is that pain is a subjective symptom, and no objective testing is available outside of research facilities. Yet, the level of medical benefit is related to the level of pain and functional restriction, and therefore the benefit varies from very high, as for a patient who has severe pain not successfully controlled by nonopioid medications and other measures; to moderate, as for a patient in pain who has not yet had a fair trial of nonopioid medications; to zero benefit, as for a person who might or might not be in pain but who intends to sell the drug for profit or to consume it to satisfy an addiction. Physicians are trained, and rightly so, to trust their patients; unless a patient has clearly proven to be untrustworthy, seeking to identify patients in the last category is a difficult but unavoidable task.

Physicians need to ask patients if they have received pain medication from other practitioners, as well as the timing and quantity of previous prescriptions. It might surprise many Canadian patients and clinicians that under the federal Controlled Drugs and Substances Act anyone seeking opioids is legally obligated to disclose to the practitioner details related to the acquisition of every such substance from any other practitioner within the preceding 30 days.[17] Given that physicians are legally entitled to seek truthful and complete disclosure, should they not warn their patients that making false statements constitutes breaking the law? Perhaps a physician who is concerned that a patient is "double doctoring" for these drugs should request a signed statement of disclosure so that the patient is aware of the seriousness of giving false information about opioids prescribed by other practitioners.

If the indication for opioid prescription is weak (eg, mild pain, minimal functional restrictions, inadequate trials of nonopioid therapies), the patient could be steered toward drug-free pain management, such as psychological counseling, physiotherapy, or rehabilitative, self-management, and complementary therapies. Even if an opioid is prescribed, concurrently offering interprofessional care with various therapies is likely to be advantageous. Currently, there is limited access to such care, but the situation might improve with physician advocacy.

Achieving full benefit from opioids requires not only judicious prescribing but also thoughtful use. The physician who prescribes an opioid shares with the patient an ongoing ethical responsibility for the proper use of the drug. This responsibility implies the physician's attention to and the patient's collaboration with keeping accurate and ongoing documentation of titration of doses, changes in level of pain, the patient's mood, functional improvements, and adverse events.

Principle of nonmaleficence. After determining the most likely benefit to a particular patient from an opioid prescription at a particular time, attention can be given to the principle of nonmaleficence. To apply this principle, which guides us to avoid or minimize harm or risk of harm, the physician considers not only the risk of immediate side effects but also the risk of misuse leading to addiction or dependency for that individual patient. In a recent survey, more than 40% of Ontario physicians reported encountering opioid-related adverse events.[18] In a study of patients with chronic pain who were selected because management was difficult or because opioid misuse was suspected, 32% of patients were noted to misuse opioids during the 1-year follow-up period, in spite of signing a "medication agreement."[19] Addiction risk in chronic pain patients was estimated to be 3.3% by a report which reviewed all available studies. However, for patients who had no current or previous history of abuse or addiction, the risk of abuse or addiction was only 0.19%. Similarly, the percentage of patients who demonstrated aberrant drug-related behaviour was 11.5% for the whole group, but this decreased to 0.6% if patients with history of abuse or addiction were excluded.[20] A more recent Cochrane review provided a similar picture.[21] In keeping with the evidence, the Canadian guideline recommends that before opioids are prescribed, physicians consider using one of the available tools to assess patients for addiction risk.[22] Screening provides an estimate of the risk of aberrant behaviour; the ethical obligation to carry out screening and to act on its findings appears to be strong. If the findings of such screening suggest that the patient has an elevated risk of addiction, then the physician might decide to avoid opioid therapy or to use it very cautiously, with close monitoring, recording, and short-interval dispensing. For patients at higher risk of misuse, the Canadian guideline recommends prescribing opioids only if patients have "well-defined somatic or neuropathic pain conditions."[22] Therefore, it is ethically problematic for physicians to prescribe more than a few days' worth of opioids for patients they do not know, whose medical records are not accessible, or whose risk cannot be fully assessed.

Applying the principle of nonmaleficence is even more difficult if the physician becomes aware or suspects that a prescription that is otherwise appropriate and safe for the patient could potentially harm others. Most of the time, physicians balance benefit and harm with exclusive attention to the patient. Opioid prescribing creates situations that might require taking possible harm to others into account. Consider that a recent Ontario study found that in 1 year, 21% of students used pain relief pills without prescriptions; most often the drug was prescribed to someone else in the student's home.[23] Consequently, if it becomes obvious during contact with a patient that the drug is likely to be stolen or extorted, it would be appropriate to consider whether the patient's short-term benefit is high enough to justify risking the serious harms resulting from narcotics falling into other hands.

After a prescription for opioids is issued, emphasize to the patient that he or she has a responsibility for safeguarding the medication. The temptation for diversion is large because in some places a single OxyContin tablet can sell for $500.[24] Patients should be advised to keep the drug under lock and key in a well-hidden location. Most patients, when properly informed, will wish to prevent the opioid from getting into the hands of a young person interested in experimenting with drugs or into the hands of someone who will sell the drug illegally.

The Canadian guideline suggests using tools designed to recognize misuse of opioids, implementing urine drug screening, or asking patients to sign treatment agreements. With patients' permission, it might be useful to get additional insight from family members or friends. Physicians might also find that interprofessional collaboration, particularly periodic contact with the dispensing pharmacists, can be very helpful in ensuring that ongoing opioid prescribing is indeed effective and safe for patients and the community.

Respect for autonomy. This principle reminds us not to impose any intervention on a competent patient. The main expression of the respect for autonomy is the process of informed consent to, or informed decline of, a treatment, although a higher level of respect for autonomy is achieved by shared decision making between physician and patient. The principle of autonomy supports the practice of giving patients as broad a choice

of pain treatments as can be medically justified. Many patients, if they are made aware of the risks associated with the use of opioids, might themselves choose less potent but safer medications. Respect for autonomy does not mean that the patient dictates what the physician will prescribe. "Giving in" and prescribing any medication that is against sound medical judgment is a disservice to patients and likely ethically indefensible, as it contradicts the principle of nonmaleficence. The Canadian guideline outlines steps that a physician can take to reduce possible conflicts.[22] If the patient continues to demand an opioid prescription that the physician decides is improper, the Canadian guidelines indicate that the physician may discharge the patient from the practice. Such a step is ethically problematic, especially if the patient is also depressed or is "high risk" because of other issues. Discharge from medical care might lead to the patient accessing drugs illegally, and might bar the patient from access to medical services, especially in communities with limited access to primary care providers. Instead, a second opinion from a colleague could be sought, or the physician could contact a professional mentoring program, such as the Medical Mentoring for Addictions and Pain program of the Ontario College of Family Physicians, or the Nova Scotia Chronic Pain Collaborative Care Network.

Principle of justice. The most difficult part of ethical assessment of opioid prescribing could well be the application of the principle of justice, which calls for fair and equitable treatment for all. The principle is compatible with the practice of screening out people who seek opioids for nonmedical use, addiction, or diversion. However, if screening were ineffective or inaccurate, it would also be unethical because it could result in injustice by excluding pain control measures for some people based on irrelevant characteristics.[25] Physicians need to be careful in accepting, without reflection, labels of their patients as "junkies" or "drug seekers" as a reason to deny pain control medication or care. First, the behaviour of a patient with undertreated pain might resemble that of a person with an addiction. Second, because addiction and uncontrolled pain can coexist, a patient with proven addiction cannot be dismissed without assessment and advice. Treatment of such patients might be most appropriately directed by a pain specialist in collaboration with an addictionist. Finally, even patients with addiction and no pain ought to be treated with respect, regardless of whether or not they are willing to enroll in substance-dependency programs.[26]

The challenge of these 4 principles is that they at times provide conflicting advice. For example, the principle of beneficence might give a strong indication to prescribe an opioid, yet the principle of nonmaleficence might warn equally strongly against it. In such a case, the physician will have to weigh the importance of each assessment in that particular situation in order to reach the preferable ethical decision. When the situation is very complex or confusing, it might be helpful to refer the patient to another professional or to seek advice from a bioethicist. Whatever the decision, one benefit of ethically focused deliberation might be that the physician will be paying more attention to other means of achieving pain relief, thereby using opioids less often.

Ethical issues requiring clarification. What is a physician's ethical obligation when he or she becomes aware that a patient who was prescribed an opioid is intentionally providing it to others? The Canadian guideline advises physicians to stop prescribing the opioid and to refer the patient for addiction treatment if the patient exhibits "aberrant drug-related behaviour," but the physician is not obliged to contact police about nonviolent crimes such as forgery of prescriptions.[22] This might be prudent legal advice at present, but is it all a physician is expected to do ethically in an effort to curb the misuse? The Ontario College of Physicians and Surgeons has recommended that the government amend provincial laws to make it obligatory for physicians to disclose to a police service all criminal activity related to drug diversion.[1] Canadian laws will likely be altered, but before this happens it would be helpful if professional associations and colleges provided more guidance to physicians on the ethical and legal options in such situations.

An increasing number of Canadian provincial governments are creating, expanding, and modernizing electronic registries of opioid prescriptions and provisions. Physicians will have concerns about burdensome paperwork, loss of professional autonomy, and risks to confidentiality, and these must be addressed in the creation and maintenance of monitoring programs. Provincial laws are currently being supplemented in order to make it legal for physicians to share the health information of their patients with these registries, but it will be necessary for professional bodies to consider if physicians' participation in this effort will be ethically optional or obligatory.

Conclusion

Physicians need to ensure that their patients' pain is properly assessed and managed. Reaching optimal pain control might necessitate prescribing opioids. But the obligation of providing pain relief needs to be balanced with an equally important responsibility not to expose the patient to a risk of addiction and not to create opportunities for opioid drug diversion, trafficking, and the addiction of others. Various guidelines and practice tools are now being offered. Their use is desirable, but requires that the physician take into account moral values, interests, rights, and responsibilities, and hence

engage in ethical analysis. The 4 basic ethical principles of beneficence, nonmaleficence, respect for autonomy, and justice can provide a framework and a starting point to help physicians make ethically appropriate and defensible decisions about opioid prescribing.

Dr Kotalik is Professor in the Division of Clinical Sciences at the Northern Ontario School of Medicine and Adjunct Professor in the Department of Philosophy at Lakehead University in Thunder Bay, Ont. He was Founding Director of the Lakehead University Centre for Health Care Ethics and is Chief Executive Officer and a radiation oncologist for Thunder Bay Regional Cancer Centre.

Acknowledgment

I thank the anonymous peer reviewers for their comments and suggestions, which much improved this paper. Special thanks to my wife, **Maria Louisa Pedri, MA,** for many stimulating discussions on this topic and for her editorial assistance.

Competing interests

None declared

Correspondence

Dr Jaro Kotalik, Centre for Health Care Ethics, Lakehead University, 955 Oliver Rd, Thunder Bay, ON P7B 5E1; telephone 807 983-3007; e-mail **jkotalik@lakeheadu.ca**

References

1. College of Physicians and Surgeons of Ontario. *Avoiding abuse, achieving a balance: tackling the opioid public health crisis*. Toronto, ON: College of Physicians and Surgeons of Ontario; 2010. Available from: **www.cpso.on.ca/policies/positions/default.aspx?id=4324**. Accessed 2010 Oct 29.
2. Fischer B, Nakamura N, Ialomiteanu A, Boak A, Rehm J. Assessing the prevalence of nonmedical prescription opioid use in the general Canadian population: methodological issues and questions. *Can J Psychiatry* 2010;55(9):606-9.
3. Popova S, Patra J, Mohapatra S, Fischer B, Rehm J. How many people in Canada use prescription opioids non-medically in general and street drug–using populations? *Can J Public Health* 2009;100(2):104-8.
4. Sproule B, Brands B, Li S, Catz-Biro L. Changing patterns in opioid addiction. Characterizing users of oxycodone and other opioids. *Can Fam Physician* 2009;55:68-9.e1-5. Available from: **www.cfp.ca/content/55/1/68**. Accessed 2012 Feb 9.
5. Meadows B. Drug abuse sparks crisis. Nearly half of reserve's adults abusing prescriptions as some kids go hungry. *Chronicle Journal* 2009 Nov 22;Sect. A1, A3.
6. Dhalla IA, Mamdani MM, Sivilotti ML, Kopp A, Quershi O, Juurlink DN. Prescribing of opioid analgesics and related mortality before and after the introduction of long-acting oxycodone. *CMAJ* 2009;181(12):891-6. Epub 2009 Dec 7.
7. Dhalla IA, Mamdani MM, Gomes T, Juurlink DN. Clustering of opioid prescribing and opioid-related mortality among family physicians in Ontario. *Can Fam Physician* 2011;57:e92-6. Available from: **www.cfp.ca/content/57/3/e92.full.pdf+html**. Accessed 2012 Feb 9.
8. Dunn KM, Saunders KW, Rutter CM, Banta-Gree CJ, Merrill JO, Sullivan MD, et al. Opioids prescriptions for chronic pain and overdose. A cohort study. *Ann Intern Med* 2010;152(2):85-92.
9. Brennan F, Carr DB, Cousins M. Pain management: a fundamental human right. *Anesth Analg* 2007;105(1):205-21.
10. Canadian Pain Coalition. *Report on pain.* Oshawa, ON: Canadian Pain Coalition; 2011. Available from: **www.canadianpaincoalition.ca/media/report_on_pain_media_release_final_en.pdf**. Accessed 2011 Mar 25.
11. Tang NK, Crane C. Suicidality in chronic pain: a review of the prevalence, risk factors and psychological links. *Psychol Med* 2006;36(5):575-86. Epub 2006 Jan 18.
12. Health Canada. *Abuse and diversion of controlled substances: a guide for health professionals*. Ottawa, ON: Health Canada; 2006.
13. Furlan AD, Reardon R, Weppler C; National Opioid Use Guideline Group. Opioids for chronic non-cancer pain: a new Canadian practice guideline. *CMAJ* 2010;182(9):923-30.
14. Rich BA. Ethics of opioid analgesia for chronic noncancer pain. *Pain Clin Update* 2007;15(9):1-4.
15. Beauchamp TL, Childress JF. *Principles of biomedical ethics.* 6th ed. New York, NY: Oxford University Press; 2008.
16. Upshur CC, Luckmann RS, Savageau JA. Primary care provider concerns about management of chronic pain in community clinic populations. *J Gen Intern Med* 2006;21(6):652-5.
17. Department of Justice. *Controlled drugs and substances act.* Ottawa, ON: Department of Justice; 1996. Sect. 4, paragraphs 1-2.
18. Wenghofer EF, Wilson L, Kahan M, Sheehan C, Srivastava A, Rubin A, et al. Survey of Ontario primary care physicians' experiences with opioid prescribing. *Can Fam Physician* 2011;57:324-32.
19. Ives TJ, Chelminski PR, Hammett-Stabler CA, Malone RM, Perhac JS, Potisek NM, et al. Predictors of opioid misuse in patients with chronic pain: a prospective cohort study. *BMC Health Serv Res* 2006;6:46.
20. Fishbain DA, Cole B, Lewis J, Rosomoff HL, Rosomoff RS. What percentage of chronic nonmalignant pain patients exposed to chronic opioid analgesic therapy develop abuse/addiction and/or aberrant drug-related behaviors? A structured evidence-based review. *Pain Med* 2008;9(4):444-59.
21. Noble M, Treadwell JR, Tregear SJ, Coates VH, Wiffen PJ, Akafomo C, et al. Long-term opioid management for chronic noncancer pain. *Cochrane Database Syst Rev* 2010;(1):CD006605.
22. National Opioid Use Guideline Group. *Canadian guideline for safe and effective use of opioids for chronic non-cancer pain.* Hamilton, ON: National Opioid Use Guideline Group; 2010. Available from: **http://nationalpaincentre.mcmaster.ca/opioid/cgop_b_app_b11.html.** Accessed 2011 Mar 15.
23. Brands B, Paglia-Boak A, Sproule BA, Leslie K, Adlaf EM. Nonmedical use of opioid analgesics among Ontario students. *Can Fam Physician* 2010;56:256-62.
24. McKinley K. We're all out, would-be pill robber told. *Chronicle Journal* 2011 Jan 7;Sect. A1.
25. Johnson SH. Legal and ethical perspectives on pain management. *Anesth Analg* 2007;105(1):5-7.
26. American Society for Pain Management Nursing. *ASPMN position statement: pain management in patients with addictive disease.* Lenexa, KS: American Society for Pain Management Nursing; 2002. Available from: **www.aspmn.org/Organization/documents/addictions_9pt.pdf**. Accessed 2011 Apr 11.