How to Reduce Fears of Legal/ Regulatory Scrutiny in Managing Pain in Cancer Patients

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More than a decade ago, physicians in the Eastern Cooperative Oncology Group ranked excessive regulation of opioids among the top barriers to effective management of cancer pain.[1] Subsequent reports from several state commissions showed that medical decisions about opioid use were influenced by regulatory policies or fear of regulators.[2–5]

In 1997, the Institute of Medicine's Committee on Care at the End of Life examined how pain management may be compromised by laws that are intended to minimize drug addiction and diversion.[6] The Committee called for "reform of drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering." State medical board members also recognized that concerns about regulatory scrutiny might impact negatively on opioid prescribing, and hence adequate control of pain.[7]

Last year, guidelines from the National Consensus Project for Quality Palliative Care identified "addressing regulatory barriers" as one of the core elements of palliative care and called on "palliative care professionals to collaborate with policy-makers, law enforcement, and regulators to achieve a balanced and positive regulatory environment for pain management and palliative care."[8]

In fact, over the past several years, there have been major collaborative efforts[7,9–11] among members of the pain community, state legislators, and federal and state regulators aimed at improving the regulatory climate—in the words of the Federation of State Medical Boards (FSMB), "to alleviate physician uncertainty and to encourage better pain management."[12] These efforts are based on application of the principle of balance: preventing abuse of prescription pain medications while ensuring that they remain available for patients who need them for pain control.[13,14]

Unfortunately, the increase in the diversion and abuse of opioids (especially oxycodone [OxyContin]),[15] high profile cases in which physicians have been charged with "overprescribing," as well as statements by the Drug Enforcement Administration (DEA)[16] threaten these cooperative efforts toward balance. Although most concerns have focused on the misuse/abuse of opioids for the treatment of chronic non-cancer pain, they could have ramifications for the care of persons with pain due to cancer, especially long-term cancer survivors with significant pain. Survivors whose disease is in remission may be at special risk for undertreatment and become victims of the increasing debate about the appropriateness of opioid therapy for chronic non-cancer pain.[17,18]

Myths That Can Cause Anxiety

At this time of increased concern about prescription drug abuse, it is critical for those who prescribe, administer, and dispense opioid analgesics to maintain proper perspective and keep focused on their fundamental responsibility—to provide relief of pain and suffering to all patients with cancer and pain. Be aware that:

- There is no evidence to suggest that those in the oncology community are at significant risk of regulatory scrutiny.
- It is not true that "hospice physicians are being led away in handcuffs."[19]
- It is not true that hundreds of physicians lose

Manuscript received January 4, 2005; accepted March 8, 2005.

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J Support Oncol 2005;3:384–388 © 2005 Elsevier Inc. All rights reserved.

their licenses each year for excessive prescribing of opioids.*

Fear based on misinformation can be a powerful deterrent to effective use of opioids for pain control. Indeed, a recent high profile case in which a physician was found guilty of racketeering and drug trafficking has dramatically heightened physician uncertainty about the prescribing of opioids.[20] To be totally safe, one could become a "therapeutic nihilist" and translate the *Just Say No* antidrug drug theme into a clinical practice that denies persons optimal pain control with opioids unless they are very close to the end of life. Even in this latter instance, the safest legal course would be to underprescribe so there could be no suspicion of assisted suicide.[21] Both approaches must be rejected, as they are morally indefensible. Furthermore, undertreatment also carries risk, as inadequate pain control is now considered a departure from standards of practice.

This article reviews the commonsense principles that should guide the use of opioids for pain control. These principles are detailed in the *Model Policy* from the FSMB[22] and in articles and guidelines written by leaders in pain and addiction medicine.[23–25] Adherence to these principles should lead to optimal patient outcomes in your practice and minimize drug diversion as well as the risk of regulatory scrutiny. The FSMB suggests that these principles form the basis for state medical boards' evaluation of a physician's treatment of pain. However, not all of these principles have relevance to oncology patients, especially those with advanced disease, and unfortunately they do not deal with physician fears of possible legal sanctions related to the treatment of patients at the end of life with large doses of opioids, to fears that they will be accused of assisted suicide.

The FSMB Model Policy

In 1998, the FSMB undertook an initiative to develop *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*.[12] Its purpose was to encourage state medical boards and other healthcare regulatory agencies to adopt policies to encourage better pain management, to clarify the role of opioid analgesics, and to address physicians' fears of being investigated for inappropriate prescribing of controlled substances.

In 2004, the FSMB revised its *Model Guidelines* to "provide state medical boards with an updated template regarding the appropriate management of pain…."[22] The title was changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document. The FSMB *Model Policy* emphasizes that treating pain with controlled substances is an integral part of the practice of medicine, that good outcomes will weigh heavily in evaluating physician conduct, and that "state medical boards should consider inappropriate treatment, including the undertreatment of pain, as a departure from an acceptable standard of care."[22]

Table 1

Guidance Points From the FSMB *Model Policy*

Guidance point
The Board *will* consider the inappropriate treatment of pain to be a departure from the standards of practice.
Diagnosis and treatment of pain *are* integral to the practice of medicine.
Appropriate pain management *is* the treating physician's responsibility.
The Board *will* refer to current clinical practice guidelines and expert review in cases involving management of pain.
The Board *will* judge the validity of treatment based on available documentation, rather than solely on the quantity and duration of medication administration.
The physician's conduct *will* be evaluated to a great extent by the outcome of pain treatment.
Prescribing *must* be based on clear documentation of unrelieved pain.
A physician-patient relationship *must* exist.
The goal *is* to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.
Physicians are *expected* to incorporate safeguards into their practices to minimize the potential of abuse and diversion.
All physicians *should* become knowledgeable about assessing pain, treating pain, and statutory requirements.
Pain *should* be assessed and treated promptly.
Quantity and frequency of doses *should* be adjusted depending upon the individual circumstances.
Physicians *should* recognize that tolerance and physical dependence are normal consequences of sustained use of opioids and are not the same as addiction.
Prescribing *should* be based on a diagnosis and documentation of unrelieved pain.
Continuation of the use of controlled substances for pain control depends upon progress toward treatment objectives.

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REPRIMANDS FOR UNDERTREATMENT OF PAIN

The Oregon Medical Board has twice sanctioned a physician who failed to provide adequate pain relief for his patients.[26] In a statement adopted in 1999, the Oregon Board urged the use of effective pain control for all patients regardless of the etiology of their pain. The Board "will consider clearly documented undertreatment of pain to be a violation equal to overtreatment and will investigate allegations in the same manner."[27]

In California, a physician was convicted of elder abuse for failing to control pain in a dying patient.[28] A complaint against the physician had been filed with the Medical Board of California, but the Board failed to take action, even though it agreed that the patient's pain was not adequately controlled.[29] In later action, the California Board did sanction a physician for failure to treat pain in a patient dying of cancer.[30] As a result, there are now two cases in which a medical board has disciplined a physician for the undertreatment of pain.

Many state medical boards have adopted the FSMB *Model Guidelines*, and some have more recently adopted the *Model Policy*, to give doctors in their states confidence that they

*In 2003, there were 963,385 physician registrants with the DEA; of them, 557 (0.06%) were investigated, 441 had action taken against them (0.05%), and 34 were arrested (< 0.01%). Data for 2004 are not available. Available at: http://www.usdoj.gov/dea/pubs/pressrel/pr103003p.html.

Table 2

Guidelines to Reduce the Risk of Legal/Regulatory Scrutiny When Prescribing Opioids for Pain Control

Make sure to conduct a thorough history and physical examination on every patient…and carefully document the results.
Take care to identify associated medical and psychosocial conditions.
Carefully outline and document a treatment plan.
Stress setting clear goals: to reduce pain and improve function.
Try to provide clear reasons for the treatment plan to patients.
See patients regularly to assess response to the treatment plan.
Strive to adjust the treatment plan as needed to achieve treatment goals.
Refer patients for additional evaluation and treatment if their response to treatments is not adequate.
Remind colleagues that they may need to refer the patient for additional evaluation, if necessary, especially when the person is "at risk for medication misuse or diversion."
Consider a written treatment agreement if a patient is at high risk for medication abuse.
Always comply with controlled substance laws and regulations.
Perhaps most important, strive to maintain complete, accurate, and up-to-date medical records.
Keep the dispensing pharmacist informed by making him/her part of the team and maintaining clear and open communication about the treatment plan.
Ask staff to educate other caregivers and family about the signs and symptoms of approaching death.

Adapted in part from the FSMB *Model Policy*[22]

can prescribe opioids without fear of reprisal. Unfortunately, physicians may not be aware of their board's position. Only 39% of California physicians said they remembered reading the Board's policy one year after it had been mailed to them for the third time.[31] It is incumbent upon physicians in every state to become familiar with their state medical board's policy. In some states, boards of medicine, nursing, and pharmacy have issued joint policy statements.[11] In a letter published in *USA Today*, Karen Tandy, Administrator of the DEA, wrote: "…the myth that the DEA is out to get doctors needs to be put to rest. Doctors acting in good faith and in accordance with established medical norms should remain confident in their ability to prescribe appropriate pain medications."[32] Unfortunately, recent actions of the DEA make it difficult for physicians to maintain that confidence.

Further Guidelines

It is important to periodically remind all physicians and nurses involved in direct patient care that prescribing practices need to conform to federal and state laws and regulations governing the use of controlled substances. Ignorance is no excuse. Readers are referred to the website of the Pain and Policy Studies Group (PPSG)[33] for a detailed analysis of all federal and state pain policies.

The website for The Legal Side of Pain[34] provides a quick reference chart (Table 1) that summarizes the guidance points from the FSMB to state medical boards. These guidance points define the responsibilities of boards and licensees that you will find to be useful "talking points" when or if you are confronted with a colleague who either is hesitant to use opioids even when it is appropriate or does not recognize the critical importance of providing effective pain control.

The *Model Policy* also provides criteria that the FSMB suggests medical boards use when they evaluate the pain treatment practices of a physician about whom a complaint has been lodged. These criteria are detailed on the website of The Legal Side of Pain[34] and are also incorporated into the commonsense approach to reducing the risk of regulatory scrutiny that is presented in Table 2. They are not clinical practice guidelines, but they do define the elements of good medical practice. The paper by Gourlay et al[25] recommends *Universal Precautions*, which consists of ten steps to guide patient assessment, management, and referral.

The application of either of these sets of recommendations depends on the location of a patient along the disease trajectory. For instance, a *Treatment Agreement* with requests for periodic urine screening has little if any relevance to the dying patient but could be appropriate for the cancer survivor with an excellent prognosis whose disease appears to be in remission but whose pain requires treatment with opioids. Furthermore, patients with cancer and pain *and* the disease of addiction should not be excluded from treatment with opioid analgesics; however, they do require extra care, monitoring, and documentation.[35]

All regulatory authorities emphasize that thorough documentation is a key element in protecting your practice. "Leave nothing to the imagination of the reader"—that is, the medical board member and/or investigator to whom your case is assigned should a complaint be lodged against you. "Chart everything you see, think, feel, and hear about your patients."[23]

Other Issues of Concern

As noted in Table 2, it is essential to develop strong relationships with your dispensing pharmacists. They have legitimate reasons for being concerned about the potential for opioids to be diverted and abused, and pharmacists are a common source of complaints to medical boards. The development of clear and open lines of communication with pharmacists is essential to eliminating that potential cause of regulatory scrutiny. Some pharmacists may not understand the important role of opioids in providing control of cancer pain; they may have little or no experience with dispensing the high doses that may sometimes be required to control cancer pain; moreover, they may have inappropriate fears about the side effects of the drugs and may communicate negative feelings to patients and family members. Be certain to keep pharmacists informed about treatment plans.

One of the guidance points from the FSMB *Model Policy* relates to the need to recognize that tolerance and physical dependence are normal consequences of sustained opioid use and not the same as addiction. Twenty years ago, many physicians were so afraid of causing addiction in patients that they

were uncomfortable about prescribing opioids, even to the dying. It is essential that clinicians and all others on the pain treatment team understand the meaning of tolerance, physical dependence, and addiction and help patients and their families understand these meanings as well. It follows that all caregivers need to work from the same definitions. Make certain that everyone, including family members and patients, understands and uses the definitions developed by the Liaison Committee on Pain and Addiction[36] (Table 3) and discussed in more detail by Savage et al.[37]

These definitions are important, because to equate physical dependence with addiction is to stigmatize patients and to risk underutilization of the opioids they need—and underutilization could trigger an investigation for inappropriate treatment. Remind your staff that confusion about the meaning of terms has led to frivolous lawsuits in which it was claimed that a patient was addicted, when in fact the patient had experienced symptoms of withdrawal because he was physically dependent.

What Is the Risk of Criminal Charges When Caring for the Dying?

Physicians have long been concerned, and those at the University of Wisconsin Hospital & Clinics are no exception, that they may be subject to criminal prosecution and other legal sanctions because the medications needed to provide adequate pain relief carry a risk of ending a patient's life by depressing respiration. Though the risk is small, it does contribute to some clinicians' reluctance to use opioids and to the undertreatment of pain.[21] Traditionally, the principle of double effect[38] has been applied to deal with these concerns: the intent of treatment is to relieve pain, not to shorten life. However, "the line between intending to hasten death and intending to relieve pain and suffering can be hazy. It is not clear if the doctrine of double effect would provide a valid legal defense."[21] A physician who intends to relieve pain and suffering could face legal sanctions because it may be difficult to prove intent. It is not possible to completely eliminate the risk of prosecution for homicide or disciplinary action by a state medical board. However, as stated previously, the risk is small if you adhere closely to the guidelines outlined in this article.

It is worth repeating that to reduce the threat of criminal prosecution, it is essential to establish clear communication with other caregivers and family members. The guidelines from the National Consensus Project wisely recommend that "the patient's transition to the actively dying phase is recognized, when possible, and is documented and communicated appropriately to patient, family, and staff. The family is educated regarding the signs and symptoms of approaching death in a developmentally, culturally, and age-appropriate manner."[8] Such communication is essential to reducing the possibility that family members will conclude that effective pain management has hastened a loved one's death.

Table 3

Definitions Related to the Use of Opioids for the Treatment of Pain

Term	Definition
Addiction	A primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
Physical Dependence	A state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
Tolerance	A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

From a consensus document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine[36]

Conclusions

Medical decisions about opioid use have long been influenced by fears of regulatory scrutiny. Such fears have impacted negatively on opioid prescribing for pain control, even for persons with pain related to cancer. Yet there is no evidence that this patient population is a source of drug diversion and no evidence that oncologists have been the target of overzealous drug regulators.

In summary, it is essential to apply a maximum dose of common sense when using opioids for pain control. Adhere to the elements of a sound approach to opioid use as articulated in the *Model Policy* from the FSMB: a thorough history and physical exam with special attention to psychological problems, a rational treatment plan based on that documented history and physical, periodic evaluation of the response to treatment with documentation of that evaluation and resultant changes in the treatment plan, and appropriate consultation if pain control is inadequate or if there is evidence of substance abuse. In brief, adhere to the essential components of good medical practice.

Maintain clear and open communication with dispensing pharmacists. This is important since they are a common source of complaints to medical boards. Also maintain clear and open communication with other caregivers and family, especially when treating patients at the end of life. Not only does this help to avoid unwarranted concerns about assisted suicide, it is basic to the provision of appropriate palliative care.

Of course, the only way to absolutely guarantee that a medical practice will not come under regulatory scrutiny is to refuse to prescribe controlled substances. Obviously, that is not a morally acceptable alternative. Furthermore, it could make you the target of legal or regulatory action.

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