To allow a patient to experience unbearable pain or suffering is unethical medical practice.1

Mine was strictly a clinical decision, and ethics should not have been a consideration.2

Many of us have encountered allusions to an apocryphal Chinese curse: “May you live in exciting times” (or sometimes “in interesting times”). Without question, the last 15–20 years have been an interesting and exciting time for health care professionals and others advocating for pain relief. Many of those who once contributed to the pervasive problem of undertreated pain, such as state medical licensing officials, now recognize that the failure to assess and manage pain harms patients and constitutes substandard care.3 Several legal cases holding health care institutions and professionals liable for failure to relieve pain have generated a remarkable amount of attention. The magnitude of the jury awards in these civil actions alleging substandard care strongly suggests a sense of moral outrage that vulnerable patients were subjected to unnecessary suffering because of the ignorance, indifference, or opiophobia of clinicians.4 Recently, publications in the clinical literature have begun to declare that pain relief is not just required by the prevailing standard of care, but also constitutes a fundamental human right.5 Indeed, even the 1997 United States Supreme Court decisions on the issue of physician-assisted suicide have been interpreted as recognizing a constitutional right to palliative care for dying patients.6

There is, however, another side to the ledger. On this side, at least for clinicians in the United States prescribing for patients with pain, lies the federal Drug Enforcement Administration (DEA) and the legion of federal prosecutors seeking to enforce their particular interpretation of the Controlled Substances Act (CSA). From this perspective, it is a high-risk proposition to prescribe opioid analgesics to patients who are not at death’s door, particularly analgesics labeled Schedule II, indicating that while they have a recognized medical use, they also have a “high potential for abuse” and may lead to “severe psychological or physical dependence.”7 Clinicians who are deemed to have prescribed these medications excessively, or without due consideration of the possibility that patients might abuse or divert them, have been charged with crimes, convicted, and sentenced to long prison terms for drug trafficking.8 The climate resulting from these prosecutions arguably creates a hostile environment for pain relief. Clinicians who in ambiguous situations elect to err on the side of aggressive pain management must engage in acts of moral courage. Balancing these seemingly conflicting societal expectations poses a daunting task to the scrupulous, conscientious, and compassionate clinician.

In order to understand the current situation, we need to begin by looking back to the earlier paradigm from which the ethics of pain management emerged. After this brief retrospective, we must address a critical ethical question: If we accept...
The proposition that patients with genuine, serious (moderate to severe) persistent pain have a moral and legal right to effective pain management, then what, if anything, would constitute an ethically legitimate basis for adopting a more conservative approach to prescribing opioids for chronic noncancer pain than for acute or cancer pain?

The Pernicious Role of Myth and Misinformation

The health professions have only recently emerged from a long dark age characterized by rampant opiophobia,9 routine undertreatment of pain, and the phenomenon produced by this toxic mixture—false accusations against pain patients of deceptive drug-seeking behavior when uncontrolled pain, not aberrant drug seeking, drives the behavior. Essential to the emergence from this dark age was a long war of attrition against pervasive myths and misinformation about the risks of addiction and the purportedly unmanageable side effects inherent in any analgesic regimen that used opioids for more than a few days or at most a few weeks.10 General acceptance of such myths and misinformation had provided both a clinical and ethical justification for avoiding opioid analgesia except for patients in the last days or hours of life. The ancient medical maxim primum non nocere (first do no harm) was invoked to support the opinion that allowing patients to suffer was clinically and ethically preferable to subjecting them to the risks of addiction or the potentially life-threatening side effect of respiratory depression. Thus, when lay commentators on the phenomenon of undertreated pain failed to find any genuine discussion or debate of its ethical implications in the medical literature, they quite naturally expressed shock and dismay.11

Unfortunately, the pendulum then swung, in some respects, so far in the other direction that “inadequate data” was offered as the basis for the new, “enlightened” view of pain management, which advocates that the risk of addiction or other serious adverse sequelae of opioid analgesia is vanishingly small and rarely a legitimate concern for physicians or their patients.12 New clinical practice guidelines, intended to reassure prescribing professionals that both cancer and non-cancer patients may require significant and sustained opioid analgesia to effectively manage persistent moderate to severe pain, allowed prescription of opioids to increase exponentially. As more opioids became available to pain patients through the liberalization of prescribing practices, so too did they become available to those who would abuse or divert them.13

We now seem to be entering a new phase, in which the need to ensure that pain patients receive appropriate relief is balanced by the equally important need to protect the public from the individual and societal tragedy of drug addiction, diversion, and trafficking. The new term for this approach to pain management is “pharmacovigilance.”14 Arriving at a professional consensus on what is “appropriate” pain management practice and what constitutes a reasonable approach to “balance” as a matter of social policy are the devilish details now confronting all health care providers. The admonition that balance should become the new paradigm and pharmacovigilance a legitimate dimension of patient care raises genuine ethical concerns. The traditional view in medical ethics, with roots in the Oath of Hippocrates, has been that the physician’s allegiance is to the well-being of the patient. When other, competing considerations are interjected, there is at least a potential conflict of interest that must be recognized and resolved appropriately. The permeation of the U.S. health care system by managed care illustrates the potentially pernicious effect on the therapeutic relationship that competing considerations, such as the financial bottom line of a managed care organization or the basis for compensating physicians, can have on the time-honored duty to pursue the best interests of patients. With regard to pain patients, it is one thing to caution physicians not to be duped by blatantly illegitimate or exceedingly suspicious demands for opioids, but it is quite another to impose the threat of serious sanctions upon physicians for giving patients the benefit of the doubt when dealing with pain syndromes that may require long-term opioid therapy for effective management.

A Realistic Assessment of Opioid Benefits and Risks

As one influential guideline on pain management stated, “The administration of medication is always a risk benefit calculation.”15 Indeed, this is true of all medical therapies and interventions. One of the root causes of undertreated pain is the apparent belief on the part of clinicians that the treatment of pain should be based upon a different set of principles and practices than any other type of patient care. Clinicians do not routinely adopt a skeptical posture when taking a medical history from a patient, or in asking for a description of the onset and symptoms of the current illness. To some extent, this approach of assuming that patients are generally truthful, unless and until a particular patient behaves in a way that warrants skepticism, is carried over to the care of cancer patients and their reports of pain. The reason, of course, is not that cancer patients are inherently more truthful, but because the diagnosis of cancer is solid, and its propensity to generate pain and other distressing physiological and psychological symptoms is beyond legitimate question. Indeed, the most compelling grounds for the argument that all types of pain are undertreated are the numerous studies revealing that even many cancer patients are deprived of adequate pain relief.16

Other explanations for the failure to adequately treat cancer pain include the persistence of myths about the inevitability of pain in the context of serious illness, the unmanageability of pernicious side effects of opioid analgesia, and the acceptance in some cultures and faith communities of the proposition that pain and suffering, particularly when associated with terminal illness, are redemptive.17 Health care professionals are not necessarily immune from such beliefs. However, while their right to hold such beliefs is unqualified, the right to subject their patients to the adverse consequences of them is not. Patients with significant pain also have a right to be fully informed of such pertinent matters as the clinician’s philosophy of pain management, experience in providing it, and knowledge of and adherence to current clinical practice guidelines.

I have noted elsewhere that there is a moral dimension to the failure of health care professionals to establish and maintain up-to-date knowledge, skills, and attitudes that affect the quality of care they are able and willing to provide to their patients that is captured in the phrase “the culpability of cultivated ignorance.”18 This cultivated, or at least tolerated, ignorance of what contemporary medical science reveals about
pain and its management is the most plausible explanation for the persistence of myths and misinformation about opioid analgesia. In a normative sense, it is a reason for the phenomenon, but it is not an excuse.

Only when clinicians have acquired the requisite knowledge and skills in assessing and managing pain should they undertake responsibility for providing it. In carrying out this responsibility, it is essential that they fully engage with the patient in balancing the risks and benefits of any particular modality of pain management. This is true regardless of the type of pain or options for treating it. Patients who are experiencing significant pain are also likely to be undergoing the psychological stress that is often associated with it. In the event the patient has been the victim of previous encounters with clinicians who discounted or dismissed their reports of pain, their anger, agitation, or frustration may suggest that they lack the capacity to calmly and rationally discuss and fully appreciate the positive and negative aspects of various therapeutic options. Such patients will benefit immensely from engagement with a clinician who acknowledges their concerns, validates their need for medical attention, and offers to work collaboratively with them to ascertain which therapeutic approach is most likely to help them.

The doctrine of informed consent, in both its ethical and legal dimensions, presupposes that patients have the capacity to assess medical risk and benefit. The traditional presumption that it is the proper role and responsibility of the clinician to determine the best interests of the patient fails to acknowledge two fundamental propositions: first, that all adult patients are presumed to possess the capacity to make decisions concerning their own well-being, and second, that the benefits and burdens of an effort to treat a medical condition, or the decision to eschew therapy and live with the condition, are ultimately borne by the patient. Consequently, what constitutes an acceptable harm or a benefit worth pursuing must ultimately be the patient’s decision, and that decision will be based only in part on clinical factors. This is why, at least heretofore, pain management has constituted a vast wasteland of uninformed consent, because too many clinicians lacked up-to-date knowledge about pain management, and hence they could not engage in an acceptable informed consent dialogue even if they were inclined to do so. Pain management went by default, and the default position was not to treat if the treatment called for was opioid analgesia.

**Ethical Considerations**

We return now to the critical question posed earlier: what, if anything, would constitute an ethically legitimate basis for adopting a more conservative approach to prescribing opioids for chronic noncancer pain than for acute or cancer pain? Obviously, if chronic, noncancer pain responded differently to opioid therapy than other types of pain, then a different approach might be justified. However, a therapeutic response to opioids cannot be predicted according to the trichotomy of acute pain, cancer pain, or chronic noncancer pain. Rather, opioids have been found to be effective for most nociceptive and much neuropathic pain. Not all pain is opioid responsive, but its unresponsiveness is not essentially related to whether it manifests as acute or chronic or is associated with a malignancy. However, some chronic noncancer patients, as well as nonterminal cancer patients, may require opioid therapy for years. There is some indication that over the course of prolonged treatment with opioids their therapeutic efficacy markedly deteriorates. In such cases, alternative methods of achieving an acceptable level of pain relief and level of function may be clinically necessary and ethically appropriate.

Thus we must turn to the alternative consideration—whether the risk/benefit ratio for opioid analgesia is dramatically and consistently different for cancer and noncancer pain. There is at least a superficial irony in the proposition that patients whose moderate to severe pain is time-limited by a terminal prognosis should be offered whatever level of opioid analgesia necessary to relieve their pain, while patients with the same level of pain that could persist for years must receive suboptimal pain and symptom management for their own good. The latter group would seem to be more deserving of aggressive therapy than the former. It may be that when the U.S. Supreme Court postulated the existence of a constitutional right to effective pain relief for dying patients, it could be explained by the fact that the plaintiffs in the litigation, and the right that they were asserting (access to a physician willing to write a lethal prescription in response to intractable pain and suffering) was couched entirely in terms of patients diagnosed with a terminal condition. One is left to wonder, however, whether patients with severe chronic but not terminal illness would ever be accorded the same right. If they would not be, one might reasonably ask the Court why dying with intractable pain or suffering is not acceptable, but living with it is.

The critical distinction in the reasonable goals of care between terminal and chronic illness, when both are associated with significant and persistent pain, appears to relate primarily to another aspect of balance—a balance between pain and symptom control and physical, psychological, and social functioning. Also, the risk of addiction from the long-term use of opioids, which is now much more realistically assessed as falling within a range of 5–24% of all patients, has much more significant implications for patients with noncancer pain and a lifespan measured in years or decades rather than weeks or months. It is for this very reason that clinicians who deliberately withheld opioids from dying patients because they believed the patients were or might become addicted have been justifiably criticized for their lack not only of a proper orientation to the role of beneficence in end-of-life care, but also of common sense.

Consensus is developing among specialists in pain management that opioid analgesics may have a legitimate and effective role to play in the management of moderate to severe chronic noncancer pain in some patients. The clinical challenge is to competently ascertain which patients are good candidates for a trial of opioid analgesia, and to determine how many other options need to be explored first and for how long. Some patients who would be good candidates are themselves (or perhaps their families) afflicted with opophobia and may resist a trial of an opioid. Others who are not good candidates may be insistent that no reasonable alternatives exist, and their demands may be interpreted as drug-seeking behavior. Negotiating these challenges requires, perhaps more than any other circumstances in clinical practice, skillful employment of the strategy of shared decision making.

Many of the most recent recommendations about how to engage with chronic pain patients about the possibility of opioid...
therapy are, from an ethical perspective, two-edged swords. Recommendations that formal written opioid agreements or contracts and urine toxicology screening be routinely used are touted as being for the patient’s welfare, but they have the appearance of a take-it-or-leave-it approach to the physician-patient relationship prompted primarily by risk management considerations. In law, such documents are characterized as “contracts of adhesion,” meaning that the party to the contract with all or most of the bargaining power imposes the terms and conditions of the contract on the other party, and there is no pretense about arriving at them by negotiation and mutual agreement. Courts strictly construe the terms of such contracts against the party imposing them precisely because it is patently obvious they were not the product of any real negotiation between the parties. It is difficult to establish and maintain the level of mutual trust and respect that is essential to an effective clinician-patient relationship when one party is dictating to the other conditions that suggest that the trustworthiness of the other party is in doubt and therefore must be rigorously monitored and routinely verified. The fact that this approach has been neither recommended nor routinely adopted in other patient care settings in which consistent adherence to the therapeutic regimen is critical at least suggests that beneficence may not be the foundation of such rigidly imposed conditions.

The Patient as Partner in the Therapeutic Dyad

An effective clinician-patient relationship is at least as important in the management of chronic pain as in the management of other medical conditions. While chronic pain patients may pose significant interpersonal challenges to clinicians, those challenges do not warrant either indifference or hostility to the patient’s plight. Nor do they warrant the adoption of a radically different paradigm for establishing and pursuing reasonable goals of care. That paradigm emphasizes the need for full disclosure of all relevant information by both parties, with a baseline presumption that the primary goal of each is to restore the patient to health or minimize functional impairment and to effectively manage pain and other distressing symptoms. Efforts to achieve these goals in the chronic pain patient can be challenging and often entail multiple therapeutic modalities and trials of various strategies in an effort to identify a long-term approach that adequately balances the associated risks and benefits. Transparency would seem to be an essential component of a solid and stable clinician-patient relationship in this setting, as in most others. Clearly written instructions to patients, along with elaboration of the risks and benefits of the approaches being considered or used, can be positive factors in avoiding confusion or misunderstanding. The fact that such documentation is not emphasized as much in other clinical settings does not mean that it would not be advisable to do so.

If and when a patient’s history, presentation, or current behaviors provide the clinician with a reasonable basis to believe that the risk of addiction, diversion, or aberrant drug-related behaviors is elevated, the imposition of more restrictive conditions for opioid prescribing and an increased level of monitoring and documentation could then be both clinically and ethically justified. The most ethically challenging cases will be those in which the clinician believes that opioid therapy might benefit the patient, but the perceived risk of addiction or likelihood of drug diversion are deemed to be so excessively high as to warrant a refusal to provide or a discontinuation of opioid therapy. Particularly in the case of a risk of diversion, societal interests are allowed to trump patient interests. Moreover, assessment of such a risk is not, strictly speaking, the exercise of clinical judgment. It is certainly not something that is taught in health professional schools. Consequently, clinicians should take a prudent, perhaps even a conservative approach in such situations, resolving reasonable doubts in favor of the patient.

References

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