

Topical review

Ethical issues in opioid prescribing for chronic pain

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Medical ethics traditionally focused on ensuring that physicians used their powers benevolently. Since cure was unusual, palliation, symptom control and relief of suffering were central to the physician's art. Not surprisingly, given their unique ability to control suffering, opioids were indispensable, and a constituent of many remedies. They were freely dispensed by pharmacists and physicians, their use being limited largely by the conscience of the individual, or by limited supplies.

At the beginning of the 20th century, drug regulations were introduced into the United States and other industrialized nations. These regulations attempted to control the import, distribution and trade of narcotics, and placed the onus on physicians to control medical use of opioids. There was thus an immediate switch of the moral imperative from patient to physician, and in fact a chilling effect on the provision of opioids for pain. The stigmatization and criminalization of opioids produced by regulations continues to interfere with the rational use of opioids for pain to this day.

Paradoxically, other changes in medicine have shifted medical decision making away from physicians, into the hands of patients. Modern medicine has the capability not only to cure, but to create, extend or terminate life, with such profound implications contemporary medical ethics have had to adapt. It is a philosophy of liberalism that now guides medical ethics in free countries. The physician is no longer seen as all powerful, or the chief decision maker in an active–passive relationship, but instead enters a guidance–cooperation relationship whereby the patient is the chief decision maker, guided by the physician [28]. This has been formalized in the concept of shared decision making in which all of the alternative treatments and outcomes are explained and patient preferences for each are assessed [9]. The evidence supporting the capability of a treatment to achieve patient chosen outcomes becomes an important basis for the process of shared decision making.

Outcomes considered desirable to patients are often encapsulated in measures of health related quality of life (HRQoL). In addition, direct measures of patient satisfaction can be used to assess patient preferences. Patient satisfaction could, in fact, be considered the only “true” outcome, and other outcomes merely “surrogates” [17]. But what does patient satisfaction actually mean when the treatment is an addictive drug and how valid and reliable are

our measures of patient satisfaction [25]? In pain studies, patient satisfaction may be the only positive finding while measures such as HRQoL, function, health care utilization and pain itself show no improvement [6,12,13,31]. It seems that simply addressing pain, even if the treatment itself has only marginal benefit, may improve patient satisfaction [21,32].

Patient satisfaction is a complex concept incorporating many dimensions including sociodemographic, cognitive (evaluative) and affective (emotional), in their turn influencing the expectation that underpins satisfaction – satisfaction being the congruence between expectation and accomplishment [17,27,29]. Patient satisfaction instruments have many limitations, including lack of psychometric standards, the poor reliability and validity of surveys, and discriminatory assessment [5]. Many patient satisfaction surveys also lack discriminatory value. Thus pain treatment may contribute to global satisfaction with medical care, while closer analysis may reveal satisfaction with pain treatment is actually less than with other aspects of care such as interpersonal interaction [23,33]. Health care organizations frequently utilize patient satisfaction ratings as an integral part of marketing and benchmarking of services [1]. This can be problematic when it comes to opioid pain treatment: clinicians may feel threatened into prescribing in order to meet the satisfaction metrics by which they and their practices are judged. Here the moral issue is whether prescribing opioids to drive up patient satisfaction metrics is justified.

In the United States, unlike Europe, 20th century regulations made it illegal to prescribe opioids for addiction. Clinicians risked censure (or loss of medical license) if they prescribed opioids (for pain, but unwittingly for addiction), and patient fears of addiction were exacerbated because addiction had been criminalized. Pain was then undertreated, and it took years of lobbying and political activism, culminating in the enactment of “intractable pain” statutes, to restore opioid treatment for intractable pain (including intractable chronic pain) [3,14,18]. Pain advocacy in the United States extended its reach even further when advocates succeeded in persuading The Joint Commission (TJC, formerly known as JCAHO) to include pain management as a quality metric for healthcare facilities [11]. Although it was never the intention of the mandate to force opioid treatment of pain, the fact that opioids are sometimes the only option for treating severe pain meant that in practice, the mandate did increase opioid prescribing, sometimes with unintended consequences [30].

Given this history, and the hard fought campaign to establish the right of patients to receive opioids for the treatment of pain

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in the wake of the intimidation caused by 20th century drug regulations, it is important to emphasize that the ensuing discussion does not question the important principle established in previous charters and mandates that opioids are indispensable for the treatment of severe pain during acute and terminal illness [3,14]. However, the idea that opioids are indispensable for chronic pain, and therefore physicians are obligated to prescribe for chronic pain will be challenged. As a basis for this discussion, let us posit that there exist circumstances under which one would be justified in not prescribing. For a new commitment to chronic opioid therapy, these circumstances might be pain that is only mildly or moderately debilitating, a history or family history of drug abuse, or a patient's refusal to try alternative approaches. Two, or worse three, of these circumstances coexisting might strongly suggest not prescribing. For ongoing treatment, the circumstance might be failure to meet the goals of treatment. Now we do not know with any certainty that these circumstances do indeed predict poor outcome, and it is not the intention of this review to examine or validate predictors, suffice it to say that on the basis of current evidence and experience few people would disagree that the circumstances outlined here do seem to be strong predictors of failed chronic opioid therapy.

Take the case then, that there are rational reasons, such as those mentioned here, that suggest that a patient will not benefit from chronic opioid treatment. In that case, the ideal would be that within the guidance-cooperation model of care [28], the clinician and patient mutually agree that opioids should not be used, based on their shared knowledge and understanding. But if the patient does not agree, who should predominate in the decision? The clinician may be in a better position than the patient to understand benefit versus risk, partly because the clinician may be better informed about treatment limitations, particularly as they relate to long-term use, and partly because the clinician is detached from the pervasive effect intractable pain has on the pain sufferer, or the influence of past or present drug use. For example, pain itself erodes patients' autonomy and dignity and compromises their decision making capacity. The inevitable development of dependence that accompanies long-term opioid therapy makes it hard to wean patients off opioids, and withdrawal phenomena including withdrawal hyperalgesia can be interpreted as needing opioids even when opioids are not providing good pain relief [7]. Dependence and addiction affect judgment, and arguably make it impossible for the dependent or addicted individual to make rational decisions about opioids. While the assumption of a patient's incompetence may be a violation of the patient's autonomy, and may represent unjustified paternalism [2,24], it acknowledges that both pain and opioids can at times compromise an individual's ability to fully understand opioid limitations.

Take now a separate case that relates more to society than to the individual patient. Responsibility for society at large has tended to be the province of politicians and the legal system, and not physicians, whose primary duty is to the patient [26]. But what if evidence suggests that for the population as a whole, opioid treatment of chronic pain comes at a very high price: because the goals of treatment are not met [8,13,15,31], and because prescription opioid misuse, abuse and related deaths increase with increased prescribing for pain [4,19,20,22], much related to unprotected prescription opioid in the community [4,16]. The case is that on a population basis long-term opioid treatment has only marginal benefit (on the basis of population studies) and is extremely costly (in terms of abuse, misuse and related deaths), so it might be considered inappropriate and therefore inadvisable to offer. One of the most difficult questions facing bioethicists is exactly this – whether patients have the right to demand a treatment that is of questionable benefit and costly [24]. The debate is centered on whether patients' wishes should override costs to society. These

debates will be judged differently according to culture and country, differences that have been starkly revealed during the recent health care debates in the United States. In the United States, the ethos is that patients' choices should be respected, regardless of cost to society. In the opioid debate, the cost to society is the cost of abuse and misuse. If the clinician sees merit in opioid therapy for an individual patient, then traditional values of duty to patient apply. But for the patient who claims a right to treatment that is not agreed upon, in that case the clinician must surely step outside the bounds of the therapeutic bond, and consider the broader consequences to society of opioids provided solely on the basis of demand. After all, when clinicians fail to control abuse and misuse, the regulatory authorities step in, and the freedom to prescribe is constrained, possibly leading back along the path to unnecessary suffering. Only practitioners, as individuals, and in their respective professional bodies, can refine and rationalize their own practices (on the basis of better knowledge) in order to improve safety, reduce catastrophic outcome, and so reduce the need for regulatory action, and this component could be considered part of their moral duty to patients.

Whatever changes there have been in the respective positions of clinicians and patients with regard to their role in medical decision making, as professionals committed to healing, clinicians will always resist being expected to dole out whatever services their patients desire [24]. Clinicians feel obligated to provide treatments that minimize harm (nonmaleficence) and are consistent with their commitment to do good (beneficence). This stance is represented by the principle of correlativity, articulated by Beauchamp and Faden [10]. They suggest that right does not exist without obligation. In other words, for someone to have the right to something, someone else must have a correlative obligation to provide it. Without the correlative obligation, the right is meaningless. So in the debate about whether it is ever ethical to deny opioids to a patient in pain, perhaps one should start with the obligation. The argument runs that when a clinician judges that a treatment will do more harm than good, there is no obligation to provide that treatment, so the patient does not have the right to demand it. At the same time, where a judgment exists that a treatment is inadvisable, all relevant viewpoints should be respected. There will be patients with chronic pain helped by opioids, and hopefully, regulatory constraints will not interfere with the ability to prescribe opioids for those who benefit. At the same time, there will be conditions such as those posited here, that strongly suggest that opioid treatment is not suitable, and should be denied, even when the patient demands it, or claims satisfaction. In this review, we have explored reasons that denying opioids in some cases is ethically justified. We should not, however, lose sight of the history of years of lobbying to establish the right to opioid treatment for those with unquestionable need, or let our efforts to moderate opioid treatment for chronic pain damage the gains made in establishing the right of patients to receive opioids for appropriate indications.

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