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IN THE LITERATURE

A Clinical Ethics Approach to Opioid Treatment of Chronic Noncancer Pain

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Ballantyne JC, Fleisher LA. Ethical issues in opioid prescribing for chronic pain. *Pain*. 2010;148(3):365-367.

We are writing both to respond to Ballantyne and Fleisher's 2010 article on the ethics of opioid prescribing [1] and to join the authors in calling for continued progress in rational, ethical, and practical decision making surrounding the use of opioids in the treatment of patients with [noncancer chronic pain](#). Given the current state of knowledge regarding [long-term opioid treatment](#), we suggest that dilemmas associated with this treatment are best approached using patient-centered clinical ethics. We believe principle-based, deontological, and classical Hippocratic ethical approaches have less relevance in sorting out [current controversies](#) surrounding opioid treatment.

We agree with the authors' concise history of how opioid use in medicine has most often been determined by fearful attitudes and politics [1] and rarely arrived at rationally [2], let alone through application of ethical models or evidence-based practice [3]. We welcome exactly this sort of thoughtful reflection on the ethical implications of opioid prescription for chronic painful illness. Ballantyne and Fleisher accurately reflect expert consensus that the most difficult clinical dilemmas involving opioid analgesics arise in treating chronic nonmalignant pain, not acute postinjury or perioperative pain [4, 5] or even terminal painful illness [6-8]. Even though there is widespread consensus about the majority of uses for opioids for chronic malignant pain, approximately 50 percent of cancer patients still face barriers to pain care [9]. If this is the status of pain care in cancer, an area about which there is reasonable ethical consensus, it is not surprising that noncancer chronic pain is even less adequately addressed. This discrepancy highlights the need to work toward greater agreement on solutions to the ethical questions involved in delivery of care to patients with this kind of pain [10, 11].

Ballantyne and Fleisher trace the most recent wave of arbitrary limitations on opioid prescribing to the early twentieth century, when physician influence on treatments offered to patients began a steady decline. This decreasing influence has been ascribed to a combination of factors, including increased regulation of the manufacture, trade, and prescription of opioids; stigmatization of opioids through special prescribing requirements and criminalization of addiction [1]; expanded tracking and limitation of physician practice through "managed" care; attention to control of medical "utilization";

and physicians' fear of review by state licensing boards [12]. Progress in managing these potentially restrictive forces has required advocacy from patient groups, professional pain treatment organizations, and coalitions of these and other stakeholders [13]. As the twentieth and twenty-first centuries have unfolded, these limiting influences have combined with [growing concerns about prescription opioid diversion](#) and [abuse](#) [14, 15], making clear the need for a solid, ethical foundation for opioid treatment of chronic nonmalignant pain.

Need for Pain Treatment and Status of Data on Opioid Treatment

Our current knowledge of unaddressed pain-related suffering and the efficacy and relative safety of opioids, at least for short-term pain control, require us to address the problem of undertreatment of chronic pain. We know more about the prevalence of, cost of, and unmet needs for treatment of chronic noncancer pain than we did in the early twentieth century.

Across the United States and Europe, up to 55 percent of patients suffer some degree of chronic pain, and up to 19 percent report [chronic pain](#) of moderate or higher intensity; an additional group, as large as 10 percent of the population, have disabling pain that undermines daily function and freedom to pursue goals and interests [4, 5]. The annual cost of chronic pain in the United States exceeds \$200 billion, with the bulk of that amount representing lost productivity, disability payments, and rising medical costs for treatments [16].

Since the early twentieth century, we have also learned a great deal more about opioids in chronic pain treatment. Opioids work on nociceptive and neuropathic pain states [17], compare favorably with gold-standard antineuralgics like tricyclics and anticonvulsants in certain disorders [18], have a reasonable safety profile, if properly titrated and taken as prescribed, do not necessarily impair psychomotor speed or prohibit driving or working [19, 20], and can reduce pain and improve quality of life in conditions studied [21-23].

Data from animal studies raise concerns that chronic use of these drugs at high dosages may lead to hyperalgesia and opioid insensitivity, but it remains unclear whether such phenomena occur in humans [24]. Another area of uncertainty is whether opioid treatment benefits extend much beyond 16 weeks in responsive patients. We are sorely lacking in high-quality long-term outcome data for opioid treatment of chronic nonmalignant pain. During the recent quarter century of more liberal use of opioids for noncancer pain, no well-designed studies of treatment longer than 16 weeks have been published. This lack of published efficacy data for the past 25 years is a scientific stumble, if not an ethical oversight, that demands correction. Anecdotal reports, case series, and extended open treatment arms of shorter controlled trials suggest possible benefits of opioid use exceeding a year [25-27], but the best studies have involved short

treatment periods of one to three months.

Ethical Approaches to Opioid Treatment of Noncancer Pain

We believe that the lack of data makes deontological and principle-based ethics difficult to apply. These are deductive forms of ethical reasoning to the extent that they rely on applying overarching concepts to data to resolve particular patient dilemmas. If we don't have long-term outcome data, deontological imperatives like "minimize suffering" and principles like "justice" become vague. Lack of data leaves us uncertain about whether painful suffering addressed in the short term might be replaced in the long term by different suffering (e.g., side effects), and it is hard to determine whether equal access is a moral fairness imperative in the case of an as-yet-unproven long-term therapy.

Certainly, foundational Hippocratic ethical values apply—for example, primacy of the patient-doctor relationship, confidentiality, and acting in patients' best interest [28]. The last Hippocratic value is relevant to opioid treatment decisions since it requires physicians to deny inappropriate treatments requested by patients, no matter how much patients or their advocates want that treatment. Opioids for pain requested by a patient who is actively abusing alcohol would therefore be prohibited. Beyond this emphasis on the clinical obligation to "say no" when opioids are not appropriate, Hippocratic values have no particular ability to clarify decisions about opioid treatment.

We argue, therefore, that, in a data-thin area of practice like chronic opioid treatment, it makes most sense to apply clinical ethics, that is, an inductive ethical reasoning process that generalizes from individual cases, because good practice will always produce rich case data. Clinical ethics is not population based; it is patient-centered, emphasizing patient autonomy, shared decision making, collaborative goal setting, attention to context and psychosocial factors, and enhancement of individual quality of life. Clinical ethics adheres to the specific realities of a particular case, such as the indications for specific treatments, education about possible adverse effects, and description of consequences of declining recommended treatments. Society-level ethical questions are not at the center of case-based ethics. For example, positing a patient right to receive pain treatment or a physician obligation to provide it doesn't revolve around individual case features and, therefore, is not best addressed with clinical ethics. Similarly, in decision making an individual patient's well-being trumps societal factors such as health care costs or equal access to care. Since we don't know the ultimate clinical value of chronic pain treatments, addressing the broader ethical and social questions like equal access and cost involves significant assumptions and speculation. In our view, therefore, clinical ethics can be most usefully applied to pain treatment at this time.

Six-Step Ethical Decision Making for Opioid Treatment

We have used clinical ethics in a six-step iterative, case-based process for deciding whether opioids are appropriate for patients with chronic, nonterminal pain. Consistent

with clinical ethics and good pain care, our process requires longitudinal treatment and comprehensive assessments. Clinical data from close monitoring is at present the best data we have for making these decisions. We outline below the six steps: narrative pain history, assessment of identifiable causes of pain, collaborative goal setting, ongoing treatment plan adjustments, updating of treatment goals, and regular revisiting of pain diagnosis.

The first step is developing a patient's pain narrative, which includes noting the contextual and psychosocial [factors affecting the patient](#). "Pain" is never an adequate chief complaint. Eliciting the narrative pain history is time-consuming and extends beyond inquiring about pain quality, intensity, and location(s) to learning about the person's experience of living with chronic pain. How do particular pains limit function; how much fear and anticipation of pain are involved; to what degree are sleep and circadian rhythm disrupted; do psychiatric comorbidities like depression, anxiety, and substance use disorders (which often complicate pain-related suffering) play a role; do seasonal changes affect the pain; and what patient behaviors are relevant, helpful, or problematic? [29-33]. Examples of helpful behaviors include communicating effectively about pain, breaking tasks into subtasks, and resting by the clock when active instead of being shut down by pain. Problematic behaviors include overexertion or becoming sedentary, denying or overfocusing on pain, and seeking a cure for conditions for which pain accommodation and control are the realistic goals. Until problematic aspects of the person's pain narrative are understood and addressed, it is difficult to estimate the effectiveness an opioid trial will have in clinical practice or research.

The second step is attempting to identify pain pathophysiology and the pain generator(s) to the degree possible in the current state of our knowledge. This step addresses the ethical duty to offer only those treatments that will be appropriate and effective. Using opioids for poorly characterized or understood pain makes assessment of their efficacy difficult. Put simply, you must have reasonable clarity about what you're treating to choose rational interventions and assess benefit. While we regularly see patients with total-body pain and widespread allodynia, using an unproven treatment for these diffuse pain presentations is problematic. Which pain component or area of pain does the clinician track? How do we know if the patient is improving? Even difficult pains like brachial plexopathy, phantom-limb pain, postherpetic neuralgia, and axial low back pain, for example, are clinically clearer entities, which makes it easier to gauge opioids' effects.

If the pain is focused enough to be tracked and the physician has a reasonable sense of pain generator(s), opioid treatment may be appropriate to prevent or treat central nervous system changes—like reorganization of pain pathways, changes in dopamine levels and other neurochemicals, and lost density in cortical and precortical brain regions—that have been demonstrated in at least some patients with chronic pain [34-38]. If further clinical evidence demonstrates that such changes occur in large numbers

of patients with chronic pain, if imaging of these changes becomes practical outside of research settings, and if these changes prove to be controllable with treatment, chronic pain itself, in the absence of clear pain generator(s), may become an adequate clinical indication for ethical treatment with opioids.

The third step, goal-setting, is the most critical. True to patient-specific practice, the goal-setting process is highly individualized and collaborative. Goals must be broader than pain reduction. Assessing only pain level—a single-variable outcome—is incongruent with the quality-of-life focus so central to clinical ethics. Goals must be specific, meaningful, and personal—for example, being able to sit through a movie in a theater, cook again, drive 45 minutes to visit aging parents, or walk a child to a school bus stop. Progress toward very specific goals can be assessed in terms of steps made toward the goal, which makes the contributions of opioids and other interventions easier to collaboratively assess. A relevant assessment question might be, what did we do that made the most difference in getting you to the movies—do you think taking your pain medication or doing your home PT exercises helped more? Specific behavioral goals to be met through opioid therapy must be accompanied by a clear description of realistic expectations for pain reduction (not elimination); discussion of side effects; and disclosure of the limitations of current knowledge, especially regarding long-term benefit. Realistic expectations of opioid therapy and possible complications have been shown to correlate with improved outcomes and increased patient satisfaction [39-41].

Fourth, we periodically reassess patient progress and consider modifications to the treatment plan. Interventions that were unhelpful in this particular case (e.g., epidural injections or deep tissue massage) will be discontinued; others that helped (e.g., acupuncture, antineuralgic analgesics like gabapentin) will be continued. If opioids have been added, the same evaluation of whether to continue or discontinue treatment occurs.

The fifth and sixth steps bring us full circle in this iterative clinical ethical analysis. In step five, goals accomplished are replaced by the next goals on the list from step three, and goals not yet completed are broken into smaller subgoals. In step six, fundamental treatment decisions are revisited in light of accrued clinical data. As pain diagnoses and treatment indications become clarified over time, as the benefits and side effects of treatments become real and not theoretical for a given patient, as shaping contextual and psychosocial factors become more evident, and as the patient's own treatment preferences change with experience, these factors inform the ongoing decision making regarding continuation of opioid therapy.

Summary

Untreated chronic pain, both cancer-related and not, remains unacceptably prevalent and costly, even in medically sophisticated settings across the United States and Europe.

Available treatments for chronic nonmalignant pain have not been shown efficacious by robust data, whether the treatment in question is cognitive behavioral therapy, biofeedback, interventional anesthesia, or ongoing opioid medication [16, 42, 43]. Combining these treatments in the setting of multidisciplinary treatment programs, on the other hand, has been demonstrated efficacious in more than 60 studies [44], so the negative results may be partly due to studying available treatments in isolation. Although we need better long-term data showing opioids' efficacy, the same can be said for all available treatments for chronic pain. In the meantime, data to date suggest that opioids are at least partly efficacious for reducing pain and improving quality of life, with acceptable safety, for those with various chronically painful conditions. Given the status of our current knowledge, we have suggested a six-step decision-making process for opioid treatment that is based in clinical ethics and relies on comprehensive evaluation and data accrued through longitudinal care.

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