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Current Concepts in Physiatric Pain Management

Current Regulations Related to Opioid Prescribing

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Abstract

It is the responsibility of medical professionals to do all that is possible to safely alleviate pain. Opioids are frequently prescribed for pain but are associated with the potential for misuse, addiction, diversion, and overdose mortality, and thus they are strictly regulated. To adhere to legitimate practice standards, physicians and other health care providers who prescribe opioids for pain, particularly on a long-term basis, need current information on federal and state laws, treatment guidelines, and regulatory actions aimed at reducing opioid-related harm. The number of opioid-prescribing policies is increasing as federal and state governments increase scrutiny to alleviate opioid-related problems in society. Failure to adequately comply with opioid-prescribing laws and policies may put a prescriber at risk for legal or regulatory sanctions. Necessary actions include thorough documentation of prescribing decisions and assessment and follow-up of patient risk for opioid misuse or addiction. Tools to check for patient adherence to the prescribed regimen include prescription monitoring databases and urine drug screening. This article presents an overview of the legal and regulatory framework surrounding controlled substances law. It further discusses recent actions at the federal and state level to prevent opioid-related harm.

Introduction

Opioids have long been mainstays of pain control in acute, cancer, and palliative settings and, as the result of a cultural shift during the past 2 decades, they are now more frequently prescribed for people with chronic noncancer-related pain. The increase in the quantities of opioids prescribed coincided with increases in abuse, misuse, addiction, and overdose mortality linked to prescription drugs, including opioids [1-4]. To examine part of this trend, see Figure 1, which shows the opioid-related overdose rate compared with opioid sales from 1999-2013 [4].

Pain is endemic to the human condition. In a 2005 media survey conducted in collaboration with Stanford University Medical Center, only half of people with chronic pain (ie, those whose pain has lasted longer than 3 months, including patients with cancer) said their pain was adequately relieved after a doctor visit [5]. A difficulty in medical practice is balancing the imperative to relieve pain with the risk associated with opioids to society and the individual patient.

Furthermore, pain management should not automatically be equated with the administration of opioid analgesics. Evidence suggests that opioids are not equally effective for all patients with chronic pain. Effectiveness data for opioids administered on a long-term basis for pain are sparse. In a review of more than 70 randomized trials that evaluated benefits or harms of opioids for chronic noncancer-related pain, nearly all were short-term efficacy studies lasting 16 weeks or less [6]. Only 3 studies followed up on patients for longer than 4 months, and most studies excluded patients at high risk for substance abuse or with significant medical or psychiatric comorbidities [6]. These particulars complicate studies of efficacy, considering the high prevalence of psychiatric comorbidities in the real-world population of patients treated with opioids [7]. Furthermore, many patients discontinue use of opioids because of inadequate analgesia or adverse effects. However, a systematic review indicated that opioids are helpful for a subset of patients with chronic pain and that they continue to demonstrate benefits for patients who are able to continue treatment for at least 6 months [8]. Just as opioids are not uniformly effective, nor are all patients at equal risk for misusing them.

The struggle to balance pain relief for patients who benefit from opioids against the potential harm from opioids to individuals and society takes place against

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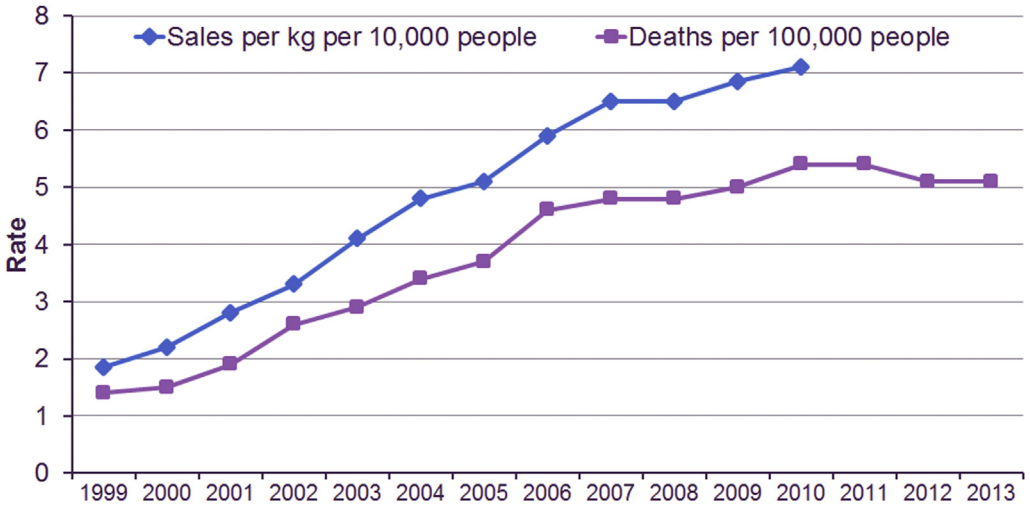

Figure 1. Rates of prescription opioid sales and deaths, 1999-2013.

a backdrop of increasing legislative and regulatory focus on eliminating the societal problems of opioid misuse, addiction, and overdose. As controlled substances (CSs), opioids are tightly regulated; physicians and others who prescribe opioids for pain management must follow federal and state laws that govern CSs or face regulatory and legal sanctions. Knowledge of the regulatory structure and best known evidence- and consensus-based prescribing practices can mitigate the potential that exists for the following scenarios:

- Contributing to individual and societal ills
- Consequences to the prescriber, such as a lost license, disciplinary action, and criminal prosecution
- Unwarranted fear of prescribing opioids, when indicated, that can lead to failure to adequately treat pain

Knowing about the potential for harm with opioids can help prescribing practitioners protect patients and their own practices. Although the prescriber of opioids has no control over the patient's behavior once he or she leaves the clinic, the prescriber is responsible for evaluating, treating, and monitoring the patient. A variety of monitoring methods exist, including state prescription drug monitoring databases, urine drug testing (UDT), and input from family members [9]. Although this article primarily addresses the topic of chronic pain, research indicates that excess opioids that are prescribed in acute, trauma, and perioperative settings contribute significantly to diversion through leftover medications and lack of patient counseling for proper disposal [10].

Recognizing the Potential for Misuse and Diversion

People misuse opioids prescribed for pain for various reasons [11]. Misuse of opioids encompasses any willful or unintentional use other than as directed, whether or not harm results [10]. In contrast, the concept of abuse is more closely associated with nonmedical use, which is the intentional self-administration of a medication without a prescription or strictly for the feeling it produces [2,11]. Approximately 4.5 million Americans are current nonmedical users of opioids [11].

Nonmedical users obtain opioids through diversion, which is the intentional removal of a medication from legitimate dispensing channels, that is, for a legitimate patient, for a legitimate condition, and for a specified period. Diversion can include obtaining prescription drugs under false pretenses, stealing them, selling or giving them to others, using them recreationally, or saving them for later use. Only 21% of abused drugs are obtained directly from 1 doctor; most are obtained from family and friends [2]. "Pill mills," which are operated by people who are not medical professionals or staffed by unscrupulous physicians, dump illicit opioids into communities; in addition, street gangs and other criminal groups are stepping up participation in the prescription drug trade [12]. The following features are typical of pill mills [13]:

- Nonphysician owners who retain physicians for their federally granted registrations to prescribe opioids
- On-site dispensing of pills
- Fake appointments at which no real medical assessment or follow-up takes place
- A cash-only basis, meaning no insurance is billed
- One form of treatment: pills

Other forms of diversion include "doctor shopping" by patients (ie, visiting different medical practices to obtain unauthorized drugs), illegal Internet pharmacies, drug theft anywhere along the supply chain, and prescription forgery [12]. People who illegally divert prescription drugs for financial gain sometimes pose as