

A Review of Forensic Implications of Opioid Prescribing with Examples from Malpractice Cases Involving Opioid-Related Overdose

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Abstract

Objective. To provide a forensic overview and trace common threads among malpractice lawsuits involving patients who overdosed while consuming therapeutic opioids.

Methods. One of us (LRW) reviewed 35 medical records of patients with chronic pain who overdosed, 20 of them fatally, while consuming therapeutic opioids, leading to lawsuits against physicians for malpractice. The reviews were requested by plaintiff and defense attorneys from across the United States from 2005 to 2009 to ascertain which drug(s) were primarily responsible for each death and whether the death was due to physician error, patient nonadherence, or some other reason. Complaints against pharmaceutical companies were excluded. Cases were examined for common trends, and comment is offered.

Results. Methadone was responsible for the most deaths at 10 (50%), and hydrocodone was second at four deaths (20%). The most common risk factors found in the medical records of decedents included prescriber error in initiating, converting or titrating doses, patient nonadherence to medical instruction, presence of comorbid mental disorders, toxicological presence of benzodiazepines, middle age, and unrelieved pain. This article focuses on examples of physician errors and how they can be prevented.

Conclusions. Common trends emerge from medical records of opioid decedents. Patient actions con-

tribute, but physician error, particularly regarding prescribing methadone for pain, is apparent as well. A focused effort to determine the types and causes of common physician errors and how they might be avoided may lead to safer, more effective clinical interventions in the management of pain.

Key Words. Chronic Pain; Legal Liability; Medical Malpractice; Methadone; Mortality; Opioid-Related Overdose

Introduction

It is one thing to cite statistics supporting the observation that opioid-related deaths have risen drastically in recent years [1,2]. It is quite another matter to obtain and interpret specifics of how the deaths occurred so as to inform clinical practice going forward. We begin by acknowledging that data are meager. This discussion of a small, select group of malpractice lawsuits involving opioid overdose is not meant to present a comprehensive or systematic analysis of deaths due to opioids but to serve as a forensic snapshot for the purpose of gaining potentially useful information about how to prevent harm. A principal way to avoid errors is to learn when and under what circumstances they may be predicted. In *Human Error*, author James Reason writes, “The accuracy of error prediction depends very largely on the extent to which the factors giving rise to the errors are understood” [3], and so we surmise that to correct errors arising from clinical practice involving opioid therapy, we must first accurately analyze cases that resulted in harm.

When possible, it is important to separate physician error from patient error to facilitate appropriate interventions. We wish to emphasize a point early in the discussion and analysis of physician error. All therapeutically intended medical interventions involve potential risk. The classic medical aphorism “primum non nocere” (“first, do no harm”) is problematic to the extent that it suggests there are risk-free measures, including nontreatment. Thus, the guiding principle for clinicians (and patients, through the informed consent process) is a thoughtful risk–benefit calculation for each and every treatment option to weigh risks (potential harms) against intended therapeutic benefits.

Methods

One of us (LRW) reviewed 35 records of patients with chronic pain who overdosed, 20 of them fatally, while

Table 1 Summary of medical records review [4]

Observation	N = 20 (%)
Morphine equivalent dose >60 mg at time of death	20 (100)
Pain level at proximate time of death >6/10	20 (100)
Decedents had been taking opioids >6 months	20 (100)
Complaint of or signs of respiratory infection at time of death	3 (15)
History of snoring	12 (60)
Known history of sleep apnea	6 (30)
Evidence of current or past substance use disorder	8 (40)
Diagnosis of mental health disorder	14 (70)

consuming therapeutic opioids, leading to lawsuits against physicians for malpractice. Plaintiff and defense attorneys from across the United States requested the reviews from 2005 to 2009. The purpose of the reviews was to assess which drug(s) were primarily responsible for each death and whether the death was due to physician error, patient nonadherence, another reason, or a combination of factors. Complaints against pharmaceutical companies were excluded.

LRW reviewed at least 1 year of medical records for each patient. Table 1 contains the criteria for the review and results from 20 cases of fatal overdose previously presented in abstract form [4].

Physician error was cited if any of the following factors were present:

- Started opioid-naive patients on dosages that exceeded 30 mg methadone per day.
- Rotated from another opioid to methadone with a starting dose >40 mg a day.
- Directed a patient to increase a dose of methadone to >40 mg within 1 week.
- Started transdermal fentanyl at ≥ 50 mcg/h in opioid-naive patients.

Patient nonadherence was determined by evidence that patients used more medication than prescribed and prescribing was otherwise appropriate.

Results and Key Trends From Case Reviews

In 20 fatal opioid overdose deaths, methadone was the most common opioid judged responsible, associated with 10 deaths (50%), and hydrocodone was second at four deaths (20%) (Figure 1) [4]. In 15 (75%) of the deaths, physician error was the cause. The remaining five deaths (25%) were due to excessive opioid consumption, patient nonadherence to medical direction, benzodiazepine and sedative overdose, a defective medication patch, and use of an illicit substance.

Eleven (55%) decedents were discovered in the morning, and 12 (60%) of them were found in bed, suggesting a relationship between sleep and overdose. Thirteen deaths (65%) occurred within the first week after a change in prescription dosage (Figure 2) [4]. This last finding suggests that some early deaths are due to too high of a starting dose and/or too rapid of a dose titration. The majority of decedents were between the ages of 36 and 59 (Figure 3) [4]. Twelve decedents (60%) were male.

Common trends, some of which are out of the hands of physicians, also emerged upon review of the medical records of decedents. These trends include the following:

- Evidence of past and current mental health disorders, suggesting the possibility that the patients may have been self-medicating with opioids to relieve psychiatric symptoms.
- Patterns of running out of medication early, suggesting use in excess of that prescribed.
- Continued high levels of pain that do not respond (or respond sporadically) despite titration of doses or rotation to other opioids.
- The common presence of benzodiazepines in autopsy toxicology reports.

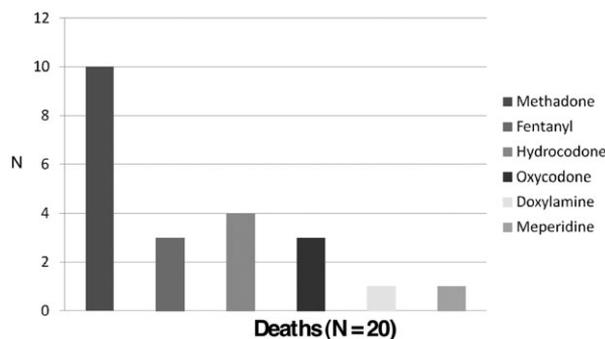


Figure 1 Drug(s) found primarily responsible for death in malpractice cases [4].

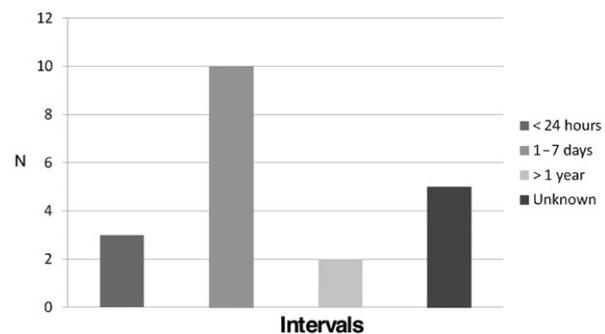


Figure 2 Interval between dosage change and death [4].

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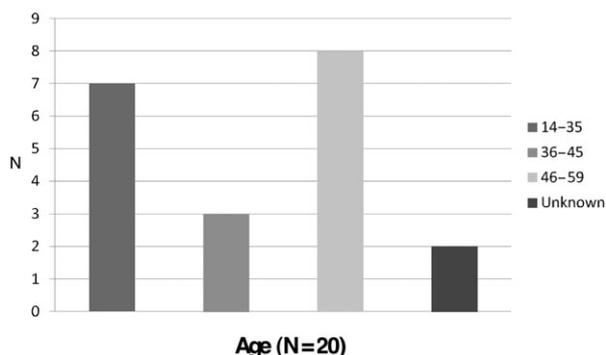


Figure 3 Age of decedents [4].

The high prevalence of physician-related prescribing errors demands attention. Determination of the types and causes of avoidable errors can lead to safer, more effective clinical interventions in the management of pain. Extracts from case reviews will be used to exemplify cardinal points.

Evidence of Physician Knowledge Deficits

A number of knowledge deficits, illustrated when physicians acted using information that was incorrect, ill-advised, or out-of-date with regard to safe opioid prescribing, emerged in the case studies. Errors of this type included:

- Initiating too high a starting dose.
- Titrating doses too rapidly.
- Converting to a different opioid using inadequate guides.
- Failing to screen and monitor for medical or mental comorbidities that can compromise opioid therapy.

Analysis of the clinical records involving opioid-related toxicity suggests that knowledge deficits are common in methadone prescribing for pain. Inadequate treatment plans are likely to follow from inadequate guidelines. For example, the label approved by the Food and Drug Administration (FDA) for methadone prior to November 2006 endorsed initial doses of up to 80 mg per day. New science emerged, and the FDA issued a public health advisory to warn of deaths from methadone and to revise the prescribing information to a 30 mg per day initial ceiling dose [5]. Today, conservative initiation, titration, and monitoring of methadone is the rule. However, some physicians remain unaware of the cautions surrounding methadone.

To illustrate, consider the following example:

A man with intractable back pain following two surgeries was switched from a short-acting opioid to extended-release oxycodone. The record begins to reflect problems with patient adherence. His pills “fall in a mud puddle,” and he habitually runs out of medication early. He is taking oxycodone 80 mg three times a day and an addi-

tional opioid for breakthrough pain. However, the regimen “is not working as well as it used to,” according to the patient. The patient enters a detoxification program and is treated with buprenorphine sublingual, which adequately controls his pain. For reasons unspecified, the successful treatment stops. The patient returns to the pain clinic, reporting symptoms of depression, anxiety, and sleep disturbance. Methadone is initiated at a dose up to 80 mg a day (in excess of the FDA-approved dose). The patient subsequently dies of methadone toxicity.

The high prevalence of methadone-related deaths points to prescriber error because those who are unfamiliar with the drug’s unique pharmacologic properties can cause problems when prescribing it. Many physicians lack familiarity with the safest available guidelines for initiating, titrating, or converting a dose of methadone for pain. Some of them know they lack this knowledge, and some of them do not know. Errors proceeding from this latter type of knowledge deficit may continue for years on the part of the practitioner.

A woman suffered from rheumatoid arthritis and chronic low-back pain. Her primary care physician prescribed a regimen of immediate-release oxycodone to treat around-the-clock pain and methadone as needed for breakthrough pain. Pain relief was inconsistent and various medication choices were tried. Prior to her death at age 48, the patient was accustomed to taking up to four hydrocodone/acetaminophen 10 mg up to four times a day. The physician, fearing acetaminophen poisoning, made the switch to methadone by initiating the patient’s dose at 20 mg three times daily or as needed up to 60 mg per day.

Knowledge deficits are apparent in this case. The converted dose of methadone was too high by FDA-approved labeling standards. At deposition, the physician claimed to have within her possession government reports mentioning 60 mg as a starting dose for methadone. She was not, however, familiar with the current FDA-approved conversion chart from the manufacturer of methadone suggesting a 10% to 20% equivalency for converting to methadone, which would have been 16 to 32 mg per day [5]. The same label notes that deaths have occurred during the conversion process and warns clinicians not to base methadone conversion solely on the chart but to individualize methadone conversion and titration. Furthermore, the patient had mistakenly been encouraged to think of methadone, a long-acting medication with a long and variable half-life, as a breakthrough pain medication to take “as needed.” The physician defended her medical decision by stating her belief that methadone is appropriate to treat the breakthrough pain of “some patients.” Some clinicians might agree that this is acceptable practice, but in our opinion, methadone used in this way arguably may pose an unnecessary risk to the patient.

An expert in pain medicine could well come to the conclusion that methadone prescribing was done outside the standard of care in this case. However, such an opinion is not tantamount to establishing said

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standard of care. Methadone prescribing is complex given its unique pharmacologic properties. Conflicting information regarding safe dosing and titration is available from multiple sources, and consensus has not yet been reached.

Given the cautions surrounding methadone, it is worth considering treating all patients starting methadone as opioid naïve regardless of prior opioid dosage.

Knowledge deficits are further highlighted in a lack of awareness of or appreciation for the emerging science of pharmacogenetics, the intersection of pharmaceuticals and genetics. This dynamic can be observed in the recent proliferation of opioid guidelines such as the ones published by the state of Washington's Agency Medical Directors' Group espousing the same opioid maximum dosage for every patient [6]. Such a policy is inconsistent with growing evidence that personalized medicine is necessary and should be based on each patient's individual opioid response [7]. This is only one illustration of how guidelines may reflect a particular bias and/or be unsupported by good data.

Legal and Regulatory Obligations in Opioid Prescribing

An important general proposition in medical malpractice law says a physician is not liable for a "mere error in medical judgment" [8]. To hold a professional to such a standard would be to demand consistent error-free performance, i.e., perfection. What is required is that a physician possess and consistently demonstrate a level of medical knowledge and skill commensurate with other physicians with similar training and experience when caring for a patient who presents with similar clinical issues.

Because medicine is one of the learned professions, physicians are charged with a responsibility to maintain current and accurate knowledge and skills that shape their practices. This professional responsibility is so foundational it has been codified as a Principle of Medical Ethics by the American Medical Association [9]. A failure to modify practices recently proven to be ineffective or to pose unacceptable risks to patients can provide the basis of a finding of medical malpractice or medical board disciplinary action [10].

Therefore, determination that a physician remains unaware of knowledge deficits may not absolve him or her of responsibility. A canon of medical liability law is that physicians are accountable not only for practicing in a manner consistent with their medical knowledge but also for knowing what a competent clinician should know. Failing to keep abreast of up-to-date clinical information is a form of negligence that, when it results in substandard care and subsequent harm, gives rise to professional liability.

Physicians who know that the knowledge base that informs their clinical practice is outdated or otherwise inaccurate but who fail to take corrective measures also may be liable. When substandard care resulting in harm to a patient is repeated or constitutes a major departure from the minimal standard of acceptable practice, the clinician may be liable not just for medical malpractice but for gross negligence or recklessness, a finding that can, in some jurisdictions, justify punitive as well as compensatory damages [11].

Clinical practice guidelines currently hold a highly ambiguous position in medical liability law. Consider the following example: In a 2001 case in California, *Bergman v. Chin* [12], the plaintiff introduced into evidence the Agency for Health Care Policy and Research (AHCPR) clinical practice guidelines for the management of cancer pain [13] in an effort to bolster the testimony of their experts that the pain management by Dr. Chin was so deficient and outside the bounds of acceptable medical practice as to constitute elder abuse. Also introduced into evidence by the plaintiffs at the trial was the policy of the California Medical Board advocating that effective pain management be a priority in patient care [14]. In his pretrial deposition, Dr. Chin denied any knowledge of either the guidelines or the policy. The jury concluded that Dr. Chin's care of William Bergman constituted elder abuse and awarded substantial damages to his family. However, we can only speculate as to the influence these documents might have had on the jury's decision.

There is no clear and consistent pattern associated with how such guidelines are handled by courts, even when promulgated by distinguished groups of clinicians as were the AHCPR guidelines on both acute and cancer pain. One might argue, for example, that they constitute an effort by the thought leaders and luminaries of the health professions to raise the current standard of care. Standard of care traditionally has been equated with the usual custom and practice of other health care professionals with training and experience similar to that of the defendant in a malpractice case or the respondent in a licensing board disciplinary proceeding. It is important to note that the standard to which the law holds health care professionals might be characterized as the minimal *standard of acceptable care* in contrast to *best practices* as those are presumably modeled by the preeminent members of the profession (see Table 2). As it would rarely, if ever, be the case that a majority of practitioners consistently follow any particular guideline, it would not be possible for a malpractice plaintiff to present credible evidence that any particular guideline reflects the usual custom and practice and hence constitutes the standard of care [15].

As previously mentioned, the state of Washington has adopted guidelines for the prescribing of opioid analgesics for chronic noncancer pain [6]. These guidelines appear to be based on a number of controversial assumptions of a clinical nature. While the group that promulgated the guidelines denied that they were intended to be binding on prescribing professionals (as opposed to advisory), it is

Table 2 Legal hierarchy of professional behaviors in medical practice

- Best practices—consistent adherence to state-of-the-art clinical practice guidelines (arguably above the minimal standard of acceptable care)
- Standard of acceptable care—conformity with the usual custom and practice of knowledgeable and skilled health care professionals with similar training and experience
- Malpractice—material departure from the prevailing standard of care with resultant harm (justifying civil liability or mild-to-moderate disciplinary measures by licensing authority)
- Distinct pattern of *negligent practice* or one or more instances of *gross negligence* or *recklessness* in patient care (justifying suspension or revocation of licensure)
- Conduct demonstrably *outside the bounds* of minimally acceptable clinical practice (the only reasonable justification for criminal prosecution)

easy to imagine legal and administrative proceedings challenging a particular professional's opioid-prescribing practices in which these guidelines are offered as corroborating evidence that conduct not in conformity to the guidelines was negligent or otherwise unprofessional.

In the criminal arena, some recent high-profile prosecutions, such as that against William Hurwitz, MD, raise legitimate concerns about the standard of practice professionals must meet in order to avoid being prosecuted and perhaps even convicted in connection with violating the provisions of the federal Controlled Substances Act (CSA). The critical issue in these cases has been whether the defendant's prescribing of controlled substances was for a "legitimate medical purpose in the usual course of professional practice" [16]. The Drug Enforcement Administration takes the position that what constitutes a legitimate medical purpose and what comes within the usual course of medical practice must be determined by the "standards of medical practice generally recognized and accepted in the United States" [17]. In the Hurwitz case, even defense experts did not maintain that the standard of care had been consistently followed [18]. The crucial point they sought to make in their testimony was that criminal law is not the appropriate means for challenging negligent or otherwise substandard care. That is the role of medical board disciplinary proceedings and malpractice litigation, both of which are civil, not criminal, in nature, they argued. It could be argued further that legitimate prosecutions for violation of the CSA that seek to impose criminal liability, including substantial monetary fines and/or imprisonment, should be grounded on practices that are so far outside the bounds of acceptable medical practice that no credible claim can be made that the defendant was acting within the context of a legitimate professional patient relationship.

When competent, credible expert testimony supports the argument that the conduct of the defendant may be negligent but not outside the bounds of medical practice, a jury in a criminal case should conclude that the prosecution did not meet its burden of proof beyond a reasonable doubt as to the defendant's criminal culpability [19]. Table 2 illustrates a kind of hierarchy of professional behaviors in this domain.

The troubling aspect of some of the high-profile criminal prosecutions of physicians on the grounds that their prescribing practices were outside the bounds of medicine and therefore tantamount to drug trafficking under the CSA is that the testimony of the expert witnesses for the prosecution tended to equate substandard practice with practice outside the bounds of medicine. If the hierarchy shown in Table 2 has any legitimacy, then the two are distinctly different and so, too, are the punitive measures they justify.

Conflicts in Real-World Prescribing

Inculcated habits frequently control a physician's routine. For example, some physicians make a habit of eschewing long-acting or extended-release opioids, or they may institute a blanket policy of refusing to raise opioid doses despite a given patient's inadequate pain relief. Rather than personalize each patient's treatment regimen, these physicians have settled upon a solution that may not reflect accurate science or clinical need but that satisfies a personal bias or adherence to an unjustified guideline. Such practices may also reflect physician fears of regulatory scrutiny of prescribing practices more than legitimate concern that the potential risks of such medications (in extended-release form or at an increased dosage) outweigh the benefits for a particular patient. Such cognitive errors and unfounded or otherwise unwarranted clinical biases often go unrecognized by physicians and are examples of unmindful practice that can harm patients [20]. Conversely, reflexively prescribing increasingly higher doses of opioids in the absence of therapeutic benefit is a similarly incoherent behavior that is observed to cause harm.

Knowledge deficits—and perhaps other types of errors—can be corrected through education. But even if all knowledge deficits were eliminated from the practice of opioid prescribing, ambiguities in patient behaviors (e.g., motivations for medication requests or nonadherence to medical direction) and potential danger would remain. This is because of the inexact nature of medical practice and the complexity of patients. The question of what action a reasonably prudent, well-trained physician would consider is not always easy to answer. Take the following example:

A woman in her 40s with severe pain secondary to poor gastrointestinal absorption has been receiving 1,200 mg of methadone per day from a methadone maintenance treatment (MMT) program. She was accepted into the MMT program with a substance use disorder diagnosis because of her physical dependence on opioids, a pattern of overuse, and a history of buying opioids from street drug dealers.

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The day arrived when the administrators of the MMT program refused to treat her further, frightened by her high dose. They have requested a transfer to a pain clinic, which primarily treats patients with chronic noncancer pain and complex diagnoses.

The patient is a habitual escalator of opioid doses and is willing to perform illegal actions to obtain drugs—a poor risk to make an adherent opioid-therapy patient. However, to her, her pain is not only real but leads to considerable debility and distress. Without treatment, she is at risk for suicide or life-threatening behaviors when the pain becomes too much to bear. The patient may live or die according to the treatment decision of the physician now in charge of her care and, indeed, may die a premature death no matter what the decision. What is prudent given such a clinical scenario? To ask an even more difficult question, what is comfortably within the current standard of acceptable medical practice?

Sound analysis and decision making cannot be conducted without access to and reliance upon relevant clinical information. The patient described earlier may well warrant transfer to a specialist who can address her misuse issues as well as her pain. Sound professional practice entails knowing when a patient's circumstances justify a specialty consult or referral. However, physicians may lack access to such expertise or patients may be obliged to expend extraordinary effort, money, or time to obtain it. In those cases, determining risk–benefit becomes harder, and providers and patients become vulnerable to a variety of health, regulatory, and legal risks stemming from perceived excessive treatment, under-treatment, or abandonment.

Final Thoughts

Physician error and nonadherence by patients are common contributory factors to prescription-drug deaths. Methadone-related deaths associated with physician error suggest a particular need to focus education in this area.

Physicians who encounter legal problems while providing care to patients with pain occupy both ends of the continuum. Some have been cavalier in their readiness to prescribe high doses of opioids for extended periods to patients who raise one or more concerns (e.g., repeatedly running out of medication prematurely or failing to demonstrate any functional improvement while pushing for increased opioid consumption). Other physicians have been so exquisitely sensitive to charges of “overprescribing” opioids that they have failed to manage pain, though the patient is suffering severe and ongoing adverse consequences. Between these extremes lie physicians who make a good faith effort to assess and manage pain but who, from time to time, fail to competently do so or lack adequate information about their patients' activities outside the clinical encounter. Such physicians certainly do not warrant criminal prosecution or draconian regulatory sanctions. Rather, they are prime candidates for continuing medical education and mentoring by pain medicine

specialists in their locality or region. Better educational methods also are needed to convince patients of the firm necessity to use medications only as directed and the possible consequences of failing to do so.

In particularly challenging clinical situations (and these are not uncommon when dealing with patients with complex chronic pain conditions), competent, compassionate care requires the art and the science of medicine, supported by reasonable regulatory policies and laws. Physicians who genuinely pursue the best interests of their patients and avail themselves of the best resources in the field of pain medicine and management have much less to fear from the regulatory and medical liability spheres than many commonly believe [21]. The conundrum we cannot currently reconcile is how conscientious physicians can accomplish this for each and every patient.

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During the past 3 years, Ben A. Rich, JD, PhD, has served as a consultant to KOL, LLC. During the past 3 years, Lynn R. Webster, MD, FACPM, FASAM, has served as a consultant for Cephalon, Covidien, King, Labopharm, MedXcel, Neuromed, and Purdue Pharma LP; on the advisory boards of BDSI, Cephalon, King, Labopharm, Neuromed, Pharmacofore, Purdue Pharma LP, and Janssen Pharmaceutical KK; and as an investigator in research for Cephalon, Collegium, Endo, King, QRx Pharmaceutical, and Reckitt Benckiser.

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