
Introduction: Pharmacovigilance and Good Medicine

Over the past decade, two important public health trends have become entwined like the twin serpents in the caduceus: (1) increasing clinical attention across all medical specialties to the undertreatment of pain, and (2) shifting patterns of drug abuse from illicit to prescription drugs—most notably a dramatic rise in diversion and non-medical use of opioid pain medications within the United States. The collision between the War on Pain and the War on Drugs has created a “perfect storm” of controversy. And, for better or worse, physicians are being enlisted to fight on both fronts: combating pain while simultaneously reducing the risk of diversion and abuse of, as well as addiction to, pain medications.

Many of us bristle at adding “pharmacovigilance” and “risk management” to our already lengthy task list. But the combination of potential therapeutic benefit and high risk associated with opioid* analgesics leave us no alternative but to become more sophisticated risk managers. Millions

** The term opioid refers to natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. These include codeine, morphine, hydromorphone, hydrocodone, oxycodone, methadone, and fentanyl among others. Opioids are often inappropriately referred to as narcotics, a legal term that is no longer used in medicine because it suggests that opioids relieve pain by inducing sedation; while sedation can be a side effect of opioids, it is not the mechanism that produces pain relief.*

of legitimate patients rely on these medications for pain relief and functional improvement, so we must include them in our repertoire of potential medication therapies. However, we cannot ignore the potential risks associated with the use of controlled substances, including addiction.

Managing risk is what we physicians do every day with every patient, whether we're considering procedures, medications, or non-medication interventions. Every treatment plan carries potential risks, as does the decision not to treat. Managing risks associated with opioids is fundamentally the same as pharmacovigilance concerning adverse reactions to any class of drugs: essentially following sound principles of medical practice and prescribing and achieving transparency in treatment decisions. The difference with opioids is that these drugs are increasingly diverted or otherwise abused.

Scope of the Problem

A statistical snapshot of prescription drug abuse and diversion in the United States reveals the scope of this alarming public health crisis:

- In 2005 (the latest year for which data are available), more than 10 million Americans were abusing prescription drugs—which is more than the combined number of people abusing cocaine, heroin, hallucinogens, and inhalants.
- The Centers for Disease Control and Prevention report that prescription opioids are now associated with more drug overdose deaths than cocaine and heroin combined: between 1999 and 2002, there was a 91.2 percent increase in the reporting of opioid analgesics on death certificates.¹

- Continuing a decade's long trend, in 2005 more new drug users began abusing pain relievers (2.2 million) than marijuana (2.1 million) or cocaine (872,000). By comparison, in 1990 only an estimated 628,000 people initiated illicit use of pain killers.²
- Data from a set of selected states show that almost 13,000 incidents of prescription controlled substances were diverted by theft from 2000 to 2003. In 2003 alone, 2 million dosages of six opioid analgesics were reported stolen from the supply chain, mainly from retail pharmacies.³

Behind these figures lie millions of individual stories of personal tragedy: untimely death, fractured families, shattered dreams, and wasted lives. Certainly the same spectrum of ills can be found in the wake of any abused drug, but the magnitude of the current problem makes it imperative that physicians become vigilant risk managers who demonstrate transparency in the decisions behind the care they deliver.

Much remains to be learned about the nature of prescription drug abuse in the United States. For example, the exact contribution of prescribers to prescription drug diversion and abuse is not presently known. Because the rise of prescription drug abuse has occurred alongside increased use of opioids in legitimate pain relief, it is tempting to assume cause and effect. However, preliminary evidence does not support this conclusion and more information about how prescription drugs are diverted is crucially needed. If we are to have responsible and effective responses to prescription drug abuse, the problem must be

considered in its full context. To avoid penalizing those with legitimate needs, solutions must factor in the full complexity of drug abuse, addiction and all of the related social and medical disorders. In particular, we must be careful with implications that prescription drug abuse is mostly related to prescribers and their patients, and be careful with implying that limiting medically appropriate use may have significant effects on reversing this disturbing trend.

A Countervailing Need

Concurrent with the epidemic of prescription drug abuse, patients and patient advocates have been pushing to address the equally legitimate cause of undertreated pain. Although these efforts began in the relatively circumscribed spheres of end-of-life care and cancer-related pain, medicine has appropriately widened its perspective to include all debilitating pain that has lost its purpose as an adaptive alarm signal, regardless of the source.

Significant effort has been made to reduce the incidence of untreated or undertreated pain in children, older patients, and in all other vulnerable patient populations. And at least at the level of clinical guidelines, policy statements, and organizational goals, the following general principles are widely accepted:

- Pain management is integral to good medical practice for all patients;
- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins;

- Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient;
- The use of opioids for other than legitimate medical purposes poses a threat to the individual and society; and
- Physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances.

If opioids had no medically redeeming value, the issue of their abuse would be tragic but physicians would have no role to play in minimizing abuse by changing their behaviors or monitoring their actions. The current need for guidance on opioid prescribing arises from the fact that, as addictive and life-destroying as opioids can be for some, they are life-enhancing and non-addictive for others.

Four key factors contribute to the ongoing problem of under-treated pain:

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;
3. Misunderstanding of addiction and dependence; and
4. Lack of understanding of regulatory policies and processes.

To these factors might be added a fifth: the lack of clearly written government regulations and professional guidelines for prescribing, or assistance with how to easily and efficiently incorporate these approaches into the hectic daily practice of physicians.

Filling an Unmet Need

This book is intended to help the responsible clinician understand and implement practices that support rational and transparent opioid prescribing. The following chapters examine each of the seven steps in the FSMB's *Model Policy*:

1. Patient Evaluation
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review
5. Referral and Patient Management
6. Documentation
7. Compliance With Controlled Substance Laws and Regulations

Each of these steps, which are only briefly described in the *Model Policy*, are here given an expanded discussion from the perspective of real-world clinical practice. Most physicians already perform many of the key steps recommended in the *Model Policy*. This book focuses on explanations and techniques that specifically address the issues that arise when prescribing opioids. Sometimes this simply means adhering to existing standards of care. At other times—such as in the creation of function-based treatment plans—a significant paradigm shift in perspective will be presented that translates into novel models for creating, monitoring, and modifying treatment goals for your patients in pain.

Prescription drug abuse and undertreated pain are both serious public health crises, but the solution to one need not undermine the other. The least we clinicians can do is make sure that the casualties of this clash are not suffering

patients who legitimately deserve relief. Informed clinicians can take simple steps to ensure that opioids are prescribed safely and transparently—and in the process, those prescribers can justify their decisions should they encounter the scrutiny of regulators.

Regulators and law enforcement agencies, such as the Drug Enforcement Administration, have urged prescribers to be vigilant when prescribing abusable drugs, particularly for patients with known or suspected risk of abuse. Clearly, effective solutions must address the current state of inadequate education that most clinicians receive on safe and effective prescribing of controlled substances. This book is intended as a much-needed step in that direction. Unfortunately, simply knowing the tenets of the FSMB *Model Policy* will not be of value without a basic knowledge of pain, substance abuse, and their treatment. Although this book will not serve this role, other resources are available, many of which are recommended in Appendix A. Moreover, this book will not substitute for maintaining the desire to relieve suffering or the recognition that an important part of mitigating pain is simply being present with your patients and showing them that you care. Although the elements of care described here are critically important for maintaining appropriate delivery of controlled substances, unless you also incorporate the personal part of care, your patients will continue to feel alone and uncared for—and may even resist treatment.

As a physician who specializes in Pain Medicine, I'm optimistic about the future of pain treatment. The confusions and frustrations that currently characterize pain management may simply be the growing pains of a wiser, saner,

and more uniformly effective patient care approach. Appropriate concerns about the potentially harmful or addictive aspects of opioid medications can be balanced with the equally valid needs of optimal pain relief with adequate risk management. Medicine is all about managing risk while improving health and easing suffering; the safe and effective use of opioids is no different. Opioids are ancient drugs that have been both glorified and demonized in past centuries. It is time we found ways to harness their very real gifts while curbing their very real dangers.

References

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