COMMENTARY

Reality and responsibility: A commentary on the treatment of pain and suffering in a drug-using society

Steven D. Passik, PhD
Howard Heit, MD, FACP, FASAM
Kenneth L. Kirsh, PhD

ABSTRACT

While opioids are a necessary part of the armamentarium of pain management, there has been a growing trend toward prescription drug abuse and diversion in our society. Meeting the goal of treating pain while not contributing to drug abuse and diversion requires vigilance and education. Physicians and patients have been singled out as the main players in the societal problem of diversion of prescription drugs. In fact, the problem can only be overcome when not only physicians and patients but also healthcare practitioners, third-party payers, law enforcement agencies and regulators, the pharmaceutical industry, and the media finally work together to prevent it, instead of fingering any one party for the blame.

Key words: opioids, pain management, prescription drug abuse, prescription drug diversion

OVERVIEW

That 50 million Americans suffer with chronic pain is not news,[1-3] and as our population continues to age, this number is likely to grow. Unfortunately, pain continues to be undertreated, and sometimes poorly treated. Between 40 and 60 percent of people with severe pain associated with life-limiting illnesses are not receiving adequate treatment for their pain.[4-6] Millions of others with pain from chronic diseases such as arthritis, diabetes, and low back problems have difficulty finding and paying for qualified professionals willing to help them gain access to the medicines, physical and psychological therapies, and surgical/anesthetic interventions that can help improve the quality of their lives.

In the twenty-first century, and in a society with one of the most advanced healthcare systems in the world, patients should not have to bear relievable pain. Undertreatment of pain is due in part to another fact of life in our society: addiction. Nearly 10 percent of Americans are addicted to illicit drugs; 15 percent are addicted to alcohol, 25 percent are addicted to nicotine; and 33 percent have sampled illicit drugs at least once.[7-9] Four million Americans used prescription drugs for nonmedical purposes last year. Healthcare professionals, patients, regulatory agencies, law enforcement, media, and payer stakeholders have failed to address relief of suffering in the face of addiction. The pendulum has swung relentlessly from providing adequate treatment of pain to preventing addiction, without solving one or the other problem sufficiently.

In 1946, the head of the American Medical Association wrote that physicians should "spare their terminally ill cancer patients the indignity of morphine addiction." More recently, pain specialists have downplayed the assessment required to quantify the risk of addiction in patients, while regulators and law enforcers crack down on prescribers for the amount of morphine they provide or the dosages they prescribe. Payers also play a role in the problem, forcing poorly monitored, drug-only therapy on patients who require more monitoring or more resources. Refusing reimbursement and seeking the least expensive and most politically expedient approaches to the problem of chronic pain lead only to personal tragedy, suffering, loss, and ruined lives. We were moved to write this commentary because we believe these issues have been oversimplified, fostering misunderstanding and failing to reconcile issues of responsibility.

Addiction, identified as a unique combination of neurochemical, genetic, and socioenvironmental factors (e.g., economics, stress, boredom, loneliness, and despair), is alive and well.[10] Thus, markets for high-quality legal and illegal controlled substances thrive. Where there is pain, there will be people seeking access to these drugs. This problem cannot be eliminated by having members of the pain community issue platitudes about how pain medicines are unlikely to be abused by "our patients." Such arguments foster further polarization. Prescription drug abuse is real; the growth curve of misuse of these medicines is steeper than that seen with

crack cocaine, and the rate at which new and young users are getting into serious trouble and requiring admission to treatment programs is unprecedented.[11-13] All pain management in our society is conducted against a backdrop of addiction, diversion, and misuse.

Addiction thrives in a world where many suffer chronic pain. Concerns about the prevention of addiction must be addressed first by acknowledging the problem of untreated pain and suffering, even before legislative or other actions are taken to combat misuse or diversion. Unintended negative effects on those who legitimately require pain relief must take precedence. Stakeholders must jointly develop realistic strategies for using pain medicines and other treatments in the real world.

The ever-shortening American attention span and the hunger for anecdotal evidence of the misuse of prescription drugs by high-profile celebrities has unfortunately reduced a highly complex social, medical, and political problem to discussion over whether pain medicines are "good" or "bad" and whether or not they should be available. Of course, there is no question that these drugs should be available, and there should also be no debate over whether all pain patients should be treated in the same way. In fact, the chronic pain population is incredibly heterogeneous and varies tremendously with regard to vulnerability to addiction and abuse. The only way to make pain treatment available to all is to tailor it in such a way as to reduce pain and suffering. An individualized regimen for each patient would be required.

The increased use of opioids in the past 10 to 15 years has been a key element in expanding the accessibility of pain treatment. As a safe and affordable mode of pain treatment, opioids will remain an important part of the pain armamentarium. The only way to keep opioids available to those who need them is to have all of the stakeholders examine their pieces of the puzzle collaboratively.

ADDICTION AND DEPENDENCE

Healthcare professionals are often poorly trained with regard to pain and addiction and the interface between them.[14] This lack of training promotes the perpetuation of myths and confusion. There is little understanding about what distinguishes addiction from physical dependence. It is not universally understood that the presence of withdrawal symptoms is not necessarily an indication of addiction. Nor is it understood that periodic upward titration, sometimes required to maintain analgesic effects, is a matter of drug tolerance, not necessarily addiction. Heroin abusers are generally physically dependent, tolerant, *and* addicted. Pain patients usually are physically dependent and tolerant, but *not* addicted.

How do we make this distinction? Addiction is a chronic brain disease that is marked by the "four Cs": **C**ontinued use of drug despite harm, loss of **C**ontrol over the drug, **C**ompulsive use of the drug, and **C**ravings for the drug. Pain patients generally enjoy stabilization or improvement in functioning when opioid therapy is appropriately prescribed, whereas addicts almost always suffer a downward decline in function and quality of life when using drugs. Aberrant behaviors in pain patients might be totally unrelated to addiction. Patients might appear to exhibit addictive behaviors that actually stem from serious pain or emotional distress. This problem is called pseudoaddiction and should be distinguished from addiction.[15]

Some chronic pain patients suffer a decline in function on opioids. Their drug use might not be "out of control" or compulsive, but they are unable to truly abide by the parameters of treatment. Although these patients are not addicted in the same sense of the term as are illicit drug users, many of them should be considered for discontinuation of opioid treatment and provided other interventions for pain.

Opioid therapy is not without risk and is not for everyone. Pain therapy and opioid therapy are not synonymous (e.g., pain therapy may involve the use of opioids, but it also might consist of adjuvant medications, physical therapy, coping and relaxation training, interventional techniques, etc., alone and in combination), and not all symptoms of pain need to be, or necessarily should be, treated with opioids. Clinical judgment is always needed in evaluating and prescribing for a pain patient. Psychological, rehabilitative, and interventional techniques might be options for patients who do poorly on opioid drugs, or in some cases might be utilized prior to opioids for patients who are seen as being at an exceedingly high risk for addiction. As addiction is treatable, so is pain. Pain in the context of addiction is also treatable, provided the time and care are taken to individualize treatments.

The major stakeholders in achieving the appropriate balance in the treatment of pain and the prevention of drug abuse and diversion are healthcare practitioners, patients, third-party payers, regulatory bodies, law enforcement, the pharmaceutical industry, and the media. These groups should attempt a thoughtful and unemotional dialogue on this issue, so that opioid treatment can remain available while efforts are made to stem the tide of prescription drug misuse and addiction.

RESPONSIBILITY OF THE HEALTHCARE PRACTITIONER

The problem of prescription drug misuse is not media hype, and it is not confined to remote areas.[12] It requires a tactical and humane approach. The healthcare practitioner should perform an appropriate evaluation of the patient before writing a prescription for a controlled substance. A medical evaluation of the pain complaint

should include a vulnerability assessment for misuse or aberrant drug-related behavior. Thus, an understanding should be reached of the patient's risk factors with regard to a history of chemical dependency, psychiatric comorbidities, social and familial situation, genetic propensity, and spirituality. The results of this assessment should be used not to exclude patients from opioid therapy but to determine the necessary level of agreed-upon boundaries or the help that might be required to manage a patient effectively. A sober assessment should be made to determine whom a particular practitioner can treat given the practitioner's time, expertise in complex psychiatric issues, and resources. Determining whom a practitioner can treat alone or who should be referred is crucial for safe pain management practices. Therefore, healthcare practitioners should arrange consultations as needed. Drug therapy should be determined within the context of a rational treatment plan, based on informed consent of the risks and benefits of all medicines prescribed. Healthcare practitioners should discuss realistic expectations about pain reduction with their patients and help them formulate achievable goals. Helping the patient understand how success or failure should be measured in terms of pain control, function (stabilized or improved), toxicities (manageable or none), and aberrant behaviors (few or none) is crucial for gaining compliance. The healthcare practitioner must, of course, prescribe all medications consistent with state and federal regulations.

RESPONSIBILITY OF THE PATIENT

The patient must follow the agreed-upon treatment plan, which should be based on mutual trust and honesty, especially if opioids are indicated. The patient must also be realistic about what can be achieved by proper pain management. Pain reduction is possible in most cases; however, being pain free is often an unrealistic goal. The patient should discuss his or her expectations with regard to functional activity with the healthcare practitioner. The patient must be responsible enough to take medications as prescribed. The medication delivery system, especially in the case of controlled-release opioids, should not be altered. For example, with a pain medication such as an 80-mg OxyContin tablet, the oxycodone is delivered over a 12-hour period. If the controlled-release system is destroyed, 80 mg of medication would be immediately released within minutes, resulting in serious harm or possibly death, especially in an opioid-naïve patient. Genetically susceptible individuals might experience euphoria by breaking the OxyContin tablet[16]; this constitutes opioid misuse.

Patients should never share their medications and should be responsible for the safekeeping of their medications, since profiting from the "street value" might be a temptation. It is never acceptable for a patient to say his or her medication was lost. At the initial evaluation and follow-up visits, the patient and the healthcare practitioner should honestly report and evaluate the "four As": **A**nalgesia, increased or decreased **A**ctivities of daily living, **A**dverse reactions or side effects, and **A**berrant drug-related behavior.[17] By adhering to a well-thought-out treatment plan, patients can decrease their pain and increase their functioning and thus improve their quality of life.

RESPONSIBILITY OF THIRD–PARTY PAYERS

Third-party payers must recognize that pain treatments vary tremendously across the heterogeneous population of people with chronic pain. Uncomplicated patients (no major psychiatric comorbidity, no history of drug abuse, no contact with a substance-abusing subculture) will require little more than routine medical management. These patients are at low risk for abuse or diversion and can be well managed through optimization of an opioid dose and minimization of side effects. Brief monthly visits should suffice when a patient is stabilized. It is likely that more than half of the chronic pain population will respond to minimal monitoring; however, other pain patients will require having third-party payers ready to support their needs for specialist care, higher levels of monitoring, and psychological and rehabilitative therapies. Others will need concurrent addiction treatment during pain management. Although pain management can be initially expensive for a large percentage of patients, it is hoped that the investment will prevent addiction-related disasters. Third-party payers must accept that it takes time to conduct responsible and proper pain management. While it might take only one minute to write a prescription, it might take as much as 30 minutes to explain why opioids are not in the patient's best interest. Patients should be evaluated in the context of their biological and psychosocial needs, i.e., the physiology of the disease or syndrome in the context of pain and suffering. This can not be achieved in a 10- to 15-minute session; however, if done properly, it can save the industry millions of dollars in unnecessary testing, hospitalizations, and emergency visits.

Cognitive services must be reimbursed consistent with their value to the patient and society. There should be parity in insurance reimbursement in treating pain and addiction consistent with reimbursement for concomitant chronic medical conditions. Access to appropriate medical care for all is society's responsibility.

RESPONSIBILITY OF LAW ENFORCEMENT AND REGULATORS

The regulatory system must strive to embody the central principle of "balance" with regard to the use of controlled substances.[18] The government should establish a system of controls that prevents misuse or diversion of

prescription medications yet ensures availability of opioids for medical, scientific, and clinical purposes. State and federal regulations ensure the safe prescribing of a controlled substance and should not make it difficult to access or practice pain management. New regulations or polices should be coordinated among states. If one state implements an enlightened policy but a neighboring state does not, then the problem is not solved; it just moves next door. In addition, all regulations should be clearly taught to medical students and healthcare practitioners.

Government and private agencies such as the Drug Enforcement Agency, the Food and Drug Administration (FDA), the Center for Substance Abuse Treatment, and private organizations have a responsibility to share data and expertise to determine the weaknesses in the system that lead to the misuse and diversion of prescription medications, including drug diversion from pharmacies, the unlawful procurement of controlled substances from the Internet, counterfeiting of medications, border trafficking of prescription medications, theft from any source, and dishonest patients or healthcare practitioners.

It is difficult to design risk management strategies for opioids, since these drugs can be easily diverted. Data on pharmacy theft have not been made available in nearly a decade, leading to the blaming of drug diversion on doctors and patients. If law enforcement agencies are educated about pain management, they will be able to appreciate patients' need for opioid medicines and understand that prescribing large doses is sometimes necessary for adequate pain management.[19] Some patients are physiological outliers who require high doses. Intractable cases sometimes require unusually high doses. There is tremendous individual diversity in how people respond to opioids. Thus, it is important not to target physicians for writing high-dose prescriptions, tying their hands as they attempt to help patients who do not respond to lower doses. Physicians, however, must educate their communities to be mindful of addiction monitoring in patients predisposed to addiction. High doses should be reserved for patients who otherwise appear to be responsible opioid users.

RESPONSIBILITY OF INDUSTRY

The pharmaceutical companies must develop safe medications for the benefit of society. Their responsibility does not end with the approval of their drugs by the FDA. The pharmaceutical industry should and does conduct post-marketing studies to determine the safety of its products. Priority should be given to improving the efficacy and safety of a product and developing reasonable risk management procedures.

Pharmaceutical companies also have an ethical responsibility to make sure that educational programs they sponsor do not focus solely on selling their products. They must educate program participants on the complexities of pain management. The industry should be commended for its support of continuing medical education programs, especially since there are few courses for healthcare professionals on the prescribing of controlled substances and prevention of addiction following pain management. The industry has also developed CD-ROM and Web-based programs through which healthcare practitioners can receive training on their own time.

Education, not restrictive regulation, is essential to ensure both the appropriate prescribing of controlled substances and prevention of misuse and diversion of these medications. Finally, the industry has the responsibility to train its sales representatives appropriately and then monitor their selling techniques. Inappropriate claims must not be made, and incentives and perquisites must be limited. The sales techniques used for "growing" the market must not interfere with the responsible use of an agent.

RESPONSIBILITY OF THE MEDIA

The media must be committed to responsible journalism based on verifiable facts and basic physiological principles. The media frequently confuses addiction and physical dependence, consequently mislabeling patients. Balanced reporting should include the benefits of pain management, not just the failures in a minority of cases. The majority of chronic pain patients on rational pharmacotherapy have experienced improved quality of life as a result of decreased pain and increased function. While misuse and criminal behavior involving the inappropriate prescribing of controlled substances should be reported, the other side of the story should be told. Focusing on visible targets, such as a high-profile pharmaceutical company, can be misleading. If an approved drug's delivery system has been altered, then the responsibility lies with the person who altered it, not with the pharmaceutical company who manufactured the drug and promoted its use as approved by the FDA.

People who are legitimately treated with pain medication rarely develop problems with addiction, unless they have genetic, social, psychiatric, and spiritual risk factors for addiction. Exposure to potentially addictive drugs does not in itself cause addiction; however, the media often portrays it as doing such. This can frighten patients who use their medications as prescribed and who are at low risk.

SUMMARY

Every American has a stake in this health, economic, and social issue. We are all aging, and many of us will experience pain. Some of us will require treatment for it. Unfortunately, some of us will also know the pain of prescription drug abuse personally or witness it in those we

love. Solutions to this problem must be devised now so that we can enjoy the comfort of knowing that safe and effective pain treatment will be there for us if we require it. It is the responsibility of all to make this a reality.

Steven D. Passik, PhD, Associate Attending Psychologist, Memorial Sloan Kettering Cancer Center, New York, New York.
Howard Heit, MD, FACP, FASAM, Georgetown University School of Medicine, Washington, DC.
Kenneth L. Kirsh, PhD, Assistant Professor of Pharmacy Practice, University of Kentucky, Lexington, Kentucky.

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