Prescription Pain Medication:

Preserving Patient Access While Curbing Abuse

CONTENTS

2 What Are Prescription Pain Medications?

3 Prescription Pain Medication Misuse, Abuse and Diversion

3 Prescription Monitoring Programs

5 Pain Management Centers

5 Negative Perceptions/ Stigma

6 Prevention

7 Conclusions

Information From The *Pain Therapy Access Physicians Working Group*

As physicians, it is our duty to ensure that our patients' pain is adequately treated. In fact, pain has been referred to as the "fifth vital sign," recognizing that it is on par with the four traditional vital signs of temperature, pulse, respiration and blood pressure.[1]

Prescription pain medications can often dramatically reduce pain and improve quality of life, allowing individuals to engage in activities of daily living, sleep better, and interact with family and friends. For example, cancer patients may gain relief from prescription pain medications as they are undergoing treatment or spending their last days with family. Individuals who have broken major bones after a fall may experience a less agonizing recovery. It is both humane and just to make prescription pain medications available to those who need them and their use would not be overly controversial except for an important problem: Pain medications are often misused, abused, or diverted for illicit uses.

Due to their abuse potential, prescription pain medications are highly regulated and are facing ever stricter policies as the rates of overdose deaths rise. Sales of prescription pain medications more than tripled from 1999 to 2008 and substance abuse treatment admissions quadrupled over this period. The number of deaths in which these medications were involved increased from 4,000 in 1999 to nearly 15,000 in 2008.[2]

"As a society, we need to address misuse, abuse, and diversion issues with prescription pain medications. However, in doing so, we must not disregard the millions of patients with persistent pain who take these medications for legitimate medical reasons. In our zeal to legislate these medications, we must preserve access for patients who would otherwise suffer in pain."

– Srinivas Nalamachu, MD

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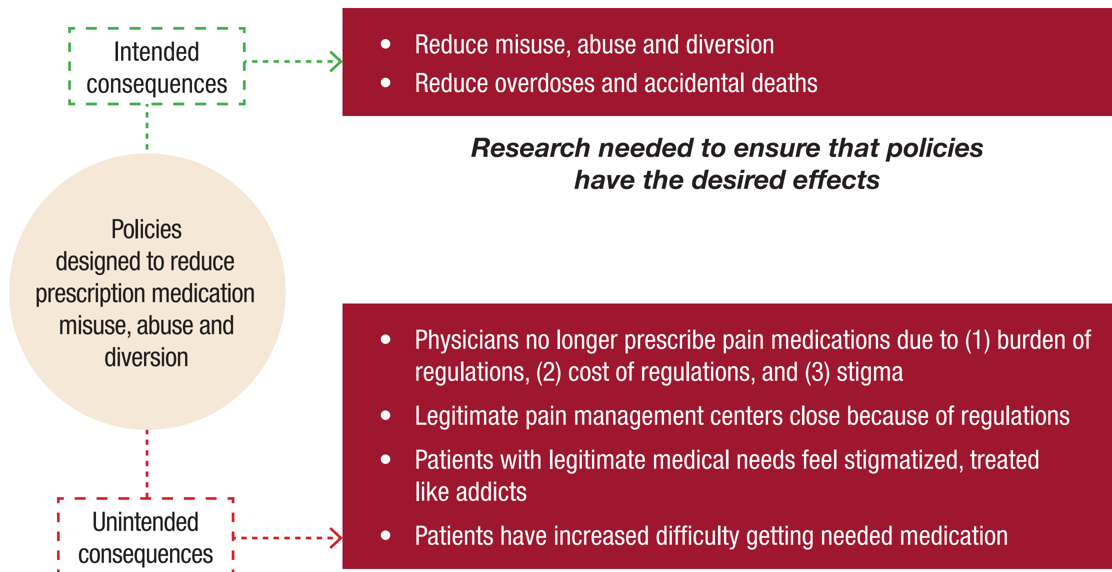
Given the human and economic tolls of prescription pain medication misuse, abuse, and diversion, it is critical that we as a society address the issues. However, in doing so, it is essential that patients with pain who have a legitimate need for these medications not be made to suffer. One way to accomplish this is to identify positive solutions for reducing the misuse, abuse, and diversion of prescription pain medications, while ensuring adequate access for patients who need them. In this paper, we consider some of the potential unintended consequences that may arise from prescription pain medication regulation.



What Are Prescription Pain Medications?

As their name implies, prescription pain medications are drugs that treat pain that can only be obtained with a prescription from a healthcare provider. The most common prescription pain medications belong to a class of drugs known as the opioids, which includes codeine, hydrocodone, oxycodone, morphine, and some others. Opioids carry the risk of addiction and can be abused. Some examples of brand names for these drugs are listed below.

- Codeine (Tylenol® with codeine #3)
- Hydrocodone (Vicodin®)
- Oxycodone (Percocet®, OxyContin®)
- Morphine (MS Contin®)

Prescription pain medications can be contrasted with over-the-counter pain medications such as ibuprofen and acetaminophen that do not require a prescription.

Prescription Pain Medication Misuse, Abuse and Diversion

Concerns with prescription pain medications fall into a number of different categories, which have been defined by the American College of Preventive Medicine.[4] Misuse refers to the intentional or unintentional use of a prescribed medication in a manner that is contrary to directions, regardless of whether a harmful outcome occurs. For example, a man may take pain medication that was prescribed for his wife's surgery for his own back pain. Abuse refers to the self-administration of medications to alter one's state of consciousness. An example of this might be a woman who takes the medication prescribed for her grandmother's broken hip to reduce her anxiety. Diversion refers to the redirection of a prescription drug from its lawful purpose to illicit (illegal) use. An example might be a young man who obtains prescription pain medication for his tooth extraction and then sells the drugs to others. Regardless of whether prescription pain medications are misused or abused, or whether they are obtained legally or illegally, they can cause overdose and death.

Prescription Monitoring Programs

Prescription monitoring programs are designed to electronically collect, monitor, and analyze data detailing the prescription and dispensation of drugs that are regulated by the government.[5] The drugs included in these programs vary by state, but most include controlled substances listed on Schedules II–IV or II–V. Currently, 49 states have operational prescription monitoring programs or have passed legislation authorizing their development.[5] Nearly all states collect information about opioids such as codeine, hydrocodone, and oxycodone.

Prescription monitoring programs have high face value; that is, they appear to be a good way to keep track of pain medication prescriptions to ensure that they are limited to patients with legitimate medical need. They would seem to be a good way to reduce "doctor shopping,"

Table. Definition of Controlled Substance Schedules[6]

SCHEDULE	DESCRIPTION	EXAMPLES
Schedule I	Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.	Heroin, lysergic acid diethylamide (LSD), marijuana, peyote, methaqualone, "ecstasy"
Schedule II	Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.	Opioids: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), fentanyl (Sublimaze®, Duragesic®), morphine, opium, codeine Stimulants: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), methylphenidate (Ritalin®)
Schedule III	Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.	Opioid combination products containing < 15 mg hydrocodone per dosage unit (Vicodin®), products containing ≤ 90 mg codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®)
Schedule IV	Substances in this schedule have a low potential for abuse relative to substances in Schedule III.	Aalprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®)
Schedule V	Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.	Cough preparations containing ≤ 200 mg codeine per 100 mL or per 100 g (Robitussin AC®, Phenergan with Codeine®), ezogabine

in which individuals attempt to obtain prescriptions from multiple practitioners.

Many physicians who treat pain support these programs but also seek to ensure that they do not interfere with the ability of patients with legitimate medical need to access pain medication. Specifically, these programs need to be (1) streamlined and user friendly, (2) not overly burdensome for clinicians, and (3) effective.

Streamlined and User Friendly: Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal. In this situation, many patients forego needed pain medication or are obliged to visit clinicians in cities located greater distances from their homes. For patients with pain, this can be an unnecessary hardship. Imagine the elderly man with a severely arthritic hip who depends on family members to drive him to pharmacies and clinic visits, the child with sickle cell anemia whose parents are already under substantial stress, and the woman with painful cancer who is undergoing chemotherapy and fighting for her life. Prescription monitoring programs were not meant to harm patients with legitimate medical need, and it is critical that such programs be thoughtfully designed to avoid the unacceptable, unintended consequences that can occur when the electronic databases are cumbersome or difficult to use.

Another important consideration is the prescribing of pain medications in busy cancer and pain management centers. Such centers often prescribe opioids for many patients per day, and programs that require center staff to spend many hours consulting electronic databases can be so time consuming as to require the hiring of additional staff. Clearly, the prescription monitoring programs were not intended to negatively affect medical practices, and it is essential to ensure that they do not.

Not Overly Burdensome for Physicians: In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure.[7] Such penalties seem excessive

"Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively. . . Preventing drug abuse is an important societal goal, but it should not hinder patients' ability to receive the care they need and deserve." [3]

Consensus Statement from 21 Health Organizations and the Drug Enforcement Administration, 2001

and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. Incentives are a much more positive method of obtaining physician compliance with regulations and should be built into prescription monitoring programs.

Effective: It is essential to conduct research to evaluate the effectiveness of prescription monitoring programs. We cannot merely assume that these programs will reduce prescription pain medication use and abuse. If state laws and regulations are not shown to improve the problem of abuse and diversion, then they must be changed and reevaluated for effectiveness or repealed.

Pain Management Centers

Pain management centers are medical facilities that specialize in the management and treatment of pain. These centers typically employ a multi-modal treatment approach to pain that may involve prescription pain medications, physical and occupational therapy, psychological counseling, antidepressant medications, and injectable nerve or muscle blocks.

The majority of pain management centers are legitimate institutions that appropriately treat patients whose pain is often intolerable and prevents them from working and participating in daily activities. Similarly, the preponderance of clinicians who work in these centers strive to help patients. Unfortunately, a small minority of pain management centers, commonly known as "pill mills," have been run by individuals who are more focused on profit than patient care, with practitioners writing excessive prescriptions for opioids that have ended up being abused or diverted for non-medical uses. Law enforcement is cracking down on these institutions and individuals, resulting in negative publicity and additional government regulations designed to prevent future abuses.

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, these centers must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and

reporting requirements. The burden of too many regulations may force pain management centers to close, and when they do, it is more difficult for patients to obtain treatment for their pain, leading many to suffer as a result. The loss of treatment options for patients with pain is an unintended consequence of targeting pain management centers and it is not even certain that the regulations are helping prevent abuses.

"Due to the negative perceptions surrounding prescription pain medications, some of my patients feel that they are being treated like addicts and no longer want to take the medicines that help relieve their suffering."

– Kelly Erola, MD

Negative Perceptions/Stigma

In addition to the reduced access patients have to prescription pain medications are the less tangible consequences of how these medications are viewed in our society. Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. Many cancer patients won't take their opioid medications because they don't want to be thought of as "addicts." Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications. This situation can lead good physicians to leave pain management and prevent others from entering the field.

The loss of physicians who specialize in pain management is a problem because pain is extremely prevalent in our society. Chronic pain affects more than 100 million adults in the United States and costs the country up to $635 billion per year in medical treatment and lost productivity.[8] The Institute of Medicine refers to pain as a national challenge that requires a cultural transformation to understand and treat.[8]

Moreover, patients with pain can be difficult to manage because they require more time and intervention than is available in a usual physician's visit. Primary care or other physicians often do not have the time or expertise to take care of these patients. Consequently, patients with pain are in danger of being passed over by the healthcare system. We cannot afford to stigmatize the professionals who want to care for these vulnerable patients. Although attitudes cannot be legislated, a more positive approach to prescription pain medication abuse and diversion may help change negative perceptions.

Prevention

Several positive approaches increase the focus on prevention of prescription pain medication abuse and diversion as opposed to restricting access. One such approach is to

make the opioid pills themselves more difficult to alter for abuse purposes. For example, some of the newer opioid pills contain ingredients that make them hard to crush and melt.[9] This reduces abuse because addicts can't snort the powder obtained by crushing the pills or inject the liquid obtained by melting them. Snorting and injecting are preferred methods of addicts because they concentrate the drug in the body all at once. When the drug is in pill form, the medication is released into the bloodstream more slowly, which reduces (but does not eliminate) the possibility that the person taking it will experience a high.

Education of both prescribers and patients is another important preventive strategy. In 2012, United States Food and Drug Administration (FDA) instituted several programs known as Risk Evaluation and Mitigation Strategy (REMS) for prescription pain medications.[10,11] These programs focus on two different classes of opioid medications: the immediate-release preparations and the extended-release/long-acting preparations. An important component of both of these programs is education for clinicians and patients about the risks and benefits of prescription pain medications.

> *"Pain represents a national challenge. A cultural transformation is necessary to better prevent, assess, treat, and understand pain of all types."*
>
> **– National Institute of Medicine[8]**

Conclusions

Pain is a pervasive and life-altering condition that affects nearly everyone at some point in his or her life. Prescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.

The potential for prescription pain medications to be misused, abused, and diverted has led to numerous regulations and policies designed to curb these problems. The policies often have unintended consequences on patients with legitimate medical need, reducing their access to medications that help minimize suffering.

Although it is critical to address the problems of opioid misuse, abuse, and diversion, it is just as critical to preserve access to these pain medications for patients who need them. Thus, the challenge is to develop policies that balance patient access with protections against misuse. Positive solutions that consider patients to be as important as addicts are essential.

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