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Mitigation of Risk During the Opioid Crisis

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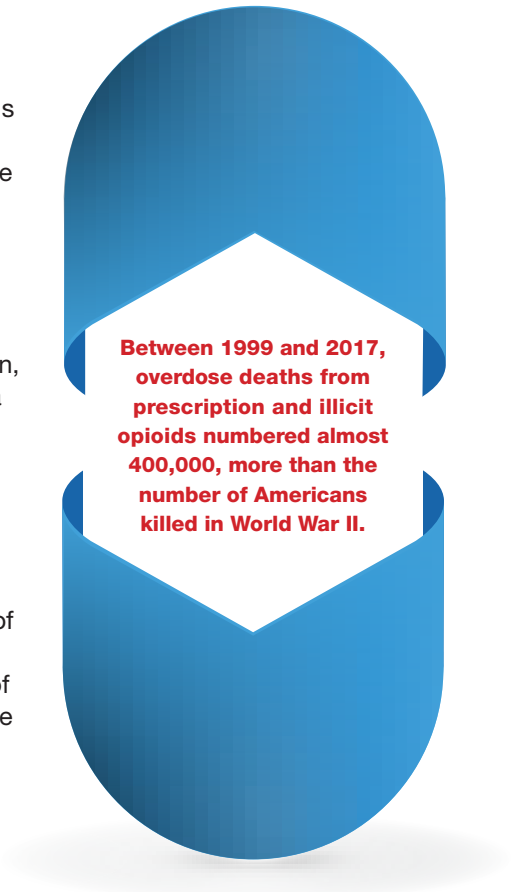
One can scarcely open a newspaper, turn on the television or engage on social media without encountering some news about the opioid epidemic. Accidental overdoses; suicides; medical malpractice claims; lawsuits against opioid manufacturers, distributors and retailers; busted pill mills; and increased federal and state regulation are all part of the environment in which healthcare providers must endeavor to provide quality care to patients while at the same time avoid unnecessary exposure to civil, administrative and potentially criminal law claims.

The Magnitude of the Problem

The statistics from existing data are overwhelming. The current opioid crisis is actually the third wave of a problem that began in 1999 with a rise in overdose deaths associated with prescription opioids, including natural, semi-synthetic opioids and methadone. The second wave of the epidemic began in 2010, with a significant increase in overdose deaths caused by heroin. The third, and most deadly, wave of drug overdose deaths began in 2013 and directly correlates with the number of opioid prescriptions written. This period has seen a massive increase in deaths associated with overdoses of synthetic opioids, such as prescribed or illicitly manufactured tramadol and fentanyl. While the number of overdose deaths attributable to natural and semi-synthetic opioids appears to have plateaued, at least for the time being, overdose deaths from synthetic opioids have continued to rise.

Between 1999 and 2017, overdose deaths from prescription and illicit opioids numbered almost 400,000, more than the number of Americans killed in World War II.[1] In 2016 alone, over 42,000 deaths were caused by overdoses of opioids including Vicodin, OxyContin, heroin and fentanyl.[2] Data from the National Prescription Audit shows that some states, particularly in the Midwest and South, had more than 100 painkiller prescriptions written for each 100 residents.[3] From July 2016 through September 2017, emergency room visits for overdoses of prescription pain medications, heroin and illicit fentanyl rose 30% in parts of 45 states, with opioid overdoses in the Midwestern region up 70%.[4]

The individual and societal costs associated with this epidemic are staggering. Partly as a result of the number of opioid overdoses nationwide, the life expectancy in the United States is decreasing. Due to opioid overdoses, accidental injury is now the third leading cause of death in the United States, behind only



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cardiovascular disease and cancer, and ahead of motor vehicle accidents.

The highest mortality rates are seen in adults in the prime of their working lives, those aged 25-54.[5] Not only has the opioid epidemic cost lives nationwide, but the increase in opioid prescriptions has correlated with a reduction in the labor force participation rate.[6]

According to a 2017 National Safety Council survey, seven out of 10 employers have been impacted by prescription drug misuse. Almost half of employers identified negative impacts associated with the crisis, which lowers productivity and increases both workplace injuries and near misses. Twenty percent of employers reported that they had an employee who had either bought and sold prescription medicine in the workplace, had a drug-related arrest or had an overdose.[7]

It has been estimated that as of 2013, before the peak of the current wave of the epidemic, the total economic impact associated with opioid overdose and abuse/dependence was $78.5 billion, almost two-thirds of which related to healthcare, substance abuse treatment and lost productivity.[8] When the cost of fatalities is considered, the total economic impact has been estimated to be as high as $504 billion.[9]

Responses

The response to the opioid crisis, although initially muted, has become much more aggressive at both the state and federal levels, and not surprisingly, through the civil and criminal justice systems. In October 2018, the SUPPORT for Patients and Communities Act was signed into law. This new federal law is intended to be a comprehensive effort to mitigate the opioid crisis and provide assistance to law enforcement and healthcare providers to prevent and treat addiction. It includes provisions that affect Medicare, Medicaid and other aspects of the of the public health system.[10] Also included are provisions that authorize additional funding for continuing medical education, prescribing limits, prescription drug monitoring programs and clinical prescribing guidelines.[11]

Numerous states have also made efforts to combat the opioid epidemic. By October 2018, 30 states had enacted some type of legislative or regulatory scheme related to the prescription of opioids. Much of the legislation limits first-time opioid prescriptions to between three and 14 days, depending on the indication. Several states place a statutory limit on morphine milligram equivalents. Others states direct or authorize another entity to establish prescription limitations.

Most state statutory schemes contain exceptions, including for chronic pain, cancer pain and palliative care.[12] There is evidence that the reduction in the number of opioid prescriptions written is an effective strategy to combat high rates of overdose. In Ohio, the state's Practice Policy Innovation and Opiate Action Team showed that a reduction in dosage also reduced the proportion of unintentional drug overdose deaths involving prescription opioids from 45% in 2011 to 22% in 2015. Pain clinics and pill mills were directly targeted by the State Board of Medical Licensing, with license revocations of 61 doctors and 15 pharmacists.[13]

In addition to the legislative and regulatory responses, numerous lawsuits have been filed by state and local governmental entities against opioid manufacturers, distributors and sellers in an effort to recoup tax dollars spent combating the epidemic. Hundreds of cases have been consolidated in federal court in Cleveland, Ohio.[14] Physicians and practices are faced with fraud and isolated malpractice claims. A wave of civil litigation, licensing actions and federal recoupment efforts could be next.

Exposure

Healthcare providers are confronted with real risks associated with their patients' use, and potential abuse, of opioid narcotics. The risks include not only adverse outcomes for patients, but exposure to civil claims, licensure actions and possibly criminal liability for providers. Virtually no healthcare provider wants to break or even skirt the law by intentionally over-prescribing opioids. In a typical office where the standard of care is met, there are essentially four types of patients who present special risks to providers.

Patient One

The first patient risk profile includes the nonaddict who overdoses while on a prescription for opioids ordered and administered consistent with reasonable medical practice. This bad outcome can subject the prescribing physician and lower-level providers, such as nurse practitioners, physicians assistants, and even office staff, to liability. Whether there is a deviation from the standard of care and resulting damages with this type of patient, will always await proof. There are multiple defenses to a medical malpractice claim, and the risk of legal liability in a civil claim is typically mitigated through an insurance or indemnity agreement.

The risk associated with a claim as a result of an adverse event in this type of patient is low, but real, because it is impossible to predict whether a patient or a patient's family will file a claim as a result of a bad outcome.

Careful documentation of patient history and indications for opioid therapy, clear patient education and informed consent, and thoughtful monitoring of such a patient's prescription use can significantly reduce the probability of an adverse event in this type of patient as well as improve the rate of success in any civil lawsuit or licensing complaint.

Patient Two

The second patient risk profile includes the known patient who is not an addict but due to accident, surgery, or some other condition is expected to and does suffer short-term pain. Short-term relief of acute pain is a necessary part of medicine, and opioids can be a safe and effective way of treating it. However, due to the inherent potency of today's opiates, particularly of the synthetic formulations and drugs like fentanyl, a nonaddicted patient with acute pain who is predisposed to addiction can easily, and quickly, become a patient with a substance abuse problem.

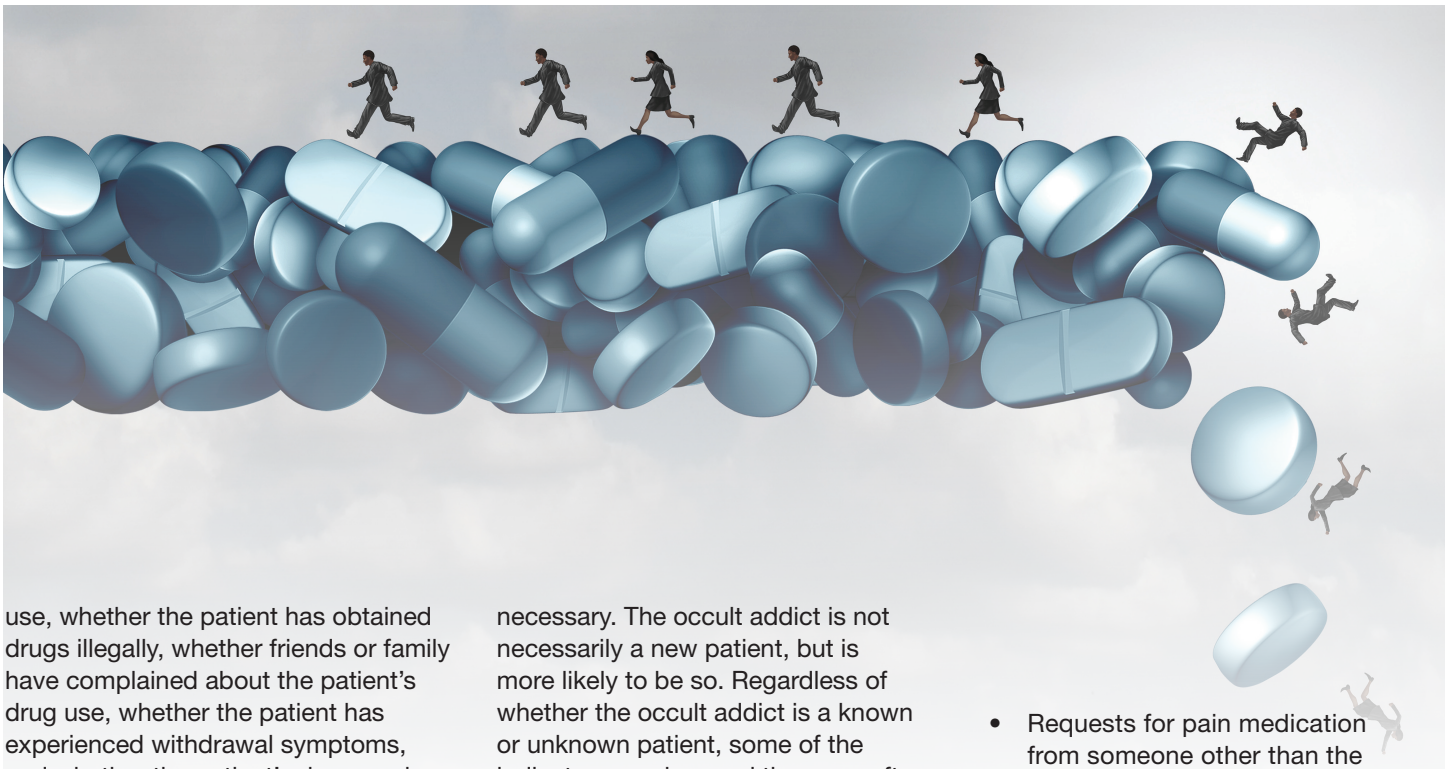
Center for Disease Control (CDC) data from 2017 shows that "[t]he probability of long-term opioid use increases most sharply in the first days of therapy, particularly after 5 days or 1 month of opioids have been prescribed, and level off after approximately 12 weeks of therapy."[15] An older but large study showed that patients with new chronic noncancer pain showed significantly higher rates of opioid use disorders than those patients who were not prescribed opioids.[16] An adverse outcome in a patient like this can include the development of an addiction where there was none, along with the sequela including overdose and death. This can result in significant exposure, especially if a pattern of abuse is missed by the practitioner. The provider's clinical judgment is always paramount, but careful documentation of any evidence of possible medication-seeking behaviors such as inconsistent laboratory results, suspicious history or physical examination, lost or stolen prescriptions, polypharmacy, frequent visits to the emergency room, and a patient's use of multiple pharmacies or new and different healthcare providers can mitigate the risk of bad outcomes and litigation with this patient.

Patient Three

The third patient risk profile includes the patient who is on long-term opioid therapy for chronic pain. Opioids must remain an option in the treatment of chronic pain. This risk profile includes patients with cancer pain, who are at some risk of accidental or intentional overdose. While the usefulness of chronic opioid therapy in patients with cancer and other types of chronic pain is well-established, it is subject to diminishing returns due to opioid tolerance and the risk of overdose, particularly in the treatment of breakthrough pain.

This risk profile also includes a patient who complains of chronic pain that is not cancer pain. This patient is highly problematic from a risk control perspective and can be the most challenging to manage clinically. If the patient is known, decisions about what treatments should be offered for pain should be easier, including whether sustained opioid therapy should be ruled out altogether or whether a referral is appropriate. If the patient is unknown, the clinician must determine whether the patient is an occult addict before prescribing any opioids.

Whether the patient is known or not known, a clearly documented, detailed history and appropriate treatment plan will mitigate most risk. This history should include questions regarding whether the patient has used drugs for nonmedical reasons, whether there is a history of blackouts or flashbacks as a result of drug use, whether the patient has tried without success to stop taking medication, whether the patient has ever felt guilty about drug



use, whether the patient has obtained drugs illegally, whether friends or family have complained about the patient's drug use, whether the patient has experienced withdrawal symptoms, and whether the patient's drug use has caused medical complications such as HIV, hepatitis or accidental injury.

Patient Four

The fourth patient type, and the most risky one from a risk mitigation standpoint, is the patient who is addicted to opiates, whether the patient is in addiction treatment or the addiction is occult, untreated, or both. The primary risk associated with the former is the risk of relapse which may result in overdose. An addict in treatment through an internal medicine or general practice office is a very high-risk patient. The treatment of an acknowledged addict in a general office requires the highest level of scrutiny and the most thorough work-up and documentation. A referral to a dedicated addiction treatment program should be considered.

The occult addict is risky as well, but is often readily identifiable. Such a patient can either undergo treatment as recommended, be referred, or be discharged from the practice if necessary. The occult addict is not necessarily a new patient, but is more likely to be so. Regardless of whether the occult addict is a known or unknown patient, some of the indicators overlap, and there are often clear warning signs that the patient is potentially suffering with dependency or addiction.

Some of these medication-seeking behaviors may include:

- Complaints of pain inconsistent with physical findings
- Requests for pain medication in the absence of physical findings
- Requests for specific types and doses of pain medication
- A clear preference for a specific pain medication or allergy to certain pain medication
- The use of street names for drugs
- Stories or excuses about lost or stolen prescriptions, which may be highly detailed
- Inconsistent history
- Exaggerated symptoms
- Polypharmacy, including the patient's use of antidepressants, stimulants or benzodiazepines
- Multiple telephone calls requesting pain medication
- Interactions with staff that are frantic, upset or angry
- Requests for pain medication from someone other than the patient, such as a family member or friend
- Residency outside the provider's normal geographic area
- Multiple short-term healthcare relationships
- Frequent visits to the emergency room or urgent care center
- The use of multiple pharmacies

Although the occult addict might be quickly identified in a clinic setting, depending on the constellation of indicators, this patient does pose substantial risk due to the likelihood of overdose and elevated probability that such a patient will make a claim in the event of an adverse outcome.

Mitigation Strategies

There may be a good explanation for a patient's pain, whether acute or chronic, and the patient's history and condition might warrant the short-term or long-term use of opiates to treat it. Careful listening, good judgment and detailed records remain the front line tools in assuring that patients who use opiates do so as indicated and in appropriate doses under

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physician supervision. The thoughtful and judicious use of opiates where indicated and based on a thorough evaluation; clear patient communication, education, and informed consent about the risks and benefits of opioid use; comprehensive documentation; and close follow up can mitigate a significant portion of the risk of adverse outcomes and claims. Some specific strategies to improve patient outcomes and mitigate risk include:

1. An opioid use protocol that defines a reasonable approach to the prescription of opiates to patients with acute and chronic pain, including patient education pamphlets and informed consent forms, limitations on length of use and medication type, and criteria for further examination of patient history and responses to any evidence of medication-seeking behavior or diversion. This may include EMR integration. The clear trend is for a state-limited initial course of treatment of treatment, although in many instances there are, rightly so, exceptions. The efficacy of the enforcement of such limitations remains to be seen.
2. Fewer opioid prescriptions should be written overall. This will directly reduce the risk of diversion, abuse, overdose and claims.
3. In patients with chronic pain, alternative pharmacological and nonpharmacological treatment options should be considered.
4. Treatment approaches should be determined in part by patient risk stratification. A low-to-moderate-risk patient, such as patient one or patient two, can generally be managed through detailed history and careful monitoring of prescription drug use. A higher-risk patient such as patient three or patient four requires intense, active management augmented by regular laboratory studies and access to prescription monitoring databases with strong consideration given to consultation with or referral to a trusted pain management or addiction medicine specialist.
5. Numerous addiction screening tools exist. These include simple, one-question surveys and more detailed surveys intended to indicate which patients might be susceptible to dependence or addiction.[17] There are online toolkits as well. The accuracy of such screening tools is unproven given that they rely on accurate patient history and may not be designed specifically to detect opiate abuse, but there does seem to be value in a detailed substance abuse screen with a forthcoming patient. Regardless of the accuracy of any of these tools, they do serve to mitigate risk in the event of a claim and if performed, should be made part of the patient's chart.
6. A patient on chronic opioid therapy should be required to sign an opioid contract whereby the patient agrees to use medication only as instructed. This agreement should be regularly updated. Of questionable effectiveness in preventing a patient from abusing pain medicine, such a contract does serve to mitigate risk in the event of a claim and should be made part of the patient's chart. In the event the patient violates such an agreement, the provider should strongly consider a referral to pain management or addiction medicine, and discharge from the practice might be warranted.
7. Prescription drug monitoring programs can be an effective method to identify a patient seeking access to opiates from more than one healthcare provider or from multiple pharmacies. Although such programs are neither fully developed nor well-integrated, they can both reveal warning signs in a patient and mitigate risk in the event of a claim.
8. A patient on long-term opioid therapy must be subject to regular drug screens to detect abuse and diversion, along with other checks including random pill counts and updated screening for consistency.
9. Pill mills must be shut down while maintaining a healthcare system that acknowledges that patient pain exists and opioids can be a safe and effective means of controlling it.

Conclusion

The treatment of acute and chronic pain is an important part of medicine. But liberal, or at least lax, prescription writing for powerful opiates, especially synthetic opiates, exposes patients

to the risk of dependence, addiction, abuse and overdose. This in turn exposes practitioners to the risk of civil and criminal liability. While it is uncertain when and how the medical and legal parts of this epidemic will turn out, the criminals will be left to the state, and practitioners will face increasing scrutiny of their prescribing practices and patient outcomes. What's done is done, but the data is clear. The failure to judicially prescribe opiates for pain and to properly monitor a patient's use of them can easily result in diversion, abuse, addiction and overdose. The prior strategies can mitigate the risk of liability for practitioners going forward.

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