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Mitigation of Risk During the Opioid Crisis

Part Two

By J. Scott Fanzini, JD

Historically, opioids played a role in the management of patient pain, primarily cancer pain. Given the now well-known addictive properties and potential for abuse, therapeutic alternatives such as nerve blocks in the treatment of pain were explored. Indeed, throughout much of the 20th century, there was a world-wide "opiophobia" documented in the contemporary medical literature, leading to under-treatment.[1]

Ever since the addictive nature and possible abuses of opioid formulations were established, there has been continuous tension between the undisputed beneficial effects of these medications and their potential for misuse and abuse. Percocet, Vicodin, and Oxycontin have provided relief from pain for millions, but are all continually subject to diversion and misuse. Pharmaceutical companies and questionable prescribing practices contribute to adverse health consequences and feed the epidemic.[2]

The current opioid crisis seems somehow different than other waves of abuse. The overall national prescribing rate for opioids increased steadily beginning in 2006. It then peaked in 2012 with an astonishingly high 81.3 prescriptions per 100 persons.[3] After peaking at this high level, however, the overall national prescribing rate fell from 2012 to 2017—to the lowest level in a decade—58.7 per 100 persons.[4] This reduction was achieved in part by the use of Prescription Drug Monitoring Programs (PMDPs) and the National All Schedules Prescription Electronic Reporting Act (NASPER).[5]

Nevertheless, 2016 saw a dramatic spike in the number of opioid-related deaths. The number of opioid deaths surged 20 percent, with most of the increase directly attributable to overdoses from illegally manufactured Fentanyl.[6] The largest absolute increase in opioid-involved deaths and deaths related to synthetic opioids occurred among males in the prime of their working lives and among all persons aged 25-34.

Synthetic opioids drove these increases. Twenty states and the District of Columbia experienced increases in synthetic opioid related deaths; half of them experienced increases of over 100 percent.[7] Increases in synthetic opioid-involved deaths are being driven by increases in Fentanyl-involved overdose deaths, and the source of the Fentanyl is more likely to be illicitly manufactured than pharmaceutical.[8] Thus Fentanyl, especially illicit Fentanyl, appears to be the primary driver of high levels of opioid-related overdose and death.

The current opioid crisis cannot be attributed to any one cause. The development of synthetic opioids in

An In-depth Look at the Opioid Crisis

This article is the second part of a two-part series. In part one[22], we:

- Examined the devastating effects of the current opioid epidemic.
- Explained how patients who use or abuse opiate-based painkillers create risks to healthcare practices.
- Demonstrated how specific patient profiles expose practitioners to the risk of adverse patient outcomes; the risk of patient misuse, abuse, and addiction; and the risk of civil liability, licensure action, and criminal responsibility.
- Identified strategies to mitigate these risks and improve patient outcomes.

As always, the most effective risk mitigation strategy remains one of practicing well within standards; establishing and implementing a thoughtful treatment plan; always documenting; and most importantly, communicating clearly with the patient.

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conjunction with poor prescribing habits and full-press marketing practices tell only part of the story. Prescription rates are down, yet deaths remain high. The current numbers are driven primarily by illicit opioids.

Certainly other factors have contributed to the crisis. One study endeavored to determine how serious adverse health outcomes vary by short-term fluctuations in macroeconomic conditions. This study strongly suggests that opioid-related deaths and emergency department visits increase during times of economic weakness. The authors found that negative economic shocks have adverse effects on both drug-related mortality and emergency department visits.

Although other causal pathways exist, the authors suspect that the "dominant factor linking macroeconomic conditions to adverse drug outcomes is that fatal and near fatal abuse of opioids often (and increasingly over time) reflects a physical manifestation of mental health problems that have long been known to rise during periods of economic decline."[9] Thus, it seems—at least with respect to certain aspects of opioid addiction—abuse and death "diseases of despair" are very real.[10]

Current Approaches

Due to the multi-factorial causes of opioid-related morbidity and mortality, broad-based approaches are required to mitigate the crisis. Thus, the overall risk exposure to health care providers in their day-to-day practices may be reduced.

The more the crisis can be mitigated at a macro-level, the greater will be the likelihood that specific office-based risk control strategies will be effective.

The Federal Approach

The Substance Abuse Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act was signed in to law on October 24, 2018.[11] This far-reaching legislation amends the Food, Drug, and Cosmetic Act, the Social Security Act, the Controlled Substances Act, and other federal laws to combat the opioid crisis through opioid use disorder prevention, recovery, and treatment. [12]

From a practical perspective, the Act provides for addiction and pain medicine training in medical school and residency programs. It also contains a significant loan-repayment program for substance abuse disorder providers who practice in high need areas. Additionally, the Act significantly opens up prescribing authority by providing greater flexibility in prescribing buprenorphine in an office setting.

The law also grants the FDA the power to require certain specific packaging such as blister packs and mail-back pouches for opioids and other drugs that pose a risk of abuse.[13] Whether such measures will cost-effectively reduce poor prescribing practices, curb diversion or abuse, or improve patient outcomes beyond the prevention of accidents that involve children or seniors remains to be seen.[14]

Other significant provisions of the SUPPORT Act make changes to Medicare and Medicaid. Significantly, the Act mandates state Medicaid prescription drug monitoring programs. The states must, "require covered providers to check the prescription drug history of a covered individual being treated by the provider through a qualified prescription drug monitoring program before prescribing a controlled substance to the individual."

Therefore, states must develop programs that permit access to information regarding the prescription drug history of a covered individual with respect to controlled substances; the number and type of controlled substances prescribed; and the identity of each covered prescribing provider. The program must facilitate integration into electronic prescribing systems.[15]

Challenges going forward include data gathering, what will qualify a state's prescription drug monitoring program, and information sharing. Prescription drug monitoring programs have been shown to be effective in reducing the number of prescriptions written. What remains unknown, however, is whether such programs will actually reduce the number of adverse patient outcomes, particularly during the current crises which is fueled by the market for illicit Fentanyl.

In June 2019, the Food and Drug Administration proposed new standards for the approval of new opioids and to promote the development of new therapeutics to treat pain and addiction.[16] Also, in September, the Drug Enforcement Agency proposed rules to significantly reduce the production of five opioid substances: fentanyl, hydrocodone, hydromorphone, oxycodone and oxymorphone.[17]

State Approaches

In addition to working with federal agencies on combating both the illicit drug trade and the recent wave of opioid-related morbidity and mortality, states have taken their own direct actions to mitigate the crisis. Some states

have experienced quick turnaround in the number of drug overdose deaths. However, many states have experienced flat, but high, numbers of opioid-related deaths or even steep increases based on current data.[18]

Many states have taken regulatory action through state medical boards to address the epidemic. These actions include the adoption of clinical practice opioid prescribing guidelines, including those from the CDC. Other states are directing regulatory and enforcement at pain management clinics. Still others are making changes to physician education and licensing requirements.[19]

State-by-state data on provisional drug overdose deaths shows the number of overdose deaths continues to trend upward in some states, while in others the number of deaths is flat at a high level or down slightly. One exception is Ohio where the Ohio Governor's Cabinet Opiate Action Plan took a multiagency approach to address opioid abuse and reduce the number of opioid-related overdose deaths. This approach addressed the crises at both the law-enforcement and public health levels.

According to the CDC provisional overdose death data, the number of opioid-related deaths in Ohio peaked at just under 5,300 deaths for the 12 months ending June 2017. Since then, the number of deaths reported in Ohio has declined precipitously, to a low of just over 4,000 deaths for the 12-month period ending in February 2019. Ohio's combined approach seems to have paid dividends.

This decrease in deaths in Ohio is particularly significant in light of the fact that in many other states, even in states that are applying a multi-disciplinary approach to the crisis, have death rates that remain persistently high even three years after the 2016 spike in morbidity and mortality. For example, Rhode Island has also implemented a broad range of initiatives to combat the crisis. Yet, the number of opioid-related deaths in Rhode Island continues to remain high.

The number of deaths from opioids has remained high but flat in other states, notably California and Florida, but in others such as Alaska, the numbers continue to trend upward. Interestingly in Missouri, the only state without a functioning prescription drug monitoring program, the number of deaths continues to rise, with the most recent data showing almost 1,700 deaths for the 12 months ending March 2019, up from 1,400 for the 12-month period ending March 2018. Given the sharp decrease in the number of opioid-related deaths in Ohio, what is happening there warrants further study.[20]

Opioid Litigation Update

The civil and criminal justice systems can serve effective risk management functions at both the macro- and micro-levels. The civil justice system is often viewed as simply a mechanism for the provision of cost-shifting via monetary compensation. The criminal justice system is often considered to be retribution on bad actors for their criminal misconduct. While long-debated, both systems have long been believed to also provide a deterrent effect.

Civil litigation and criminal prosecution are important tools to combat the current epidemic. On the criminal side, law enforcement is working to target the illicit trade and so-called "pill mills." In August, the Department of Justice announced the suspension of seven pharmacies and two providers accused of the diversion of approximately 23 million oxycodone, hydrocodone and carisoprodol pills. In addition, 36 search warrants were executed on 15 pharmacies and six "pill mill" clinics.[21]

On the civil front, the National Prescription Opiate Litigation is the multi-district litigation currently pending in the United States District Court in Cleveland, Ohio. There, the plaintiffs allege that the manufacturers of prescription opioids grossly misrepresented the risks of long-term use of those drugs for persons with chronic pain. They also allege that distributors of prescription opioids failed to properly monitor suspicious orders of those prescription drugs.

Conclusion

Public and private institutions have brought numerous resources to bear once it became apparent that the current opioid epidemic was in full bloom. Certainly, much more data gathering, testing and research remains to be done. The causes, outcomes and effects of risk mitigation strategies—whether macro-strategies, such as federal bureaucratic solutions, through the courts or in a medical office—need to be addressed.

Fewer at-risk patients make it easier to focus attention on behaviors that demonstrate addiction.

There are some bright spots. Data gathering and assessment is in full swing. Law enforcement and professional licensing bodies have turned greater attention to pill mills and the illicit Fentanyl trade. Private healthcare institutions and healthcare providers are working together to implement mitigation strategies. The civil and criminal justice systems are responding. Prescription rates are down.

Given the continued high rates of opioid-related overdoses and deaths, particularly with respect to the illicit drug trade, the efficacy of any of the current approaches remains to be seen. Fewer opioid prescriptions result in fewer opportunities for diversion and abuse. Fewer patients on chronic opioid therapy means fewer new addicts will be created, thus allowing the office-based practice to effectively implement risk analysis and mitigation strategies.

Fewer at-risk patients make it easier to screen and track a patient population. While there remains the risk of addicted patients trafficking in the illicit opioid

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market, for the high-risk patient, more focused attention can be paid to behaviors that demonstrate addiction, diversion and misuse.

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[4] *Id.*

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[8] Seth, P, et al., Centers for Disease Control Morbidity and Mortality Weekly Report, March 30, 2018, 67(12): 349. See also Spencer, M., et al., *Drug Overdose Deaths Involving Fentanyl*, National Vital Statistics Report, March 2019, 68(3); 1-19 (While the number of drug overdose deaths attributable to Fentanyl were stable at around 1600 in 2011 and 2012, they began to increase in 2013, and spiked to over eighteen thousand in 2016).

[9] *Id.* At 26.

[10] Shanahan, L., et al., *Does Despair Really Kill? A Roadmap for an Evidence-Based Answer*, Am J Public Health. 2019 June; 109(6): 854–858 ("After decades of improvement, premature mortality (i.e., unfulfilled life expectancy) is on the rise among US non-Hispanic White adults with a high school degree or less. . . [S]uicide, drug poisoning (particularly from opiates), and alcoholic liver disease are among the main culprits, and their prevalence has especially risen in geographic regions hit hardest by economic decline (e.g., the Rust Belt, parts of Appalachia))(citations omitted).

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[12] Statement from FDA Commissioner Scott on the Support for Patients and Communities Act, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-how-new-regulatory-authorities-will-assist-agency-more.

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[19] Federation of State Medical Boards, *Pain Management Policies Board-By-Board Review*, http://www.fsmb.org/siteassets/advocacy/key-issues/pain-management-by-state.pdf (last accessed October 29, 2019).

[20] Ohio's neighbors Indiana and Kentucky have also experienced modest reductions in opioid-related deaths, with Illinois' progress trailing but trending downward.

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