

## Opioids

### *Finding the appropriate balance between preventing opioid abuse and managing pain*

#### **Key Takeaways**

Opioids initially were introduced at a time when pain was believed to be undermanaged. However, their widespread legal use, combined with the rise of illegal and more powerful drugs, has resulted in high rates of addiction and tens of thousands of deaths annually in the U.S.

The United States has struggled with managing the balance of pain tolerance and opioid addiction due to the challenge of ensuring appropriate prescribing, unintended consequences, and political barriers to implementing many treatment options.

Restrictions on opioid prescriptions can reduce the number of patients addicted to the drugs, but also cause some individuals to resort to illegal and more dangerous alternatives.

The targeting of several key players – manufacturers, distributors, and providers – has led to little success in solving the issues that afflict the current and future opioid-addicted population.

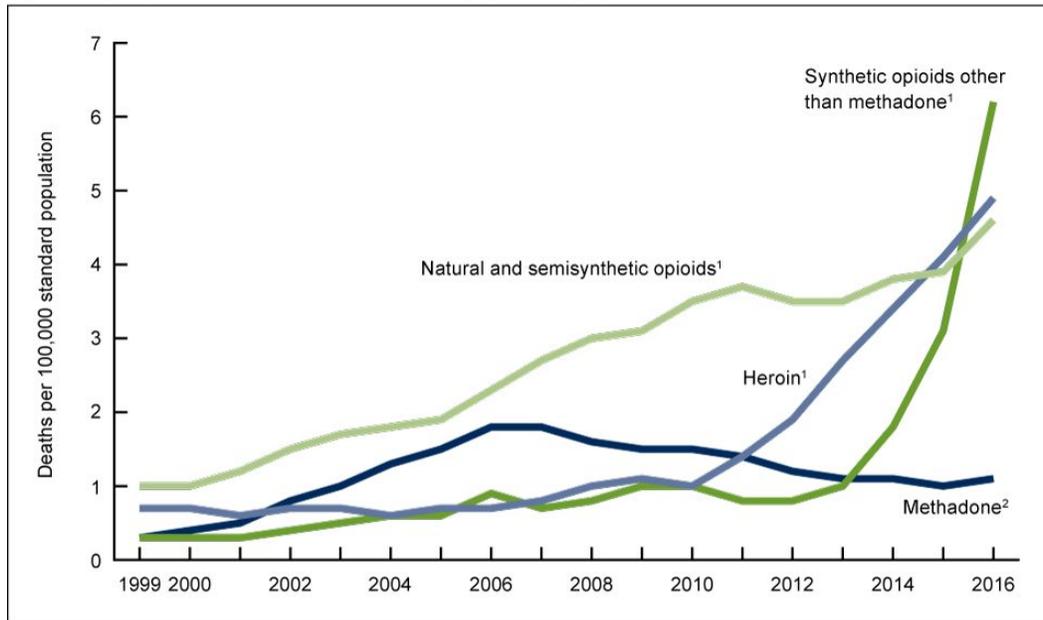
Some effective treatments for opioid addiction, such as supervised consumption spaces and medication-assisted therapy, are politically controversial and thus implemented infrequently.

#### **Background**

In 2017, the United States experienced 72,000 opioid-related deaths, with an estimated economic toll of \$504 billion. Despite the efforts of payers, providers, and policymakers, this epidemic continues unabated. The crisis has resulted in death and disability, while also increasing infectious and other comorbid diseases. One set of Stanford researchers demonstrated that current policy has not gone far enough with proven addiction treatment modalities. CDC forecasts another 510,000 American deaths from opioid overdose in the coming decade. Questions remain as to the balance that lies between restricting access to opioids and individuals suffering from pain due to these restrictions. CMS and the federal government have dedicated resources to Electronic Health Record infrastructure that would expand restrictions on opioid prescription. While efforts have yielded some success

in decreasing prescription opioid overdose, illicit opioid overdose has worsened. Many observers believe that there is no one solution to the problem; successful approaches can include a portfolio of options. Despite the CDC’s [current estimates](#) of addiction, there are many viable policies that have demonstrated promise in lessening opioid related mortality [1].

Figure 4. Age-adjusted drug overdose death rates, by opioid category: United States, 1999–2016



<sup>1</sup>Significant increasing trend from 1999 to 2016 with different rates of change over time,  $p < 0.05$ .  
<sup>2</sup>Significant increasing trend from 1999 to 2006, then decreasing trend from 2006 to 2016,  $p < 0.05$ .  
 NOTES: Deaths are classified using the *International Classification of Diseases, Tenth Revision*. Drug-poisoning (overdose) deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Drug overdose deaths involving selected drug categories are identified by specific multiple-cause-of-death codes: heroin, T40.1; natural and semisynthetic opioids, T40.2; methadone, T40.3; and synthetic opioids other than methadone, T40.4. Deaths involving more than one opioid category (e.g., a death involving both methadone and a natural or semisynthetic opioid) are counted in both categories. The percentage of drug overdose deaths that identified the specific drugs involved varied by year, with ranges of 75%–79% from 1999 to 2013, and 81%–85% from 2014 to 2016. Access data table for Figure 4 at: [https://www.cdc.gov/nchs/data/databriefs/db294\\_table.pdf#4](https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#4).  
 SOURCE: NCHS, National Vital Statistics System, Mortality.

## The State of the Crisis Now

The history of the opioid crisis can be seen in three overlapping spikes of rising mortality, all with varying levels of severity: (1) Prescription opioid-related deaths spiking beginning in 1999; Heroin-related deaths spiking beginning in 2010; and (3) Fentanyl- and other non-methadone-synthetic-opioid-related deaths spiking in 2013. The opioid crisis has shown a clear pattern: the rise of extremely addictive opioid derivatives leading to a widening black market for the alternative substances.

More recently, the Kaiser Family Foundation evaluated the illegal drug market and found that it was the largest growth area in the opioid crisis, with more people transitioning from prescribed opioids to illicit sources than ever before. Another study from the Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse found in their large cohort study that 50 percent of people aged 18-33 who began heroin use had first reported misusing opioid medications, mostly misusing OxyContin.

Fentanyl and other non-methadone-synthetic-opioids are often produced in China and smuggled into the United States, often through dark web internet transactions. Top Drug Enforcement Administration official Paul Knierim has states, "The ease with which dealers can buy fentanyl from China is a challenge because it's creating traffickers who are not affiliated with larger organizations or with cartels."

## **Support for Tighter Restriction of Opioids**

Advocates of tighter restriction on opioid use support multiple strategies:

**Overdose reversal drugs.** In April of 2017, the U.S. Department of Health and Human Services outlined its five-point Opioid Strategy that has been in action for almost two years. The plan included improving access and distribution of overdose-reversing drugs like Naloxone, improving access to prevention treatment, strengthening public health data reporting and collection, supporting pain and addiction research, and advancing alternative pain management strategies. Many states and cities have since enforced and, in some cases, continued to develop Overdose Education and Naloxone Distribution (OEND) programs. The OEND Program has demonstrated that 7.6 percent of those who complete their training go on to administer a lifesaving dose of naloxone at some point.

**Prescription Drug Monitoring Programs.** Another tool used to combat the crisis has been PDMPs, which have gone into effect in every state save Missouri, along with the collaborative project called InterConnect that 46 states are a part of. Research regarding the effectiveness of PDMPs has been mixed, as some studies have shown an association with reduction of misuse and diversion, while others have demonstrated a link between PDMPs and unchanged opioid mortality rates. Most notably, New York has been able to



establish interoperability of its PDMP with 25 other states and Washington DC, achieving the most interconnected web of data the US has seen in a medical setting.

**Clinical guidelines.** In 2016, the Centers for Disease Control and Prevention published its guidelines for primary care clinicians prescribing opioids on an outpatient basis for chronic pain, outside of three categories: cancer care, palliative care, and end-of-life care. The CDC report found that “evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent.” The guidelines also suggested that opioids for acute pain be prescribed for three to seven days .

**Electronic Health Records.** KLAS Research found that 60 percent of healthcare providers relied on their EHR platforms to inform their decisions about prescribing opioids. In 2018, CMS unveiled a three-pronged strategy to fight the opioid epidemic that included use of electronic health records to aid in utilizing data to make informed clinical decisions. This has been part of a larger CMS operation to increase EHR interoperability with the goal of improving the current landscape in which existing data often are too fragmented for prescribers to access. CMS also plans to incorporate tools like a Medicare “heat map” that would illustrate prescribing rates that are happening around the country in live time. This would afford clear visualization to federal entities for targeted preventions and targeted OUD treatment. The Trump Administration has also echoed this call for improved data sharing within EHR systems as well as PDMPs existing in 49 states, by pledging to compile an ideal minimum data set for EHR platforms and PDMPs that would give clinicians the information they need to prescribe.

**Legal limitations on opioid prescriptions.** In the 2020 presidential election, many candidates have come out publicly in support of limiting the prescription opioid supply. Senator Rob Portman (R-Ohio) shared a proposal that caps prescription limits for acute-pain to three-day maximums. Another candidate, Senator Kirsten Gillibrand (D-NY), touted her co-sponsored bill that would limit opioid prescription for acute pain to seven days. The Gillibrand-Gardner bill is targeted toward individuals coming out of surgery with acute, rather than chronic, pain. This bill goes further than existing state laws that currently

allow prescribers to override existing limits, instead mandating that patients return in person to their physician to receive more medication past the seven-day maximum.

## Opposition to Tightening Restrictions on Opioids

Opioid prescription rates rose initially in response to a wide perception that pain was undertreated, and - despite the epidemic - there is still significant concern among a cohort of experts that policies restricting access to them will lead to increased suffering and interfere with providers' ability to effectively manage pain. The CDC's advice to moderate opioid prescriptions has ultimately led to confusion in both providers' offices, where clinicians who decide to prescribe opioids have to overcome laborious federal and state reporting requirements.

Stanford researchers conducted a study evaluating the policy mechanisms used by the federal government to restrict the flow of opioids. They reported that interventions such as drug rescheduling , restricting the availability of opioids, and promoting expansive prescription drug monitoring programs actually *increase* overdose deaths by forcing those addicted to painkillers toward more lethal alternatives. The researchers agreed there is no silver bullet for the opioid crisis, but their findings indicated the most effective interventions were medication-based treatments, psychosocial treatment, needle exchange, and naloxone distribution. Their overall conclusions shed light on the success of harm reduction approaches related to the opioid crisis and exposed two conundrums:

- Curtailing the prescription opioid supply decreases quality of life and increases the likelihood that affected individuals will use illicit drugs such as heroin or fentanyl as a replacement for prescribed opioids

“Chronic pain patients, who are stable and arguably benefiting from long-term opioids, are now facing draconian and often rapid dose reductions. Sometimes, alternatives to opioids for chronic pain are not offered, not covered by healthcare insurers, or not readily accessible or available to patients.”

- Stefan G. Kertesz,  
Adam J. Gordon &  
Sally L. Satel,  
HealthAffairs Blog

- Restricting opioid flow is positive in the long term as fewer individuals become addicted to opioids in the first place

The Stanford report's findings raises the central question: How can we use policy to ensure that providers have the tools they need to treat pain and prevent those in pain from turning to illicit drugs while at the same time preventing abuse and addiction from developing in the first place?

## Potential Options

Supervised consumption spaces (SCS) are a harm reduction approach intended as a place for opioid users to safely inject drugs. These consumption sites provide sterile needles to prevent disease transmission among users, as well as staff trained in proper dosage and the signs of overdose. Some sites also offer as-needed counseling and addiction treatment facility referrals. Though not yet legal in the United States, by the end of 2017 this policy idea had been implemented in 100 facilities across ten countries. The sole supervised consumption space (also known as "safe injection site") in North America is in Vancouver, a site that in 2017 logged 175,464 visits and prevented 2,151 of the overdoses at the facility from proving fatal. This was a 35 percent reduction in mortality amongst this vulnerable population at Vancouver's Insite facility. Looking toward disease prevention, this Vancouver facility also reported a reduction of 35 incident cases of HIV annually through this intervention.

Needle exchanges have proven to be a harm reduction approach with some domestic success. There are 185 active needle exchange programs operating in the US, and 97 percent of those programs also offer referrals and counseling services to those trying to seek addiction treatment services. NEPs have an average operational cost of \$160,000 annually, whereas one individual with AIDS or HIV will require more than \$120,000 in public health care expenditures. One study conducted by a group of researchers from Stanford found that over five years, increasing naloxone availability, promoting needle exchanges,

and expanding medication-assisted addiction treatment increased life years and quality-adjusted life years while reducing opioid related mortality by five percent.

## Conclusion

Opioid addiction is a public health crisis with a variety of causes and no clear solution. The problem has expanded from prescription drugs to those acquired and/or manufactured illegally, posing different but overlapping challenges in preventing addiction. It's difficult to ensure appropriate opioid prescribing while sufficiently managing pain and avoiding the unintended consequence of patients seeking illegal (and more dangerous) alternatives. Once patients are addicted, the question of how to mitigate both the short-term and long-term effects of opioid addiction remains unanswered. The need to balance pain management with restricted use remains, often with a conflict between short-term and long-term goals. Moreover, many of the more promising harm reduction programs are politically controversial and thus difficult to implement. So the question remains: How do we balance the risk of abuse and addiction with the very real suffering of individuals?

## Discussion Questions

How should we attempt to ensure appropriate opioid prescribing?

What should provider organizations do to address the problem?

What is the role of payers and PBMs in restricting opioid use?

How should drug distributors prevent misuse of opioids?

To what degree is the opioid problem a function of legal vs. illegal drugs? How can the healthcare system help prevent addiction to illegal opioids?

Can regulation (e.g. prescription caps) help strike a balance between pain treatment and addiction risk, or should decisions be left to individual providers?

Should the United States push to legalize supervised consumption sites, also known as safe injection sites?

Should the use of needle exchange programs be expanded to reduce the impact of opioid abuse?

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Should the US invest in more naloxone distribution programs?

Should prescription drug monitoring programs be expanded?

Does changing drug scheduling increase or reduce opioid addiction?

How could better use of EMRs help with the addiction problem?

Given criticism and lawsuits aimed at opioid manufacturers, what lessons should we apply to future marketing of pain medications?

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