

Toward an Effective Strategy to Combat HIV, Hepatitis C and the Opioid Epidemic: Recommendations for Policy Makers



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MAKING AIDS HISTORY

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Introduction

A dramatic increase in opioid use has led to drug-related overdose deaths surpassing motor vehicle accidents as the leading cause of mortality among adults under 50. In the most recent estimates, 63,632 people died from drug-related causes in just one year (2016).¹ Dubbed an opioid epidemic by the U.S. Drug Enforcement Agency (DEA),² this public health crisis has spurred a wide array of efforts to increase access to addiction treatment services, reduce trafficking of high-potency synthetic opioid drugs, and reduce overprescribing of prescription drugs. However, an underappreciated concern is the intersection between opioid use and infectious diseases such as HIV and hepatitis C (HCV), infections that are efficiently transmitted via shared syringes or other injection equipment. A coherent legislative strategy is urgently needed to holistically and effectively address this trifecta of public health threats.

The United States alone consumes 80% of the world's oxycodone supply.

The etiological beginnings of the opioid epidemic are in overprescribing of prescription opioid analgesic drugs (Fig. 1). The Centers for Disease Control and Prevention (CDC) reports that from 1999 to 2014, the prescribing of opioid drugs increased nearly fourfold, while reported levels of pain remained constant overall.³ Two separate studies, published in 1980 and 1986, reported that opioids posed a low risk for addiction and were safe to be prescribed for patients with non-cancer pain. This body of work served as an evidence base that justified broader prescribing of opioids, and despite considerable contemporary literature discrediting these findings, narcotics now account for approximately one-quarter of all prescription costs and amount to more than 650,000 opioid prescriptions dispensed every day.^{4,5}

In 1996, Purdue Pharma released a novel time-released formula of oxycodone, marketed as OxyContin, accompanied by aggressive physician education campaigns and accompanying literature outlining the safety of long-term use for non-cancer pain. Yet this formulation, which the Food and Drug Administration (FDA) initially erroneously labeled as having a lower potential for abuse, contained an atypically large amount of oxycodone and was easily dissolved for injection. Today, OxyContin accounts for one-quarter of all prescribed narcotic drugs, with the United States alone consuming 80% of the world's oxycodone supply.^{6,7}

Key Messages

Mitigating the long-term harms for people with substance use disorders will require a multifaceted strategy that increases access to treatment, reduces the risk of HIV and hepatitis C (HCV) acquisition, and lowers the risk of fatal drug overdoses. This report describes a set of recommendations to accomplish these aims:

Access to Treatment

1. Increase funding and reduce barriers to addiction treatment programs, including medication-assisted treatment;
2. Maintain insurance coverage for people with substance use disorders;
3. Support research for new treatment options and overdose prevention.

Reducing HIV and HCV Infections

4. Lift the ban on the use of federal funding for syringes;
5. Develop state legislation authorizing the operation of syringe services programs (SSPs) and increase funding for SSPs;
6. Remove barriers to receiving treatment for HCV;
7. Maintain funding for services for people with HIV;
8. Support surveillance for HCV, HIV, and other infections.

Preventing Drug Overdoses

9. Develop new funding streams to purchase naloxone and to make naloxone available to first responders and community members;
10. Enact naloxone access and Good Samaritan laws;
11. Consider implementation of supervised consumption sites.

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The impact of overprescribing was ultimately felt in the more than 2.4 million Americans now meeting the criteria for severe opioid use disorder (OUD) involving dependence on prescription opioid analgesics, heroin, or both.⁸ Yet in 2016, nine out of ten people who reported needing treatment for substance use disorders were not receiving it.⁹ Several barriers have been identified as contributing to low rates of treatment, including patients choosing not to seek treatment, but also a significant gap between treatment need and availability. Among all states and the District of Columbia, 96% are found to have opioid abuse or dependence rates higher than their buprenorphine capacity.¹⁰ While recent guidelines from the CDC on prescribing practices have reduced access to prescription opioids, a shift toward increasing use of heroin, fentanyl, and other synthetic opioids has continued to push the overdose death count higher.¹¹

Rising rates of drug injecting, both of prescription and non-prescription drugs, has created another public health crisis: a rise in incidence of infectious diseases like HIV and hepatitis C among injection drug users. This critical convergence was recently observed in a 2014 outbreak of HIV and hepatitis C among a network of people injecting the prescription opioid Opana-ER,

which led to more than 200 people acquiring HIV, nearly 100% of whom were co-infected with hepatitis C.¹² This devastating outbreak portends future similar rapid increases in HIV and HCV infections; indeed, an assessment by the CDC has found that more than 220 counties are vulnerable to a similar outbreak of HIV and HCV among people who inject drugs.¹³

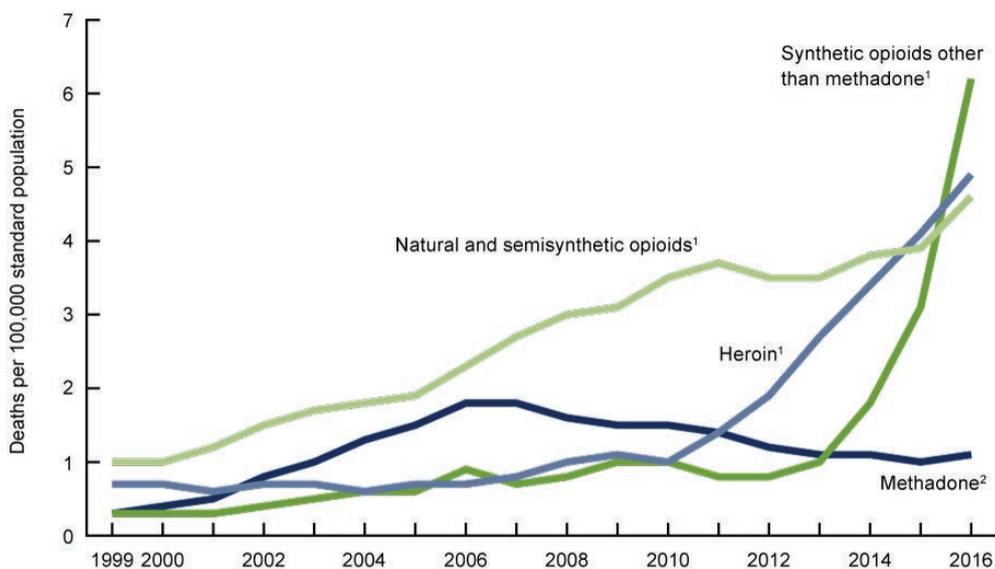
Response to date

The response to the opioid epidemic has primarily focused on reducing the overprescribing of opioid drugs, increasing the uptake and success of addiction treatment services, and reducing harm among those who use drugs. In 2016, the CDC released guidance on opioid prescribing for patients with chronic pain, addressing the correct indication for initiating opioid prescribing for pain and the appropriate dosage, opioid type, and duration of prescribing.¹⁴ To increase monitoring capacity and to reduce ‘doctor shopping,’ every state has now adopted a prescription drug monitoring program (PDMP). Several states have established free continuing medical education (CME) curricula and webinars to disseminate best prescribing practices to physicians.¹⁵ Ongoing policy efforts center on establishing statutory or guideline limitations on opioid

prescribing, increasing the use of PDMPs, strengthening the FDA’s opioid approval and monitoring process, and increasing the availability and uptake of training and re-training programs for healthcare providers.

Reducing overprescribing is an important avenue for addressing the epidemic. Mitigating the long-term harms for those with substance use disorders, in parallel and over a longer time horizon, will require a multifaceted strategy that increases access to treatment, reduces the risk of HIV and HCV acquisition, and lowers the risk of fatal drug overdoses. This report describes a set of recommendations to accomplish these aims, collected from a review of peer-reviewed articles, popular news reports, and databases including but not limited

FIGURE 1: Age-adjusted drug overdose death rates, by opioid category: United States, 1999–2016.



Source: NCHS, National Vital Statistics System, Mortality (<https://www.cdc.gov/nchs/nvss/deaths.htm>)

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to the National Institutes for Health (NIH), CDC, FDA, and HHS. In addition, recommendations are drawn from a series of blueprints, roadmaps, and collected recommendations from organizations and associations including the National Governors Association, the President’s Commission on Combating Drug Addiction and the Opioid Crisis, the American Medical Association (AMA), and from witness testimony in Congressional hearings. In compiling this document, data were drawn from amfAR’s Opioid & Health Indicators database, a public resource compiling data from CDC, SAMHSA, and other sources.¹⁶ These recommendations are not exhaustive, but are tailored to addressing both opioid use and infectious diseases, chosen for both the evidence base on each intervention’s efficacy and the reasonable ability for state and federal actors to legislate in these areas.

Increasing access to treatment

According to the World Health Organization (WHO), treating substance use disorders is an important step in mitigating the social and health harms associated with drug use, including

infection with HIV. While no treatment regimen is appropriate for all patients, the WHO, UNAIDS, National Institute on Drug Abuse (NIDA), and the United Nations Office on Drug Policy recommends medication-assisted treatment (MAT) as one of the most effective regimens for people with opioid dependence (Table 1).^{17,18} In the U.S., MAT comprises three FDA-approved medications: methadone, buprenorphine, and naltrexone.

Despite the availability of effective treatment for drug dependence, only 10% of the 27 million Americans who suffer from addiction receive treatment.

By facilitating reductions in opioid use, MAT has been shown to be both safe and cost-effective in reducing the risk of overdose. For example, a study of heroin overdose deaths in Baltimore found that increasing the availability of buprenorphine and methadone decreased the number of overdose deaths by 50%.¹⁹ A 2010 study

TABLE 1. Characteristics of the three approved medicines for medication-assisted treatment.²¹

	Methadone	Buprenorphine	Naltrexone
Brand names	Dolophine, Methadose	Subutex, Suboxone, Zubsolv	Depade, ReVia, Vivitrol
Class	Agonist (fully activates opioid receptors)	Partial agonist (activates opioid receptors but produces a diminished response even with full occupancy)	Antagonist (blocks the opioid receptors and interferes with the rewarding and analgesic effects of opioids)
Use and effects	Taken once per day orally to reduce opioid cravings and withdrawal symptoms	Taken orally or sublingually (usually once a day) to relieve opioid cravings and withdrawal symptoms	Taken orally or by injection to diminish the reinforcing effects of opioids (potentially extinguishing the association between conditioned stimuli and opioid use)
Advantages	High strength and efficacy as long as oral dosing (which slows brain uptake and reduces euphoria) is adhered to; excellent option for patients who have no response to other medications	Eligible to be prescribed by certified physicians, which eliminates the need to visit specialized treatment clinics and thus widens availability	Not addictive or sedating and does not result in physical dependence; a recently approved depot injection formulation, Vivitrol, eliminates need for daily dosing
Disadvantages	Mostly available through approved outpatient treatment programs, which patients must visit daily	Subutex has measurable abuse liability; Suboxone diminishes this risk by including naloxone, an antagonist that induces withdrawal if the drug is injected	Poor patient compliance (but Vivitrol should improve compliance); initiation requires attaining prolonged (e.g., 7-day) abstinence, during which withdrawal, relapse, and early dropout may occur

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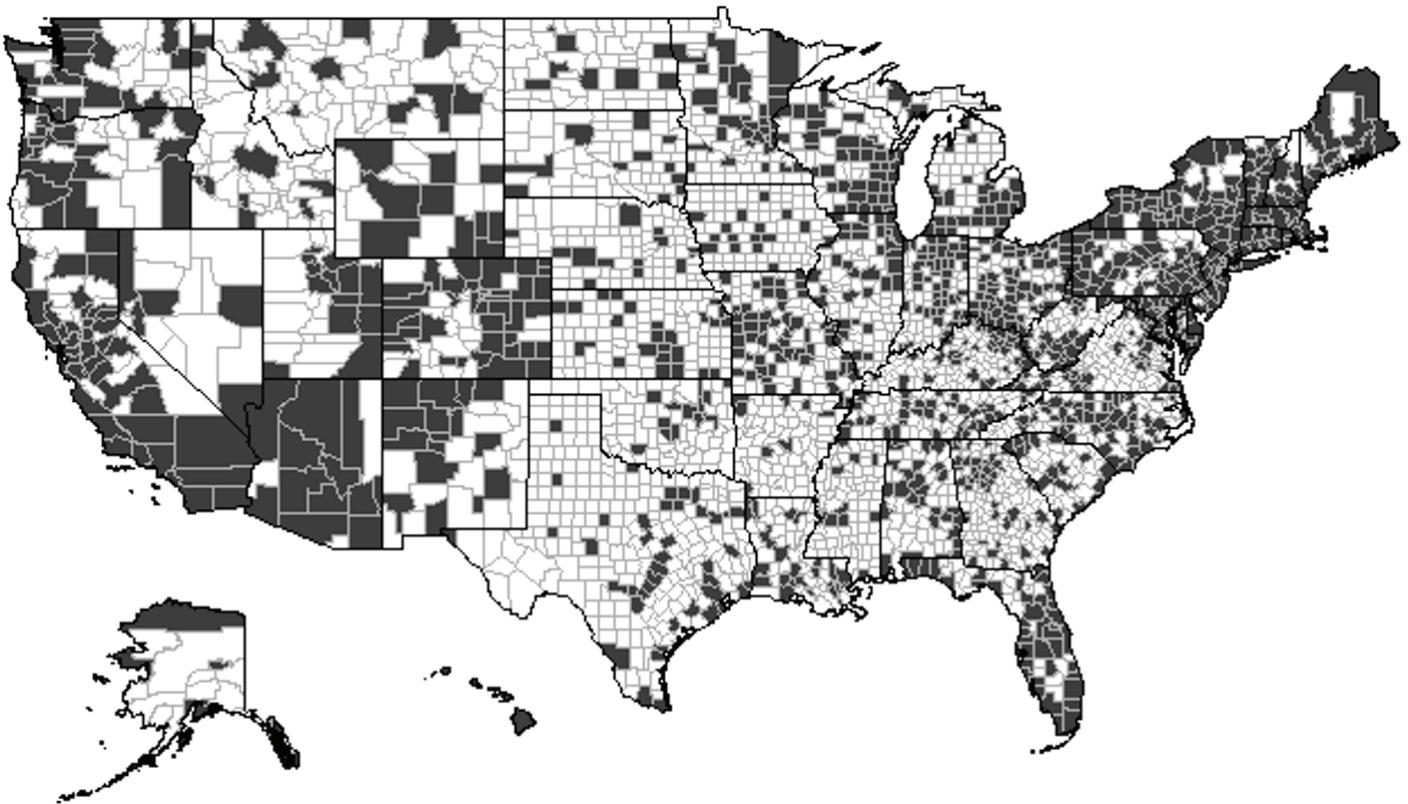
found that over a five-year period, patients on MAT had 50% lower total annual health costs than those who had two or more visits to an addiction treatment department.²⁰

Yet despite the existence of effective treatment for drug dependence, only 10% of the 27 million Americans who suffer from addiction receive treatment.²² Treatment programs that do not have enough beds or space to accept new patients create waitlists, sometimes in excess of 12 months, which not only prolong drug use and associated risks but are compounded by additional financial and employment-related disruption and, in extreme cases, may lead to deliberate overdoses intended to expedite admission to a treatment program.²³ The operation of treatment facilities is further limited by the Institutes for Mental Diseases (IMD) exclusion in the Medicaid program, which prohibits the use of federal

Medicaid funding for residential addiction treatment programs with greater than 16 beds.²⁴

The availability of MAT within treatment programs is even more restricted. An assessment of N-SSATS data, an annual survey of all facilities providing addiction treatment services, finds that in 2017 61% of counties in the U.S did not have any treatment programs that offered at least one MAT drug (Fig. 2).²⁵ Since 2000, buprenorphine may be prescribed outside of SAMHSA-certified opioid treatment programs through a certification process with the DEA, in which physicians receive waivers from the registration requirements normally required by the Controlled Substances Act when prescribing controlled substances.²⁶ As part of this process, physicians must first maintain a caseload of 30 patients, with the option to increase the number of patients to 100 or 275, via an

FIGURE 2. Counties with treatment facilities that offer at least one MAT medication (methadone, buprenorphine, or naltrexone) are indicated in black, counties with no facilities offering MAT are shown in white.



Source: N-SSATS (2017).

additional certification procedure. However, in one study of more than 3,000 buprenorphine prescribers in the U.S., nearly one-quarter prescribe buprenorphine to fewer than three patients per month.²⁷ According to SAMHSA, approximately 40% of physicians do not prescribe buprenorphine at all,²⁸ citing concerns about reimbursement, staff training, visit time, access to counseling, and availability of buprenorphine.²⁹

In addition, uptake of addiction treatment is dependent on the affordability of care. Medicaid is an important funder of MAT and in 2016 reimbursed 24% of all buprenorphine prescriptions in the U.S.³⁰ While the expansion of Medicaid provided an important source of insurance for low-income adults, any changes to these policies risk creating significant barriers for people seeking care. Yet 38% of substance abuse treatment programs did not accept Medicaid as payment in 2017, and eleven state Medicaid programs place a lifetime limit on the use of buprenorphine.³¹ Furthermore,

38% of substance abuse treatment programs did not accept Medicaid as payment in 2017.

buprenorphine prescriptions require prior authorization as part of some state Medicaid or private insurance company policies, policies that organizations like the AMA have urged state attorney generals to eliminate.³² Other insurance-related barriers include caps on dosages, lifetime limits on medicines or mental health services, or so-called 'fail-first' policies in which patients must first experience treatment failure under counseling regimens before beginning MAT.³³

Finally, accessing addiction treatment will require creating specialized venues for care for certain populations. Pregnant women and women of childbearing age are at particular risk, with the rate of neonatal abstinence syndrome increasing by 300% from 1999 to 2013.³⁴ While no addiction medication is FDA-approved for the treatment of pregnant women, combining methadone or buprenorphine maintenance therapy with specialized prenatal care may reduce the impact on infants.³⁵ Incarcerated populations similarly require special considerations, with an estimated 65% of all inmates identified as having a substance use disorder, yet only 11% receiving any treatment.³⁶ Methadone is only permitted for the use of detoxification and not for routine maintenance;³⁷ as such, less than 0.6% of all prisons and jails offer either methadone or buprenorphine,³⁸ despite evidence that forced opioid withdrawal is both harmful to the health of prisoners and produces substantial

societal costs.³⁹ The WHO, which identifies methadone on its List of Essential Medicines, recommends access to methadone for all incarcerated persons.⁴⁰ In addition, while incarcerated persons are eligible for Medicaid coverage, coverage is often suspended while a person is incarcerated and must be reinstated upon release in order to prevent gaps in access to treatment.⁴¹

Recommendations

1. Increase funding for addiction treatment programs.

Increasing the number of substance abuse treatment facilities, and the capacity of existing programs, will require a sustained fiscal commitment from both federal and state governments. Maintain appropriated funding levels for important programs including the state grants under the *21st Century Cures Act* and SAMHSA's Substance Abuse Prevention and Treatment Block Grants, as well as state funding streams for treatment facilities. Remove the IMD exclusion to allow federal Medicaid funds to reimburse treatment in all residential programs. Pilots of MAT implementation in correctional systems have resulted in significant reductions in overdose-related deaths after release.⁴²

2. Maintain insurance coverage for people with substance use disorders.

Given the important role of Medicaid in reimbursing the cost of substance abuse treatment, ensure that federal legislative action on Medicaid maintains health insurance coverage for low-income adults. State Medicaid programs should cover the full range of treatment-related services, including inpatient detoxification, hospitalization, and long-term case management.⁴³ Ensure that private health insurance plans reimburse substance abuse treatment by conserving and enforcing the Mental Health Parity and Essential Health Benefits provisions of the *Affordable Care Act*.

3. Increase access to buprenorphine treatment.

The gradual deregulation of buprenorphine prescribing, first in the initial DATA-2000 bill allowing for prescribing outside of opioid treatment programs, and subsequently in amendments lifting the patient caps to 275 patients and allowing nurse practitioners and physician assistants to receive waivers, has been instrumental in increasing access to treatment. However, patients continue to experience significant barriers to care, suggesting that these limits may be inadvertently restricting access to treatment. Reduce administrative barriers to the waiver process and administer continuing medical education to increase prescribing rates among waived healthcare workers. Additionally, the Centers for Medicare and Medicaid Services can mandate that healthcare staff at federally qualified healthcare centers receive DATA-2000 waivers.

- 4. Reduce administrative barriers to treatment.** Amend state Medicaid program policies to reduce the prior authorization requirement for prescribing associated with medication-assisted treatment, lift lifetime caps on mental health treatment, and end 'fail-first' policies. In 36 states, Medicaid currently covers all three FDA recommended medication-assisted treatments; in the remaining states, amend Medicaid policies to cover all approved medications.⁴⁴
- 5. Support research for new treatment options.** Increase funding for the NIH to conduct research on new medications for use in treating opioid addiction as well as implementation research to increase access to, and success of, treatment programs. Support the CDC to evaluate the effectiveness and efficacy of treatment methods and delivery options.

Reducing HIV and HCV infections

While not all those who abuse opioids inject drugs, people who do inject drugs are at higher risk of transmission of blood-borne pathogens like HIV and HCV, since sharing needles, syringes, or other materials is an efficient route of viral transmission. Other risk factors associated with drug use, including sex without a condom, sex with multiple partners, and transactional sex also place people who inject drugs at high risk for HIV or HCV infection.⁴⁵ In the U.S., injection drug use is the most common transmission route of HCV and is one of the most efficient routes of HIV transmission.^{46,47} In the last five years, the rate of new HCV infections has nearly tripled, driven primarily by drug use.⁴⁸ Additionally, rising HIV and HCV infections place an enormous economic burden on the community; the estimated lifetime treatment cost for HIV, for example, is well above \$400,000.

The most effective mechanism for reducing the transmission of HIV and HCV among people who inject drugs is to reduce the sharing of syringes. Syringe services programs (SSPs) are programs in which used needles may be exchanged for unused injection equipment. Not only have these programs been shown to be effective in reducing needle sharing and re-use, but they also serve as an important contact point with social services for people who inject drugs.⁴⁹ Most SSPs provide counseling and referrals for treatment programs and other mental and physical healthcare, provide condoms and HIV pre- and post-exposure prophylaxis, and distribute the overdose-reversing medication naloxone. In one study, new users of SSPs were over five times more likely to enter treatment than those outside of the programs.⁵⁰ Another found

Despite a history of demonstrated efficacy in reducing harm among drug users, only 6% of counties have a syringe services program and 10 states have none at all.

that within six months of accessing SSPs, clients were 25% more likely gain access to mental health treatment and 45% of clients saw an increase in employment.⁵¹ For every dollar invested in SSPs, an estimated \$3–7 in cost savings is realized by preventing new HIV infections alone.⁵²

While historically federal funding has not been used for SSPs, since 2016 federal grants through SAMHSA and the CDC may be used for SSP operational expenses after states have undergone a consultation with the CDC. This consultation requires states to demonstrate that the state or jurisdiction is experiencing, or is at high risk of, outbreaks of HIV or HCV related to drug use. Federal funding can be used for all expenses except for the purchase of the syringes themselves. The use of state funds for SSPs is highly variable, with several states explicitly prohibiting their use and 16 states requiring legislative action to legalize SSPs (Fig. 3).

Despite a history of demonstrated efficacy in reducing harm among drug users, SSPs remain sparse. In the U.S., only 6% of counties have an SSP; 10 states have none at all (Fig. 3).⁵³ The efficacy of SSPs is limited by the travel time required to reach a program; by one analysis, use of SSPs decreases dramatically beyond a ten-mile radius. Indeed, a study of all young people living with HCV in the U.S found that 80% lived more than ten miles from an SSP.⁵⁴ Mobile SSPs may provide a workable solution in rural communities or in cities where people who use drugs are concentrated in multiple areas.

Health service provision for people diagnosed with HIV and HCV is an important step toward improving health and social outcomes for current and former injection drug users. While HCV is treatable and curable using modern treatment regimens, insurance coverage of treatment is variable. For example, in 24 states Medicaid programs require a period of abstinence from alcohol and drugs before a person is eligible for HCV treatment,⁵⁵ a practice that delays treatment and is ultimately anachronistic given that the costs of treatment have fallen dramatically in recent years. Other Medicaid programs limit treatment based on grade of liver damage or HIV co-infection criteria, or require that treatment be provided by providers specializing in hepatology, infectious disease, or gastroenterology.⁵⁶

3. Increase funding for SSPs. Both Congress and state legislators, in concert with SAMHSA and the CDC, should develop specific grant programs in order to fund SSPs without diverting resources from other existing evidence-based prevention programs. Additionally, state legislators in collaboration with city health commissioners should establish SSPs in counties with high rates of drug use, either as freestanding facilities or as mobile units.

4. Remove barriers to receiving treatment for HCV. Remove sobriety, fibrosis criteria, HIV co-infection, and prescriber specialty requirements for HCV treatment in Medicaid programs.

5. Support surveillance for HCV and other infections. Increase funding for the CDC Division of Viral Hepatitis and for the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) grant program, which helps strengthen an effective public health workforce and supports nimble surveillance systems, modern and efficient laboratory facilities, and more integrated information networks. Appropriate state funding to increase surveillance capacity and improve data quality.

6. Maintain funding for services for people with HIV. Maintain appropriations for federal surveillance, prevention, and treatment programs for people living with or at risk of HIV and HCV, including the CDC's Division of HIV/AIDS Prevention and the Division of Viral Hepatitis, SAMHSA, the Ryan White HIV/AIDS program, and HOPWA.

Preventing drug overdoses

Since the use of opioid drugs can lead to fatal respiratory depression, rising opioid use and rates of addiction have led to devastating increases in drug-related mortality. The number of unintentional drug poisoning deaths in the United States has more than quadrupled since 1999 and the rate of emergency department visits related to nonmedical opioid use more than doubled from 2005 to 2015.⁶⁰ Naloxone is a non-addictive opioid antagonist that quickly reverses overdoses and is an important public health response to the opioid epidemic. Since the life-saving medication does not have potential for abuse and can be administered by nasal spray, increased access to naloxone is an important strategy for preventing overdose deaths. Additionally, naloxone distribution when combined with linkage to addiction treatment can not only be cost effective but cost saving as well.⁶¹

In spite of its life-saving potential, significant barriers to accessing naloxone remain. In four states, it is available only through a prescription given to a person at risk of an overdose. In all other states naloxone is available by third-party prescription, whereby those who regularly make contact with people who use opioids may purchase naloxone for use in the case of a drug overdose, or by a standing order that allows pharmacists and nurses to provide naloxone without the need for physician approval.⁶² Other ancillary policies are variable across states; for example, while many states have implemented 'Good Samaritan' laws to protect bystanders providing emergency aid for overdoses, in one-quarter of states laypersons may be subject to criminal liability when administering naloxone.⁶³ Naloxone prescribing has also been recommended as a co-prescription to patients receiving opioid medications, to reduce the risk of opioid-related overdoses.⁶⁴

Rising opioid use and rates of addiction have led to devastating increases in drug-related mortality.

Additionally, due to the high demand for naloxone, the costs to patients and the health system have increased drastically. For example, the price of injectable naloxone more than doubled from \$62 in 2012 to \$142 in 2016.⁶⁵ Rapidly rising naloxone pricing is compounded by rising use of extremely powerful narcotics such as fentanyl, which require multiple doses of naloxone in order to achieve efficacy. High demand for naloxone has resulted in several jurisdictions and cities experiencing shortages; others report using the entirety of ambulatory care budgets on naloxone alone. While some states and pharmaceutical companies have agreements for provision of naloxone at lower costs to clinics and hospitals, making naloxone nationally available to first responders, community organizations, and members of communities will require significant reductions in naloxone pricing and increased resources for state and local public health departments.

Finally, one of the most innovative strategies for harm reduction among people who use drugs is supervised consumption sites (SCS), which are private, secure, and hygienic spaces for people to use illicit drugs under the supervision of trained staff. These facilities, where implemented outside the U.S., have successfully increased access to medical and social services and reduced public drug use, without increasing the frequency of drug injecting or crime.⁶⁶

Recommendations

1. Develop new funding streams to purchase naloxone.

The demand for naloxone continues to outpace the ability to pay for it, and additional federal resources are critically needed to support state and local jurisdictions in purchasing the drug. In addition, the Department of Health and Human Services may declare a public health state of emergency, enabling it to negotiate naloxone pricing with pharmaceutical manufacturers.

2. Make naloxone available to first responders and community members.

All medical responders should carry naloxone, and businesses or community centers that experience drug overdoses on their premises should have access to naloxone. Legalize the purchase of naloxone by standing order or by third-party prescription.

3. Enact Good Samaritan laws.

Thirteen states have no Good Samaritan laws to protect individuals who provide help to someone experiencing a drug overdose, and many states have existing legislation that is weak or not comprehensive.⁶⁷ Enact Good Samaritan and naloxone access laws in all states.

4. Increase funding for overdose research.

Continuing to develop effective overdose reversing agents will require continued support for the federal research institutes that conduct addiction research, including the National Institute for Drug Abuse (NIDA) and the National Institute on Mental Health (NIMH).

5. Consider implementation of supervised consumption sites.

By providing a safe environment for people who use and inject drugs, communities can reduce public drug use while facilitating access to addiction treatment and other medical services.

Ending the opioid epidemic is possible,
but we must begin to act now.

Conclusions

Preliminary data from the CDC indicate that the number of drug-related deaths has increased by 21% in the last year alone.⁶⁸ Turning the tide on the opioid epidemic will require a concerted and appropriately-funded effort to deliver evidence-supported public health interventions where they are most needed. These recommendations provide a summary of federal and state actions that will be necessary to reduce drug-related deaths, reduce secondary infections like HIV and hepatitis C, and improve health outcomes for all people with substance use disorders. Ending the opioid epidemic is possible, but we must begin to act now.

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