

Expanding Access to Naloxone: Reducing Fatal Overdose, Saving Lives

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A serious but largely overlooked crisis has taken root in the United States. This epidemic continues virtually unchecked despite the existence of practical, low-cost interventions.

More than 100 people die every day in the United States from a drug overdose.¹ Overdose rates have tripled since 1990² and increased more than 140 percent between 2000 and 2008.³ More than twice as many people die every year from an accidental drug overdose than from firearms.⁴ In December, the Centers for Disease Control and Prevention (CDC) announced that poisoning surpassed auto collisions in 2008 as the leading cause of accidental death in the United States. Drug overdoses account for 9 out of 10 poisoning deaths, and more than 75 percent of drug overdoses are accidental.⁵

A national response is urgently needed and long overdue. Elected leaders, public officials and medical professionals can no longer delay the implementation of effective overdose reduction measures in every state and community. Failure to do so has already resulted in thousands of needless deaths every year.

Today's overdose crisis touches the lives of every type of family and individual, regardless of age, class, ethnicity or gender. Contrary to popular belief, it's not teenagers who die from drug overdose in the greatest numbers, but their parents – people in their 40s and 50s are more likely to die from an accidental drug overdose than adolescents. Furthermore, it's not illicit opiates like heroin that are primarily responsible for this growing crisis – more people die from prescription opioid overdoses than from all illicit drugs combined. (Opioids are a synthetic form of opiate – such as oxycodone or hydrocodone – that are available by prescription only, typically only for moderate-to-severe pain.)

By expanding the availability of proven, effective overdose interventions and improving education and outreach for people at risk of accidental overdose, policymakers can help to prevent the tragic and unnecessary loss of life.

Naloxone Saves Lives

Chief among today's highly effective available practices to halt and reverse the growing toll of accidental overdose fatalities is naloxone hydrochloride (also known as Narcan™), a low-cost medicine available generically that was first approved by the FDA in 1971. Naloxone is an opioid antagonist that blocks the brain cell receptors activated by prescription opioids such as oxycodone, as well as by illicit opiates such as heroin. It temporarily restores normal breathing within two to three minutes of administration.

Naloxone is the first line of treatment for emergency room physicians and paramedics upon encountering a patient experiencing an overdose. Ideally, emergency medical responders are summoned as soon as an overdose is detected. A dose of naloxone is then administered and rescue breathing is initiated if necessary. If the victim has not been revived after two minutes, another dose of naloxone is administered and so on until the naloxone has the desired effect. Naloxone's effects last for 30 to 75 minutes, allowing time for the arrival of emergency medical assistance.⁶ Though the research is contradictory, some studies suggest that once the naloxone effect wears off, opioids in the circulatory system may become toxic again and without medical attention victims can subsequently cease breathing again.⁷ However, naloxone can be administered repeatedly without harm.

Naloxone is most commonly administered via intramuscular injection, but it can also be administered intranasally using an atomizer device that delivers a mist to the nasal mucus membrane. The device used for this latter form of administration is not yet FDA approved, but it is in use by overdose prevention programs in Massachusetts, New Mexico and elsewhere.⁸

Naloxone's only effects are to reverse respiratory failure resulting from an opiate overdose and to cause uncomfortable withdrawal symptoms in the dependent user.⁹ It has no pharmacological effect if administered to a person who has not taken opiates¹⁰ and has no potential for abuse.¹¹ It is impossible to overdose on naloxone.

Expanding the Availability of Naloxone

One key barrier to broader naloxone access in the U.S. is its status as a prescription drug. Depending on state law, prescriptions for naloxone must either be written to individuals who have requested to carry the drug or may be made by programs operating under standing orders from a physician.

Advocates in some states are examining an alternative approach to increasing access to naloxone – changing the drug’s FDA status from “prescription only” to “over the counter” (OTC). Given that it has little to no potential for misuse, naloxone could meet OTC standards, making this option worthy of further consideration.

Providing take-home naloxone to prescription opioid patients and their care providers is a simple step to help reduce accidental deaths. In a study researching naloxone distributed for later administration in case of overdose to people who inject heroin, it was determined to be a “simple, inexpensive measure that has the potential to significantly reduce mortality caused by heroin overdose.”¹²

Another major barrier to expanding access to naloxone has been its status as a generic medication that is generally only used by emergency medical professionals. Because naloxone has limited use and is a generic medication, producing it does not yield substantial profits. Many pharmaceutical companies are unwilling to manufacture it, which has resulted in a scarcity of the medicine as demand increases for it. The scarcity of naloxone has increased its purchase price, which is another barrier to encouraging its distribution by service providers and other stakeholders with limited funding.¹³

Improving Naloxone Awareness Among Professionals

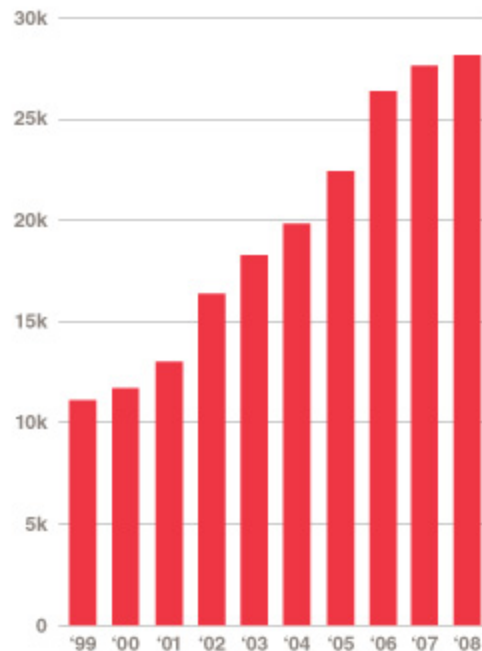
Although naloxone is the standard treatment for reversing respiratory failure due to opiate overdose and is widely used by EMS and other medical personnel,¹⁴ lack of awareness about public need and physician bias against drug users are ongoing obstacles to wider naloxone distribution. In a 2006 survey of 571 physicians, just 23 percent were aware of the practice of prescribing naloxone to prevent heroin overdose, and 54 percent said they would not

“consider prescribing naloxone and explaining its use to a patient (who uses injection drugs) because of their own negative views of injection drug users.”¹⁵

Support is growing among some physicians and other health professionals for regularly pairing naloxone with all opioid prescriptions.¹⁶ Under this scenario, physicians would routinely write a prescription for naloxone to accompany every prescription for opioid medications. Such a convention would have the dual benefits of safeguarding the life of the patient and normalizing naloxone by educating the greater public about its function and proper use.

It is particularly important to make naloxone available in methadone clinics, addiction treatment programs, syringe exchange programs and emergency rooms. Law enforcement professionals and prison personnel should also be trained on how to respond to opiate overdose, including rescue breathing and administration of naloxone. Individuals who are released from incarceration are at elevated risk of an overdose and should be provided naloxone prior to release into the community.¹⁷

1999-2008: Accidental Overdose Deaths Skyrocket



Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics. CDC Wonder, Compressed Mortality/Underlying Cause of Death, 1999-2008; ICD-10 codes X40-X44

Naloxone Training for the Public

Overdose prevention programs provide a variety of vital services. In states like California, New Mexico, New York and Massachusetts, these programs provide target populations with naloxone and train them in rescue breathing and the importance of dialing 911 before naloxone administration. Overdose prevention programs also provide drug treatment program referrals, and connections to healthcare, social services and a variety of other programs.

Naloxone distribution programs train potential overdose witnesses to correctly administer the drug to a peer in need, greatly reducing the risk of accidental death. Most programs typically teach all aspects of overdose prevention, recognition and response, including teaching life-saving skills such as rescue breathing ('mouth-to-mouth'). Unfortunately, the number of these life-saving programs remains much too small when compared to the scope of the national accidental overdose crisis, but their results are highly encouraging. A recent CDC report credits naloxone distribution programs with saving more than 10,000 lives since the first program opened fifteen years ago.¹⁸

Overall, participation in naloxone distribution programs has been found to improve participants' recognition of and response to overdose. A 2008 study, conducted by Yale University researchers, found that people who use drugs can learn to identify and respond to opioid overdoses just as effectively as medical professionals. The study, funded by the National Institute of Mental Health, found that people who use heroin who receive training can recognize an overdose and determine whether and when naloxone should be administered.¹⁹

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Furthermore, research suggests that people who use drugs are enthusiastic and increasingly knowledgeable about naloxone-availability programs.²⁰ A survey of people who inject drugs in San Francisco revealed that 87 percent would actively participate in an overdose prevention program that included take-home naloxone and overdose response training.²¹

Syringe Exchange Programs Demonstrate Public Interest in Naloxone

Community programs in a growing number of metropolitan areas are making important strides in increasing public access to naloxone. As of 2010, there were more than 180 naloxone distribution programs operating in fifteen states and the District of Columbia.²² A number of syringe exchange programs make naloxone available to people who inject illicit drugs, which creates important linkages between services that can help prevent both accidental overdose and the spread of HIV/AIDS, hepatitis and other infectious diseases among people who use injection drugs.

Public health authorities are also implementing overdose prevention programs that are tailored to unique populations. People who do not inject drugs but are at risk of an opioid overdose from prescription pain medications are being trained and provided with naloxone in a growing number of locations including North Carolina, Pennsylvania and Massachusetts. Individuals living with HIV are at heightened risk of a fatal overdose and would benefit from overdose prevention programs tailored to their needs.²³

Naloxone distribution programs are being implemented and integrated into diverse community settings such as social service organizations, addiction treatment programs, parent support groups, and physicians' offices in order to meet the needs of unique populations and adjust to the rapid increase in opiate overdose from both prescription and illegal drugs.²⁴

Naloxone-availability efforts have been undertaken in cities and states around the country with considerable success:

- A 2011 evaluation of a program in Pittsburgh found that 89 individuals reported administering naloxone in response to an overdose in a total of 249 separate overdose episodes. Of these 249 overdose episodes in which naloxone was administered, participants reported that 96 percent resulted in overdose reversal.²⁵
- An evaluation of a program in New York City found that, of 122 participants trained and provided with naloxone, 71 (nearly 60 percent) reported using naloxone in response to an overdose, and 83 percent of those individuals who received care from program participants were successfully

revived by the naloxone.²⁶

- An evaluation of the Chicago Recovery Alliance program – launched in 1998 and expanded in 2000 – in which physicians prescribe naloxone through mobile vans,²⁷ found that an estimated 10,211 people had engaged in the program and that 1,011 overdoses were reversed through naloxone administration as of December 2007.²⁸ Chicago, which had experienced a 135 percent increase in heroin overdose deaths between 1996 and 2000, saw a 30 percent decline in opioid overdose deaths, from 466 in 2000 to 324 in 2003.²⁹
- In 2011, U.S. Army medical personnel at the Fort Bragg Military Installation in North Carolina implemented Operation Opioid SAFE. The program provides overdose prevention training and naloxone to active duty soldiers who are returning to the United States from overseas assignments and are at higher risk of opioid overdose.³⁰
- The Baltimore City Department of Health announced in 2004 that at least 52 overdoses had been reversed through its naloxone overdose prevention program.³¹ Reduction of overdose deaths in Baltimore to a 10-year low in 2005 was partly attributed to naloxone distribution.³²
- San Francisco reported 148 heroin overdose reversals over three years (2004-06) as a direct result of its naloxone availability efforts.³³ Overdose deaths in the city declined in 2004, while overdoses in the rest of California increased by 42 percent.
- Reported overdose deaths in New Mexico, which has had a chronically high drug-related death rate, have dropped by 20 percent since the state's Department of Health began a naloxone-distribution program in 2001.³⁴
- Following the introduction in 2006 of a naloxone-access program, Boston recorded 60 peer overdose reversals using naloxone in just over a year.³⁵
- A December 2004 study of the Overdose Prevention and Reversal Program at the Lower East Side Harm Reduction Center in New York

City revealed that naloxone is “undeniably advantageous for individuals to effectively revive an overdosing friend or family member, instead of resorting to potentially harmful and less effective methods of resuscitation.”³⁶

- New York State passed legislation in 2005 establishing that physicians may lawfully prescribe naloxone explicitly for potential future opiate overdose.³⁷
- In 2007 in North Carolina, recognizing the rising rate of overdose among pain patients, the state medical board approved Project Lazarus in Wilkes County. The program asks providers prescribing opioid pain medications to also prescribe naloxone to a broad range of patients who may be at high risk of overdose. It also dispenses naloxone nasal sprays to other high-risk populations leaving hospital emergency rooms, detox centers and jails.³⁸

As of 2010, there were more than 180 naloxone distribution programs operating in fifteen states and the District of Columbia.

Some European countries are promoting increasingly unrestricted naloxone access for more effective overdose prevention:

- In June 2005, the United Kingdom added naloxone to the list of medicines (such as emergency adrenaline, glucagons and snake antivenom) that may be given by injection “by anyone for the purpose of saving life in an emergency” without specific medical instruction.³⁹
- The drug has also been available over the counter without problems for many years in Italy.⁴⁰

Managing Unintended Consequences

Some physicians and policymakers have expressed concerns that expanding access to naloxone could promote unintended consequences. The fear is that naloxone availability will encourage additional risky behavior on the part of overdose victims, including failing to seek medical attention, using larger dosages and/or injecting or ingesting additional opioids after naloxone administration to counter the unpleasant effects of naloxone-induced withdrawal.

Ongoing research does not support such claims. Two European studies found no serious adverse effects and observed no increase in risky behavior associated with naloxone availability.⁴¹ One survey of people who inject heroin found that few would use more heroin following administration of naloxone.⁴² In another, participants in naloxone programs reported no interest in increasing dosage or injecting more frequently as a result of naloxone availability.⁴³

Some encouraging data are also emerging regarding the provision of care. A 2005 study of San Francisco's pilot naloxone access program found that, of 20 overdoses witnessed by drug users trained in overdose response, 19 victims received CPR or naloxone from the trainee and all 20 survived.⁴⁴ Expansion of naloxone availability and carefully monitored analyses of its impact would provide important evidence on its potential and on whether concerns about unintended effects are justified.

Recommendations

The following public policy recommendations, if implemented, would significantly reduce the incidence of accidental fatal overdose, especially those involving opioids, in the United States.

- 1) Enhance overdose prevention education.
- 2) Improve monitoring, research, outreach and coordination to build awareness of the overdose crisis, its ramifications, and public health approaches to reducing it.⁴⁵
- 3) Remove barriers to naloxone access.
- 4) Promote 911 Good Samaritan immunity law reform.

Congress should:

- make ongoing NIDA grants to existing research projects for determining: the circumstances and risk factors of overdose deaths due to contaminants; the efficiency of current naloxone protocols; what overdose and drug abuse prevention messages work best; and who is overdosing, what they're overdosing on, why they're overdosing and how it can be prevented.
- fund clinical trials necessary to assess the feasibility of nationwide over-the-counter access to naloxone and direct the FDA to fast track research and decision making. Federally funded research and design around an FDA-approved intranasal delivery device (similar to an asthma inhaler or nasal decongestant spray) would help enable over-the-counter naloxone.
- act to improve overdose data collection and collaboration between relevant federal and state agencies.
- develop a national annual report on nonfatal and fatal overdoses that includes trends in polydrug use in victims, full toxicology and victim profiles. Ideally, such a report would document which drugs were in the bloodstreams of overdose victims; underlying drugs resulting in overdose deaths; age, sex and race of victims; and location of death, i.e. home, hospital or street.

- quickly disseminate SAMHSA information on model overdose prevention programs and fund training and technical assistance to implement them.
- develop a national alert system for handling regional overdose-related emergencies and widely share DEA information on drug contaminants or other factors affecting the potency and purity of street drugs.
- direct the U.S. Department of Health and Human Services to work with the above-mentioned agencies and the FDA to describe the overdose crisis for Congress, with a state-by-state review that includes overdose patterns, prevention methods, data collection recommendations and programs to improve emergency responses.
- establish trial research programs that examine the efficacy of supervised injection facilities and gather more data.

Congress and states should:

- expand funding for overdose prevention programs to include naloxone distribution and training.
- pass legislation to shield medical professionals, law enforcement and laypeople from civil or criminal liability for participating in naloxone programs or for emergency administration of naloxone.
- support uniform training of first responders, emergency medical technicians and law enforcement personnel on overdose prevention and management and on the proper use of naloxone.

States and cities should:

- provide education in prevention and overdose reversal to people residing in homeless shelters and to individuals prior to their release from jails, prisons, residential treatment and detoxification programs.
- provide overdose education at methadone clinics and all syringe exchange programs.
- support public education initiatives to foster and

improve cooperation with ambulance and police services.

- train drug users in CPR and rescue breathing and address treatment and relapse concerns.
- encourage doctors to prescribe naloxone to opioid pain patients and better educate their patients about the risks inherent to opioid analgesics.
- devise overdose trainings and education campaigns targeted at general- and family-practice physicians, registered nurses, pharmacists and other medical personnel.
- enact 911 Good Samaritan immunity laws at all jurisdictional levels to protect overdose witnesses from criminal prosecution.
- shield first responders from liability should the use of naloxone prove ineffective.
- consider the benefits of medically supervised injection facilities as a method of reducing drug-related harm to individuals, reducing crime and improving public safety and quality of life.

Doctors should:

- provide patients using prescription methadone or other opioids for pain management with overdose prevention instruction that covers diversion to “non-medical” use.
- be encouraged to prescribe naloxone to opioid pain patients and better educate their patients about the risks inherent to opioid analgesics.

Conclusion

Rising incidences of injury and death related to accidental drug overdoses remain a hidden crisis in the United States. The first step in combating this crisis must be the promotion of informed public discussion and debate about the problem, which claims tens of thousands of lives each year.

The public health crisis of accidental fatal drug overdoses can be substantially addressed. Proven strategies exist to reduce the incidence of overdose and to dramatically lower the chance of fatality when an overdose does occur.

By employing the appropriate public health approaches, federal, state and local authorities can effectively reduce overdose risk and fatality rates. Together, improved gathering and dissemination of critical drug-related information, expansion of access to naloxone, and provision of basic legal protections for good Samaritans and medical personnel, as well as genuine exploration of more cutting-edge strategies, can prevent overdoses and save thousands of lives.

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