

Concepts in Disaster Medicine

Cite this article: Houser R. Expanding access to naloxone: A necessary step to curb the opioid epidemic. *Disaster Med Public Health Prep.* 17(e245), 1–4. doi: <https://doi.org/10.1017/dmp.2022.199>.


Keywords:

epidemics; health policy; public health practice; vulnerable populations; community health planning

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Expanding Access to Naloxone: A Necessary Step to Curb the Opioid Epidemic

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Abstract

The COVID-19 Pandemic has exacerbated the already worsening opioid epidemic within the United States. With a continuing increase in opioid overdose deaths, measures are needed to halt the needless number of deaths and begin on a path of recovery to address all the factors that impact the epidemic. The CDC has provided various recommendations to combat the increases in opioid overdose deaths. These recommendations have included expanded distribution and use of naloxone and overdose prevention education as essential services for people most at risk of overdose. While strategies should include the increase in community resources for those with opioid disorder and shifting the perspectives of healthcare to view opioid disorder as a chronic illness that can be treated with medication such as buprenorphine, these methods are not immediate enough to stop the trend in deaths. The United States must take immediate action to expand access to and use of Naloxone for the public and first responders. Naloxone alone cannot address the magnitude of this epidemic, but it is an essential first step in preventing immediate death while a multimodal strategy is enacted to fully protect those most at risk.

In just the 12 months preceding May 2020, over 81,000 drug overdose deaths occurred in the United States, which was the highest number of overdose deaths ever recorded in a 12-month period.¹ This follows increases in the number of overdose deaths before the emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).¹ The acceleration of overdose deaths within the pandemic suggests immediate action is needed to address the worsening opioid epidemic within the United States.

The Centers for Disease Control and Prevention (CDC) has provided various recommendations as a result of the increases in opioid overdose deaths. These recommendations have included expanding the distribution and use of naloxone and overdose prevention education as part of the need for essential services to remain accessible for people most at risk of overdose.¹ This is a similar tenet held by the Department of Health and Human Services, which has identified naloxone as one of the top 3 strategies for combating the opioid epidemic.² Naloxone is a high priority in response to an opioid overdose as it can reverse an overdose when given intranasally, intramuscularly, or intravenously.² The Food and Drug Administration (FDA) has referred to naloxone as a “critical tool for individuals, families, first responders and communities to help reduce opioid overdose deaths.”³

Even with the consideration of the necessity of this medication in the face of an opioid overdose, there remains various barriers that limit access to the lifesaving medication. To best respond to the drastic increase in opioid overdose deaths, a multipronged strategy is needed to address the various components of this epidemic. While strategies should include the increase in community resources for those with opioid use disorder and shifting the perspectives of health care to view opioid use disorder as a chronic illness that can be treated with medication such as buprenorphine, these methods are not immediate enough to stop the trend in deaths. To halt the increasing rate of opioid overdose deaths, the United States must take immediate action to expand access to and use of naloxone for the general public as well as first responders.

Naloxone Use and Availability Landscape

The FDA approves of 3 forms of naloxone, including injectable, auto-injector, and nasal spray.³ As recently as 2019, these forms of FDA-approved naloxone required a prescription. Naloxone is becoming increasingly available at some pharmacies through a standing order, but various barriers exist, including cost, stigma, and disparate availability with the market for naloxone remaining relatively small with only US \$290 million in annual sales.² The FDA has estimated, however, that the national naloxone sales have doubled from 2013 to 2017 as a result of the worsening epidemic.⁴ Most of the naloxone sales were to non-retail locations of care and institutions, which supply the non-retail settings of care.² These non-retail locations of care include hospitals, clinics, and health departments that are likely to see patients who would benefit from access to naloxone. The vendors supplying the care organizations will also supply first responders, emergency medical services, and community groups who are engaged in the community and

have the best access to ensure that access to the lifesaving medication is maintained. Any pharmacy using naloxone as a standing order can also help provide naloxone directly to first responders and individuals as a harm reduction strategy, which will further saturate the market with the lifesaving medication. In just 1 year from 2016 to 2017, the number of naloxone prescriptions doubled in US retail pharmacies, increasing from 134,000 to 330,000.² This was followed by an overall naloxone prescription count of 556,000 in 2018.⁵

Part of the cost barriers comes from the domination of the market by brand names. More than 68% of prescriptions for naloxone filled in retail pharmacies during 2017 were for nasal spray Narcan®, while 20% was for the autoinjector Evzio®.⁶ This is likely a result of the listing prices for the 2 products with a 2-pack of Narcan® costing around US \$150 and Evzio® costing around US \$4,000 for a 2-pack of autoinjectors. This is in contrast to the cost of formulation as injection formulations are much less expensive, but the sales of these products are dominated by the branded medication specifically targeted and designed for bystander use.² In April 2019, the FDA approved the first generic naloxone hydrochloride nasal spray and was granting priority review to all generic applications of products that could be used in an emergency application for treatment of a known or suspected opioid overdose.³ The FDA also took unprecedented steps in January 2019 to encourage the development of over-the-counter naloxone products. The FDA designed, tested, and validated the key labeling requirements necessary to approve an over-the-counter version of naloxone.³ This proactive approach encourages drug companies to use the information within their applications for approval for over-the-counter naloxone, which would increase access to the general public removing barriers that would prevent those in need from seeking the medical evaluations necessary for a prescription.

Opioid use disorder affects over 16 million people worldwide and over 2.1 million within the United States.⁷ This makes the potential need for naloxone to be large; however, the barriers to access pose a significant risk to health. By focusing on naloxone distribution strategies that target those who need access the most, including first responders, people with opioid use disorders, their social networks, and the communities in which these patients reside, the lifesaving medication will be better available to promptly reverse the deadly respiratory depression that is associated with an opioid overdose.

Increase First-Responder Access

Law enforcement, emergency medical services, and community-based naloxone distribution programs can work with their state or local health departments to order naloxone or can apply to be a Qualified Purchaser.⁸ With the number of emergency medical requests increasing and due to the location restraints of various emergency medical services, communities have increasingly equipped and trained police and fire personnel with naloxone.² With police often being the first to arrive on-scene of overdose emergencies in certain jurisdictions around the country, it is necessary that they have access to this lifesaving medication. Nearly 2,500 law enforcement agencies have reported that their officers carry naloxone.² While comprehensive data on the success of such programs does not exist, the implications of not having the ability to administer naloxone when in need are far greater than having the medication, but not needing to use it. An Ohio county found that a program that supplied police with naloxone led to a decrease

in opioid overdose and mortality within the year after implementation.⁹ The disparate standards across the country within Emergency Medical Services protocols, especially in Basic Life Support, also serve as a barrier to administering naloxone when a patient is having an overdose. States, such as New Jersey, have recently permitted the use of naloxone by Basic Life Support Emergency Medical Services providers, but have left the decision of whether or not to carry and utilize naloxone to individual agencies and their medical directors. The lack of standardization within the space and lack of access and use in the first responder community serve as a major gap that needs to be filled, especially if there are barriers to the general public having access to naloxone. When Emergency Medical Services are requested, the expectation is that the first responders will have the ability and the tools necessary to treat the patients who are presented to them. Until all first responders are equipped with naloxone, the United States will continue to face unnecessary losses of life that could have been prevented by first responders having access and being mandated to carry this lifesaving medication for overdose situations that are increasing in prevalence.

Increase Public Access

As discussed, naloxone is a medication that is increasingly widely used by emergency medical personnel and other first responders when trying to prevent an opioid overdose death. However, depending on the location within the United States, by the time a person having an overdose is reached by first responders, it is often too late.⁸ While first responders are still necessary for continued treatment and evaluation as naloxone is active in the body for only 30 to 90 minutes,⁸ the immediate administration by a member of the public or a family member, relative, or friend could be the difference between life and death. Increasing access to naloxone for public use is thus a necessary step to combating opioid overdose deaths.

While the number of prescriptions for naloxone doubled from 2017 to 2018, increasing access to those who are most at risk, only 1 naloxone prescription is dispensed for every 70 high-dose opioid prescriptions.⁸ This lack of access is also evident in rural counties, which are nearly 3 times more likely to be ranked low dispensing than metropolitan counties,⁷ even though rural counties are more likely to have an increased response time of first responders increasing the likelihood that naloxone will not be administered to a patient in time if not available to family or friends. This serves as a potential gap in cover, which could place those with opioid use disorder at an increased risk for death.

As of 2019, there were 23 states within the United States that have issued a statewide standing order, while 24 others had allowed jurisdictions to pass standing order laws. Standing orders are mechanisms by which a health care provider with prescribing privileges, including a state health officer, writes a prescription that covers a large group of people.¹⁰ Nine of these states give pharmacists the direct authority to dispense naloxone without a prescription and sell naloxone to the public. In addition, some states allow pharmacists prescriptive authority for naloxone using their own National Provider Identifier (NPI). These states have seen a significant decrease in overdose deaths with effects that grew stronger over time with overdose deaths decreasing by an average of 34%.¹¹ Even within states that rely on standing orders for supply, there is a large lack of proper implementation limiting access in states where it is permitted. In California, which has a statewide standing order, just 23.5% of 1,147 pharmacies indicated that

naloxone was available and could be dispensed without a prescription.¹² Similarly in Pennsylvania, which also has a statewide standing order, 45% of 682 pharmacies said that naloxone was available. Additionally, less than two-thirds of pharmacy staff members correctly answered questions about the standing order, and quotes of out-of-pocket costs ranged from US \$50 to \$4,000.¹³ Only 38% of New York City's 720 pharmacies had naloxone in stock and were willing to dispense it without a prescription. This included pharmacies that were on the state's standing order.¹⁴ The lack of universal application and access within these regulations suggests that there needs to be an additional avenue to access, through over-the-counter naloxone. There are now 47 states (excluding Idaho, Nebraska, and Oregon) that do not have a standing order.¹⁰ Additionally, 48 states allow third-party prescribing, which "allows a prescriber to write a prescription for a medication to someone other than the intended user of the medication."¹⁰ Research from the National Bureau of Economic Research has shown that states that adopt a naloxone access law have a 9-11% decrease in the number of opioid-related deaths.¹⁰

The administration of naloxone is considered safe as administering naloxone to someone who is suffering from a different illness or a non-opioid overdose will not have any effect.¹⁵ There is no evidence of significant reactions to naloxone¹⁶ and the risk of an adverse reaction to naloxone is far less than not administering it when someone is having an overdose.^{17,18} This suggests that the increase in over-the-counter access could prove to be a successful tactic to address the worsening epidemic. Similar to opioid education and naloxone distribution programs, providing access and education can prevent deaths and be overall cost-effective.² Providing this education for community members may be a challenge of changing to an over-the-counter model since there may not be a trained medical provider or pharmacist present to educate on use. However, using the Internet or other means to share videos with purchasers either in the store or at their residence or other place of habitation can help overcome this challenge. The greater access to naloxone should increase the opportunities to reverse the number of opioid overdoses providing a large stopgap while working on longer-term solutions. This access could be done in coordination with health system distribution through co-prescribing, which co-prescribe naloxone to patients with opioid prescriptions who are at risk for opioid use disorder. Only 1.5% of 140,000 high-risk patients, who were commercially insured, were prescribed naloxone despite numerous interactions with the health care system.⁹ The CDC, the Substance Abuse and Mental Health Services Administration, and the American Medical Association all recommend that physicians consider co-prescribing naloxone and opioids for high-risk patients,² yet this remains an underutilized protective measure.

The increase in public access can also not occur without consideration of the cost and affordability for those in the public who would benefit from access; 71% of Medicare prescriptions for naloxone required a copay compared to 42% for commercial insurance.⁷ Medicaid, Medicare, and private insurance companies may cover the cost of naloxone but are not required to do so by law, which is a potential barrier to access as the out-of-pocket costs as previously mentioned range from US \$140 to \$4,000.¹⁸ While little information on effectiveness and cost-effectiveness of co-prescribing is available, an observational study in community health centers found that co-prescribing naloxone to chronic pain patients was associated with fewer opioid-related emergency department visits, which could be a benefit in reducing health care costs, a significant way to pay for the initiative. There is concern that

insurance providers may not cover naloxone if it is changed to over-the-counter status, which is why national lobbying and legislation are needed to ensure that this is available over-the-counter to anyone who needs it or could provide it to someone who needs lifesaving intervention.

Only after naloxone becomes widely available to the public can the country truly have meaningful and adequate coverage of the naloxone, which would help reduce the needless number of opioid overdose deaths within the United States. The best way to increase access is to fund the development of over-the-counter naloxone products, which will decrease the costs of products with generics entering the market and to ensure that the barriers to access are eliminated. Increasing the concentration of naloxone increases the likelihood that those suffering an overdose will be able to be saved by someone in their community who has naloxone, such as first responders or even those within the patient's social network who may have more immediate access to a patient. Additionally following the Opioid Rapid Response team model, which leverages federal resources and harnesses operations, workforce readiness, technical assistance, and partnerships are necessary to build a broader public health response capacity to support the protracted epidemic response.¹⁹

Discussion

Not all overdoses have to end in death. While there are various stakeholders who have a role in responding to the pandemic, including policy-makers and public health/community organizations, the immediate interventions must include the public and first responders in order to halt the troubling trend of increasing opioid overdose deaths. The FDA has an important role to play in leveraging its regulatory authority to address the crisis to work with partners in the pharmaceutical industry, health care space, and the general public to expand the availability and access to all forms of naloxone. Accompanied with longer-term initiatives, efforts to increase the access to naloxone will be vital for combating the worsening opioid epidemic by equipping those who need it the most, first responders and friends and family of opioid users, with the tools to reverse the deadly effects of an overdose. Naloxone alone cannot address the magnitude of this epidemic, but it is an essential first step in preventing immediate death while a multi-modal strategy is enacted to fully protect those most at risk.

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