SPTAC
STRATEGIC PREVENTION
TECHNICAL ASSISTANCE CENTER

UNDERSTANDING NALOXONE USE & ACCESS

UNDERSTANDING THE NEED

Opioid misuse remains a major public health problem in the United States. In 2021, over nine million people misused opioids, and there were 80,411 fatal opioid-involved overdoses—a 61.3 percent increase from 2019.[1,2] The Centers for Disease Control and Prevention estimated the annual economic cost of fatal opioid-involved overdoses at $550 billion in 2017 when there were 30,000+ fewer opioid-involved fatalities than in 2021.[3]

Stopping overdoses from becoming fatal is a crucial component of prevention, and naloxone is a vital tool in that effort. Naloxone is a U.S. Food and Drug Administration (FDA)-approved opioid overdose reversal medication that is administered to a person showing suspected signs of an opioid-involved overdose.[4] Naloxone works by binding to opioid receptors in the brain in place of opioids and blocking their effects.[5] Many studies have established naloxone's safety and that it presents little danger of addiction or abuse.[6,7,8] Naloxone is available in all 50 states as a nasal spray or injectable solution.[9]

Despite a slate of federal and state laws and policies that support access to naloxone, many extralegal barriers prevent naloxone from becoming as accessible as existing laws intended. A review of the literature points to several evidence-based strategies that may further improve access.

Want to learn more about how naloxone works?

Watch SAMHSA's What is Naloxone? video!

This product for prevention professionals and other public health partners describes:

- The current state of naloxone access

- Non-legal barriers to naloxone access
- Strategies to improve naloxone access
- Further factors to consider
- Existing resources that can support access expansion

STATE OF NALOXONE ACCESS

At the federal level, naloxone has been approved by the FDA as a prescription-required medication since 1971. This meant that individuals were required to obtain a prescription to get naloxone, which limited access to it. As such, during the opioid misuse epidemic, states began undertaking legal efforts (i.e., naloxone access laws) to work around the federal prescription requirement to further expand its reach.

While the first state naloxone access laws were implemented in the early 2000s, most states began implementing these laws in response to rising overdoses as fentanyl use increased in the 2010s. These legal changes have led to real, "on-the-ground" improvements in access to naloxone for many people.[10,11,12] Collectively, these laws have expanded legal access to naloxone beyond people directly at risk of an overdose; they have also granted legal authority to non-pharmacists to distribute naloxone.[13,14,15,16]

As of January 2023, all 50 states, the District of Columbia, and Puerto Rico (referred to collectively as "jurisdictions") allow people to purchase naloxone without an individual prescription.[17] Each jurisdiction has implemented one or more laws that allow for alternate methods to fulfill the FDA's prescription requirement.[*]

Types of Access Laws

Access laws fall into four general categories:

- **Third Party Prescriptions.** These prescriptions primarily authorize organizations to obtain naloxone and then distribute it to others through their staff, such as professional first responders and trainers seeking to provide education and distribution of naloxone within their communities.[18] They can also authorize naloxone distribution to individuals who are not at-risk of an overdose themselves, such as laypersons who may witness an overdose and other community members.

[*] Each law expands access to prescription naloxone, but the specifics can vary dramatically. The details of each jurisdiction's laws should guide local prevention activities.

All jurisdictions have at least one third party prescription law. These laws are often implemented alongside another type of access law—standing orders—so that these "third parties" don't need an individual prescription for naloxone.

- **Standing Orders or "Non-Patient-Specific Prescriptions."** [19] Standing orders are blanket prescriptions issued to pharmacies by prescribers that allow them to distribute naloxone to individuals who request it. The laws authorizing standing orders seek to better enable individuals at risk for an overdose to obtain naloxone, as well as interact with third party prescription laws to improve their reach. As of January 2023, 33 jurisdictions have jurisdiction-wide standing orders issued by a single authorized agency or prescriber to every pharmacy in the state. In the other 19 jurisdictions, individual prescribers are authorized to develop their own standing orders with the pharmacies they work with.[20]

- **Co-prescribing laws.** These suggest or require that naloxone be co-prescribed alongside opioid prescriptions. As of January 2023, 20 states had co-prescribing laws, 12 of which require co-prescribing in certain situations.[21]

- **School access laws.** These allow schools to have naloxone on-site; many authorize employees to administer it. School access laws often require schools to develop naloxone policies, and some require schools to stock naloxone. As of January 2023, 30 states had some form of school access law.[22]

Liability Protections

Many jurisdictions have also implemented liability protection laws for people who distribute, carry, or administer naloxone.[23,24] It is not a crime to distribute, carry, or administer naloxone in accordance with state law. So, technically, many liability laws are not necessary to confer legal protection. But these laws provide additional peace of mind for people and may protect against allegations of negligent or incorrect naloxone administration.

Liability laws are often implemented alongside another type of liability protection: Good Samaritan laws. These laws generally protect individuals from arrest or prosecution for substance possession or use if the discovery of possession or use occurred due to the person reporting a suspected overdose to emergency services.[25]

The Over-the-Counter Future

In 2023, the FDA first approved naloxone products for over-the-counter (OTC) status, setting the stage to make them available for purchase without a prescription.[26] The four-milligram brand name Narcan® nasal spray was approved in March, followed by a generic nasal spray product in

July.[27] As of September 2023, OTC Narcan was made available for purchase in stores and online through several major retailers. The generic OTC naloxone nasal spray, RiVive, is expected to be made available for purchase from retailers in early 2024. As of September 2023, OTC status has not been granted for non-nasal (e.g., injectable) formulations or for any other dosages.[28]

Despite this major milestone, barriers remain for OTC access.[29] Many logistical challenges must be addressed by a combination of the FDA, other federal agencies, retailers, insurers, naloxone manufacturers, and other partners. It may be several more months before OTC naloxone is fully available across all areas across the country and even longer before knowledge about its availability becomes widely known to the public. As a result, alternative methods continue to be crucial for ensuring access to naloxone.

NON-LEGAL BARRIERS TO NALOXONE ACCESS

Naloxone is now a primary and accepted standard of care for opioid overdose. However, while legal changes have significantly expanded access to naloxone—and the FDA's OTC approvals will likely further expand access—many barriers remain. These include, but are not limited to, a lack of **knowledge** about naloxone, **attitudes, values, and beliefs** towards naloxone and substance misuse, and **logistical barriers** to obtaining naloxone. Each of these barriers is described below.

Knowledge

Lack of knowledge about what naloxone is, and how, why, and when to use it, remains a significant barrier to access. Lack of knowledge can refer to any of the following:

- **Limited understanding of naloxone's benefits.** Awareness of and knowledge about naloxone's purpose remains relatively low among the general population in the US.[30]

- **Insufficient knowledge of when to administer naloxone.** Awareness among the wider public about the specific risks of opioid use, the kinds of substances that can contain opioids, and how to identify and respond to an overdose remains insufficient. Many people have difficulty recognizing the signs and symptoms of an opioid overdose and may not realize when naloxone is needed.[31]

- **Insufficient knowledge of how to administer naloxone.** Knowledge about how to use or administer naloxone remains low among the wider public. Though higher among individuals with a history of opioid misuse or prior exposure to opioid misuse, expanded education on administering naloxone is needed among this population as well.[32]

- **Lack of consensus around best practice training standards for prescribing, distributing, or receiving naloxone.** Many jurisdictions require people to complete a naloxone training program before they are allowed to legally prescribe, dispense, distribute, or administer naloxone—with separate trainings sometimes required for non-patient-specific distribution.[33] Different types of trainings exist for these many different audiences. However, there is a lack of best practice standards for individuals to learn and implement, and trainings may be missing important information or may not be communicated properly. This lack of uniformity may negatively impact naloxone in various ways, including affecting pharmacist dispensing practices or the effectiveness of pharmacist-delivered naloxone use training. [34]

- **Fear of prosecution.** A lack of understanding about legal protections can lead to fear of arrest or police involvement and prevent some individuals from calling emergency medical services during an overdose.[35] While most jurisdictions have Good Samaritan laws, these can differ significantly across and within each jurisdiction. Proper awareness and knowledge of these laws and how they are to be enforced also appear to vary significantly across policing agencies. Among other negative impacts, this can present a risk that the laws will not be applied correctly and lead to fears among the general public of unjust arrest and prosecution.[36] In addition, the public's knowledge of these laws further impacts their effectiveness, with studies suggesting that public awareness may range from 15 percent to 77 percent.[37] If the general population does not know they are protected by these laws, they may be less likely to call first responders for support in the event of an overdose.

Attitudes, Values, and Beliefs

Dismissive or negative attitudes, values, and beliefs about substance misuse and people who misuse substances can negatively impact naloxone access. These negative attitudes, values, and beliefs (i.e., stigma) often manifest in prejudice and discrimination. For example:

- Stigma among professions that treat or work with individuals who misuse substances (e.g., **health care providers, pharmacists**) can impact how or even if naloxone gets dispensed if the distributor holds negative views towards those who are seeking it. [38,39]

- Continued stigma among **law enforcement officers** has led some officers to refuse to carry, distribute, or administer naloxone. A study from 2020 found that 83

percent of law enforcement officers continue to believe that naloxone access may be used as an excuse to continue substance misuse.[40]

- Stigma **in the public** around substance misuse remains high.[41,42] Among other impacts, it can reduce the likelihood that individuals go to a pharmacy to get naloxone due to concerns that family, friends, or others could find out.[43]

Misinformation about naloxone also prevents many prescribers, pharmacists, and schools from providing **young people** with naloxone—despite the fact that there are no age restrictions on accessibility.[44] Some health care professionals believe that prescribing naloxone to youth may reduce the perceived negative consequences of substance misuse and lead to riskier patterns of opioid use—despite several recent studies showing that broader availability of naloxone did not increase adolescent heroin or injection drug use.[45,46,47,48] These beliefs may contribute to low implementation of youth-focused harm reduction efforts, including naloxone distribution. It may also explain why few pediatric providers offer naloxone co-prescriptions alongside prescription opioids or naloxone prescriptions to patients with prior opioid misuse, and why few schools have naloxone available on-site and/or staff trained in proper naloxone administration.[49]

Finally, discriminatory health care practices related to structural racism can play a significant role in reducing naloxone access. Structural racism is a main source of health inequity and occurs when decisions are made on a system-wide scale that benefits people of a certain race and creates chronic adverse outcomes for people of other races.[50,51] Studies have demonstrated that non-Hispanic Black people are less likely to be prescribed naloxone compared to their white counterparts, even when controlling for other demographic factors. This is consistent with research finding that Black patients regularly experience a lower quality of system-wide health care in the US.[52] Similar findings exist among Hispanic individuals, where issues such as language barriers, lack of Hispanic/Latino-focused naloxone education or social marketing campaigns, lack of culturally responsive health care providers, and fears or stress related to immigration status when seeking health care all contribute to significantly lower rates of naloxone access.[53] This is despite large, recent increases in fatal opioid-involved overdose rates among Hispanic individuals compared to non-Hispanic individuals.[54,55,56]

Logistical Barriers

Despite laws designed to ease legal access, other logistical barriers can reduce naloxone access. Some examples include the following:

- **Cost.** Naloxone can be cost-prohibitive. Prices vary based on manufacturer retail price, insurance coverage, state pricing regulations, and retailer fees and prices.[57,58] Out-of-pocket costs diverged by more than 630 percent between 2015 and 2018 for people with versus without insurance.[59] Prices can range from a few dollars to several thousand dollars per dose.[60] Naloxone pricing also varies by type.[61] Injectable naloxone tends to be less expensive, sometimes significantly so, than nasal naloxone. However, many states are using their federal opioid grant funds to purchase the more expensive nasal naloxone. which limits how many units can be purchased and therefore distributed to those in need.[62]

Naloxone Costs and Insurance

The impact of OTC naloxone on pricing is not yet fully known. Costs may vary as both private insurers and Medicaid programs determine whether and how to cover OTC naloxone. Even among plans that will cover it, there are questions about how many doses will be covered.

- **Limited support for recently incarcerated individuals.** Many people re-entering the community from carceral settings do not have access to naloxone. They often lack access to the support services that might provide naloxone, such as health care providers. Research shows that approximately 20 percent of all overdoses are among people recently released from incarceration. Overdoses are the leading cause of death among formerly incarcerated individuals, with the risk of overdose death between 40 and 129 times greater for an individual within the first two weeks post-release.[63,64,65,66,67]

- **Limited funding for naloxone education and distribution.** Despite significant expansions, funding often remains limited for organizations that distribute naloxone. Many funding barriers continue to exist, including restrictions on what types of distribution activities may be funded.[68] Additionally, while funds for naloxone can come from a wide variety of sources, they can be highly competitive and difficult to obtain.

Naloxone Access in Rural Communities

Rates of illicit substance misuse are often lower in rural areas but the negative effects from misuse can be higher. Opioid-involved overdoses have significantly risen in rural areas since the mid-2000s, yet research indicates that rural communities dispense naloxone at much lower rates than urban areas. Rural communities face additional barriers that further compound their access to naloxone. These include:

- **Limited access to trained emergency medical services (EMS).** EMS are often the first to administer naloxone. But EMS coverage in many rural areas is inconsistent and paramedic education programs are less common. In 2018, only 22 percent of rural residents lived within 30 miles of a paramedic education program, compared to 73 percent of other US residents.
- **Pharmacy environment.** The rural pharmacy environment presents several different barriers that can impact naloxone access for community members. Rural communities may have fewer corporate pharmacies, which are more likely to issue naloxone than independent pharmacies. In addition, rural pharmacies are less likely to keep naloxone in stock. Rural pharmacists are also more likely to report moral objections to providing naloxone to customers (relative to their urban and suburban counterparts).
- **Economic hardship.** The individual cost burden of naloxone is relatively high in rural communities that have been hard hit by economic instability and the opioid epidemic.
- **Transportation.** Lack of access to stable and affordable transportation services can prevent rural residents from reaching locations where naloxone is distributed.

STRATEGIES TO OVERCOME BARRIERS TO ACCESS

While a substantial body of research has identified barriers to naloxone access, research into evidence-based strategies to address those barriers remains more limited. The strategies outlined below address only some of the previously identified barriers. More research is needed to better understand those mechanisms that will be most effective in addressing the unique and oftentimes intersectional barriers that individuals face when accessing naloxone.

- **Implement overdose education and naloxone distribution programs.** Research has shown that overdose education and naloxone distribution (OEND) programs can reduce overdose deaths. OEND programs train participants on how to quickly prevent, recognize, and respond to a suspected overdose. They teach the importance of naloxone, how to correctly administer injectable or nasal naloxone during an overdose event, rescue breathing techniques, and the critical urgency of alerting emergency services.[69]

- **Expand existing distribution channels.** Some examples include the following:

  - *Service Providers*. Enhancing the ability of service providers (e.g., working in needle exchange programs, administering medication for opioid use disorder) to effectively distribute naloxone to those in need is associated with increased naloxone access among clients.[70,71]

  - *Mail-based programs.* Authorizing programs to mail naloxone kits upon request may further expand access, especially during times of restricted movement, such as those that occurred during the COVID-19 pandemic.[72] These programs can serve as a replacement option when other naloxone access points may not be easily available, as well as a primary distribution method for people facing transportation barriers.

  - *Leave-behind programs.* Programs that allow EMS or other first responders to register and distribute naloxone kits to people they deem at risk of an opioid overdose or to people likely to encounter an opioid overdose are associated with increased access. These programs have been more commonly implemented in urban settings, but efforts have been made to expand them in rural areas as well. Programs may be directed toward friends and family of high-risk individuals or other community members.[73]

- **Provide free, self-service distribution channels.** These can help to remove the stigma of access by allowing individuals to remain anonymous. These also normalize naloxone as a prevention tool and help to ensure its availability at any time. Two studied self-service methods include *"grab-and-go" fishbowls* and *vending machines:*

  - *Grab-and-go "fishbowls"* are containers with naloxone kits inside that are placed in prime locations where individuals can easily access them. They may be another way to increase naloxone access, especially in carceral settings.[74]

- *Vending machines* are most frequently placed in the lobbies, release areas, or other public spaces in or around jails.[75] They typically provide naloxone and other harm reduction materials, such as fentanyl test strips, for free or low cost. First implemented in June 2019 in the Los Angeles County jail, these machines dispensed more than 20,000 doses of naloxone in the first nine months of 2020.[76,77] There is potential for their expansion to other areas in the community, such as community centers, libraries, and other spaces where people gather.

- **Automate naloxone distribution upon release from incarceration.** Providing all individuals returning to the community from a carceral setting with naloxone upon release ensures that this at-risk population will receive a naloxone kit at a crucial time.[78]

- **Expand naloxone training.** Training for prescribers, distributors, people who use substances, and community members is another effective way to increase access to naloxone. Much of the research around training has focused on people who prescribe and dispense naloxone, such as pharmacists and other medical personnel.

    - *Pharmacists.* Improved pharmacist training is associated with increased access to naloxone in their communities.[79,80] Evidence suggests that having a centralized web-based resource hub can help to ensure that pharmacists have access to relevant information on prescribing practices and helpful counseling tips and information to share with individuals seeking naloxone from them.[81]

    - *Prescribers.* Training for medical providers is associated with improved screenings for overdose risk and rates of prescribing naloxone. One study found that, after training, the number of new providers prescribing naloxone increased by 573 percent, and the number of unique patients receiving naloxone kits increased by 789 percent. Naloxone kit distribution among patients identified as high risk of an overdose quadrupled.[82]

    - *Prescription holders.* Research suggests that naloxone training and education for people who have an opioid prescription can increase their willingness to also obtain naloxone as a safety precaution by ~26 percent.[83]

  - *Broader public*. Layperson training has been associated with increased readiness and intention to acquire and carry naloxone. It is also associated with increased naloxone attainment and use in overdose events.[84]

- **Implement best practice standards in pharmacies.** Offering a private area for people to speak with pharmacists confidentially, having pharmacy staff who are willing and able to make external referrals if naloxone is not in stock, and participation in naloxone subsidy programs to reduce the cost of the prescription are all associated with increased naloxone access. Developing and following these best practices as pharmacy standards may help naloxone access on a wider scale.[85]

- **Exempt naloxone prescriptions from fill limits.** This could help increase naloxone uptake and potentially help prevent opioid overdose deaths—particularly among Medicaid enrollees. Fill limits restrict the number of prescriptions that can be filled within a month by an individual seeking the medication. Fill limit policies are estimated to reduce access to naloxone among 20 percent of all adult Medicaid enrollees in the US.[86]

ADDITIONAL FACTORS TO CONSIDER

Additional factors should be taken into consideration when working to expand naloxone access and use. These include the following:

- **Polysubstance use**. Polysubstance use is the use of more than one drug at a time or in short succession. In 2019, almost 50 percent of overdose deaths involved multiple substances.[87] Combining substances can increase the risk of overdose and lead to naloxone being necessary for non-primary opioid users. Opioids are also increasingly being mixed with xylazine, a powerful non-opioid sedative.[88] Naloxone will not reverse the effects of xylazine in an overdose event and may require other life-saving reversal techniques, such as rescue breathing.

- **Naloxone dosing**. Stronger opioids, such as fentanyl, may require more than one dose of naloxone to reverse an overdose.[89] Naloxone reverses an opioid overdose for about 30 to 90 minutes, but opioids may remain in the body longer, and overdose effects may return after the naloxone dose wears off.[90] While waiting for emergency care to arrive, an individual who has been given naloxone should be monitored for signs of a subsequent overdose.

- **Opioid withdrawal syndrome**. Opioid withdrawal syndrome (OWS) can occur after naloxone administration.[91,92] The symptoms of OWS can be severe and include body aches, diarrhea, fever, vomiting, seizures, delirium, sweating, abdominal cramps, weakness, increased blood pressure, and increased heart rate.[93] These symptoms are more likely in individuals who are opioid dependent. While uncommon, acute OWS can be life-threatening.[94] Clinicians in emergency room settings can be trained to provide patients immediate relief after an opioid overdose is reversed.[95]

- **Overdose follow-up care.** Establishing overdose follow-up care can help direct people to harm reduction and treatment services while also affording a prime opportunity to provide naloxone to at-risk individuals and those around them. The most effective time to do a follow-up is 24 to 72 hours after the overdose event.[96] These visits offer the chance to share information about future overdose prevention options and access to services. Programs can also share overdose prevention literature, peer support contact information, and syringe exchange information (if available).

CONCLUSION

Despite significant progress, lack of access to naloxone remains a persistent barrier to unlocking its full potential to safely and effectively reverse opioid overdoses and save lives. Recent approval of OTC status for certain naloxone formulations should further improve access. However, OTC access alone will not solve this complex issue. The strategies outlined here present evidence-based approaches for addressing naloxone barriers that remain relevant, even as the prescription status of naloxone continues to shift. Continued advocacy for policy change to address these barriers and inequities can further increase access to naloxone and bring about a greater acceptance of mainstream naloxone use, and ultimately improve public health outcomes.

RESOURCES TO HELP EXPAND ACCESS

This section provides a selection of additional resources related to naloxone access. Please note that this is not intended to be a comprehensive list of resources.

General Information on Opioid Use and Naloxone

- Department of Health and Human Services Overdose Prevention Strategy is an online resource that includes information on substance misuse and overdose, and links to prevention, harm reduction, evidence-based treatment, and recovery support resources.

Accessing Naloxone and Emergency Services

- The Naloxone Finder is an online resource for people who use drugs in the US (including Puerto Rico) to access free naloxone and other harm reduction supplies in their community.
- Never Use Alone is a 24/7, 365 national toll-free overdose prevention, detection, crisis response, and reversal lifeline services for people who use drugs while alone (for help, call 800-484-3731).
- NEXT Distro is an online and mail-based harm reduction service where individuals, organizations, and first responders can access naloxone and other harm reduction supplies.
- OpiRescue is a free smartphone app that helps first responders recognize overdoses, reverse them with naloxone, report them, and access local treatment resources.

Resources for Health Care Providers, First Responders, and Laypersons

- Get Naloxone Now is an online resource to train bystanders and first responders to recognize and respond effectively to an opioid overdose emergency.
- Prescribe to Prevent is an online resource for prescribers and pharmacists that includes information on opioid use and overdose in different health care settings, helps providers educate their patients about overdose risk, and start providing naloxone rescue kits.
- SAMHSA's Opioid Overdose Prevention Toolkit is a resource that provides information on opioid use disorder, first responder guidelines, prescriber guidance, patient and family safety advice, and recovery from an opioid overdose.

Criminal Justice System Resources

- Bureau of Justice Assistance's Law Enforcement Naloxone Toolkit is a clearinghouse of resources to support law enforcement agencies in establishing a naloxone program, including answers to frequently asked questions about naloxone and sample documents and templates.
- Primer for Implementation of Overdose Education and Naloxone Distribution in Jails and Prisons is a resource designed to promote and support implementation of OEND programs in jails and prisons to help prevent opioid-related overdose deaths among people who are incarcerated.
- The Prescription Drug Abuse Policy System is a source of legal data that tracks key state laws related to prevention, substance misuse, and harm reduction.

Other Opioid Misuse Prevention and Naloxone Access Toolkits

- American Medical Association's State Toolkit to End the Nation's Drug Overdose Epidemic is a toolkit that provides actionable resources that states can use to take specific actions to increase access to evidence-based treatment for substance use disorders and expand harm reduction efforts.
- Dose of Reality is a toolkit that includes articles, flyers, handouts, social media materials, and other resources related to opioid misuse and harm reduction opportunities.
- Rural Community Toolbox is an online resource with information on addressing substance use disorder and the opioid crisis in rural communities, including opportunities for technical assistance, finding funding for a new program, and a community overdose mapping tool.

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