

# What is Naloxone?

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## **Naloxone reverses opioid overdose.**

- Naloxone hydrochloride is a generic, low-cost, non-narcotic opioid antagonist that blocks the brain cell receptors activated by opioids like oxycodone and hydrocodone, as well as heroin and other opiates.
- Sold under the name Narcan, naloxone is a fast-acting drug that, when administered during an overdose, blocks the effects of opioids on the brain and restores breathing within two to three minutes of administration.
- Naloxone is not psychoactive, has no potential for abuse, and side effects are rare.<sup>1</sup>

## **Naloxone is used both in the U.S. and abroad.**

- Approved by the FDA in 1971, naloxone has been used safely and effectively for over 40 years in ambulances and emergency rooms across the U.S.
- In the U.S. and around the world, naloxone distribution programs are currently training potential overdose witnesses to correctly recognize an overdose and administer the drug, greatly reducing the risk of accidental death.<sup>2</sup>
- By providing training on and access to naloxone, overdose prevention and treatment programs have enabled bystanders to save thousands of lives by reversing overdoses.<sup>3</sup>
- Forty-two states as well as the District of Columbia have passed laws providing for some form of access to naloxone access among first responders and/or laypeople.<sup>4</sup>
- Initiatives to expand the availability of naloxone have been undertaken in cities and states around the country with considerable success.<sup>5</sup>
- In April 2014, the FDA approved a handheld naloxone auto-injector device called Evzio, which employs voice prompts to guide the user through the accurate administration of naloxone.

- In November 2015, the FDA approved an intranasal naloxone formulation to be marketed under the brand name Narcan Nasal Spray.<sup>6</sup>

## **Naloxone works.**

- Systematic reviews have shown that take-home naloxone programs prevent overdose fatalities.<sup>7</sup>
- The Centers for Disease Control and Prevention (CDC) reports that, between 1996 and 2014, community-based overdose prevention programs trained and equipped more than 150,000 laypeople with naloxone, who successfully reversed over 25,000 opioid overdoses.<sup>8</sup>
- In Massachusetts, such programs successfully trained nearly 3,000 laypeople in the use of naloxone, who reported more than 300 overdose reversals between 2002 and 2009. A 2013 study published in the *British Medical Journal* found that opioid overdose death rates were significantly reduced in communities that adopted naloxone programs compared to those that did not.<sup>9</sup>
- The Chicago Recovery Alliance has trained 36,450 people and reversed 5,430 overdoses since 1996.
- The DOPE Project/HRC in San Francisco has trained 5,321 people and reversed 1,500 overdoses since 2003.
- The People's Harm Reduction Alliance in Seattle has trained 8,000 people and reversed 4,967 overdoses since 2005.
- The Harm Reduction Action Center in Denver has trained 307 people and reversed 101 overdoses since 2012.
- The North Carolina Harm Reduction Coalition has trained 2,232 people and reversed 115 overdoses statewide since 2013.
- The Prevention Point Overdose Prevention Project in Pittsburgh, PA, has trained 1,023 people and reversed 1,002 overdoses since 2005.

### **Naloxone is cost-effective.**

- Providing take-home naloxone to people who use opioids – and their family, friends and caretakers – not only saves lives; it also saves money.
- A 2013 cost-benefit analysis published in the *Annals of Internal Medicine* concluded, “Naloxone distribution to heroin users is likely to reduce overdose deaths and is cost-effective, even under markedly conservative assumptions.” Specifically the study found that one life could be saved for every 164 naloxone kits that are distributed.<sup>10</sup>

### **Naloxone saves lives without increasing drug use or risk-taking behavior.**

- Ongoing research shows that expanding access to naloxone does not promote unintended consequences. Several studies have observed no serious adverse effects and no increase in risky behavior associated with naloxone availability.<sup>11</sup>
- Specifically, evidence shows that naloxone does not promote increases in drug use. Replicating previous studies, a 2014 study of naloxone program participants found “no clear evidence of increased heroin use” and concluded that “this concern should not impede expansion of [overdose education and naloxone distribution] programs or policies that support them.”<sup>12</sup>

### **Expanding naloxone access in pharmacies is vital.**

States are beginning to make naloxone more readily available in pharmacies. Some, like Rhode Island, New York and Washington, permit pharmacists to dispense naloxone to patients as long as a physician

has an agreement with the pharmacy to do so. States such as New Mexico have added naloxone to the list of drugs pharmacists are permitted to furnish without a prescription. In 2014, California passed a law allowing for direct pharmacy dispensing of naloxone without a standing order or prescription – joining Vermont as the two states with the most expansive laws of their kind in the country. CVS pharmacies now sell naloxone without a prescription in 14 states.<sup>13</sup> CVS, along with Rite Aid, Duane Reade and Walgreens, sell naloxone over-the-counter in New York City, while Ralph’s pharmacies do so throughout California.

### **Law enforcement embraces naloxone.**

A growing number of law enforcement departments across the country are now equipping their members with naloxone. As of late 2014, law enforcement agencies in roughly a dozen states (California, Illinois, Indiana, Massachusetts, Michigan, New Jersey, New Mexico, New York, Ohio, Oklahoma, Rhode Island, Vermont) were providing, or plan to provide, naloxone to their officers, deputies and other personnel – with several more departments expected to follow suit.

The Obama administration has affirmed its support for expanding access to naloxone as part of an effective strategy to combat heroin and other opioid overdose. The Office of National Drug Control Policy encourages law enforcement agencies to train and equip their officers w/ naloxone, and Attorney General Eric Holder has stated that “expanding the availability of naloxone has the potential to save the lives, families and futures of countless people across the nation.”<sup>14</sup>

<sup>1</sup> Substance Abuse and Mental Health Services Administration, "Opioid Overdose Prevention Toolkit," (Rockville, Maryland: SAMHSA, 2014) <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>.

<sup>2</sup> See, e.g., European Monitoring Centre for Drugs and Drug Addiction, "Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone," (Luxembourg: Publications Office of the European Union, 2015) <http://www.emcdda.europa.eu/publications/emcdda-papers/naloxone-effectiveness>; A. V. Williams, J. Marsden, and J. Strang, "Training family members to manage heroin overdose and administer naloxone: randomized trial of effects on knowledge and attitudes," *Addiction* (2013); S. E. Lankenau et al., "Injection drug users trained by overdose prevention programs: responses to witnessed overdoses," *J Community Health* 38, no. 1 (2013).

<sup>3</sup> Eliza Wheeler et al., "Opioid overdose prevention programs providing naloxone to laypersons—United States, 2014," *MMWR Morb Mortal Wkly Rep* 64, no. 23 (2015).

<sup>4</sup> Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin.

<sup>5</sup> C. Davis, D. Webb, and S. Burris, "Changing law from barrier to facilitator of opioid overdose prevention," *J Law Med Ethics* 41 Suppl 1(2013).

<sup>6</sup> Food and Drug Administration, "FDA moves quickly to approve easy-to-use nasal spray to treat opioid overdose: Naloxone in nasal spray form provides important new alternative for family members, first responders," [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM473505](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM473505).

<sup>7</sup> European Monitoring Centre for Drugs and Drug Addiction, "Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone; Angela K. Clark, Christine M. Wilder, and Erin L. Winstanley, "A Systematic Review of Community Opioid Overdose Prevention and Naloxone Distribution Programs," *Journal of Addiction Medicine* 8, no. 3 (2014).

<sup>8</sup> Wheeler et al., "Opioid overdose prevention programs providing naloxone to laypersons—United States, 2014."

<sup>9</sup> A. Y. Walley et al., "Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis," *BMJ* 346(2013).

<sup>10</sup> Phillip O. Coffin and Sean D. Sullivan, "Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal," *Annals of Internal Medicine* 158, no. 1 (2013).

<sup>11</sup> Wilson M Compton et al., "Expanded access to opioid overdose intervention: research, practice, and policy needs," *Annals of internal medicine* 158, no. 1 (2013); Substance Abuse and Mental Health Services Administration, "Opioid Overdose Prevention Toolkit."

<sup>12</sup> Maya Doe-Simkins et al., "Overdose rescues by trained and untrained participants and change in opioid use among substance-using participants in overdose education and naloxone distribution programs: a retrospective cohort study," *BMC Public Health* 14, no. 1 (2014).

<sup>13</sup> Arkansas, California, Massachusetts, Minnesota, Mississippi, Montana, New Jersey, North Dakota, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah and Wisconsin.

<sup>14</sup> Department of Justice, "Attorney General Holder Announces Plans for Federal Law Enforcement Personnel to Begin Carrying Naloxone," (2014), <http://www.justice.gov/opa/pr/2014/July/14-ag-805.html>.