

# Counteracting the Effects of an Opioid Overdose

To ameliorate the opioid crisis currently happening in the US, nasally inhaled products may be the solution for those who are at grave risk of overdosing

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Respiratory depression can occur from accidental and/or intentional overdose of opioid type substances. The neurochemical process, by which the opioid substance binds with opioid receptors in the brain stem and then desensitises the level of carbon dioxide in the blood stream, fails to activate the breathing mechanisms, leading to respiratory failure and death (1). The overdose process can be interrupted and reversed with the administration of an opioid antagonist, such as naloxone, thereby blocking the effects of the ingested opioids.

In 1971, the FDA approved naloxone, the opioid antagonist, reversal medication for public use. This life-saving medication was initially labeled for intravenous, intramuscular, or subcutaneous use. For nearly 50 years, naloxone has been used by emergency medical personnel to counteract the effects of opioid overdoses (1). According to the Centers for Disease Control

and Prevention, the administration of naloxone from the years 1996 to 2014 assisted in reversing the effects of opioid overdoses in an estimated 26,000 opioid users (2).

Recognising that friends, roommates, and family members are often the first to encounter an opioid overdose victim, the notion of increasing the access and availability of naloxone could actually assist in reducing the opioid fatalities. To expand the availability and utility of naloxone, off-label intranasal kits were developed. Such kits included a syringe and a mucosal atomiser device in which the atomiser was inserted into the victim's nostril and the volume of the syringe was discharged, half into one nostril and the remaining dosage into the other nostril.

Efforts to develop an intranasal route of administration of naloxone – besides using the off-label atomiser – persisted, and in 2015, Narcan was approved by the FDA. Narcan is dispensed through a single unit dose intranasal medical device manufactured by Aptar Pharma. The single unit dose device is

packaged in a small plastic container allowing the user to easily dispense the naloxone nasal spray. The first responder places an index finger and middle finger on the sides of the device in finger ledges. The fixed nozzle of this device is inserted into the victim's nostril and thumb pressure is applied to the plunger stick delivering the required dose. Two doses are bundled in each package of Narcan.

Once FDA approval was granted, Narcan was rapidly adopted by emergency medical responders as an opioid overdose resource and continues to be regularly deployed by professional first response units.

To assist in reducing the opioid overdose fatalities, the US Health and Human Services (HHS) developed a five-point strategy to combat the opioid crisis. The five point strategy consists of:

1. Access: better prevention, treatment, and recovery services
2. Data: better data on the epidemic
3. Pain: better pain management
4. Overdoses: better targeting of overdose reversing drugs
5. Research: better research on pain and addiction





Number four relates to improving public emergency access to overdose reversal medication.

To increase access and availability to those ingesting opioid medications, another intranasally dispensed device, the CounterAct Cap, was designed to provide another means of counteracting the effects of an opioid overdose. The CounterAct Cap aligns with the HHS five point strategy by integrating a single unit-dose nasal spray of life-saving Naloxone into the pill bottle cap holding an opioid patient's prescription pills. The CounterAct Cap sits atop the bottle of opioid medication and can be readily deployed in the event of an opioid overdose emergency. The combination of the CounterAct Cap and pill bottle provides instant access to a counteragent paired with the agent in one dispensing system.

In the event of a suspected opioid overdose, the CounterAct safety cap twists off to reveal a folded nozzle that readily extends and clicks

into a locking position. Once the nozzle is fully extended, it can be placed into the overdose victim's nostril, and with slight thumb pressure, the spring-loaded trigger is activated and instantly releases a therapeutic dosage of naloxone to the victim. Specific features in the CounterAct device are incorporated for non-emergency, non-medical trained personnel suited for home use.

CounterAct is working towards a FDA 505(B)(2) regulatory path as a drug-device combination product and has begun endeavouring the



requisite studies to bring this medical device to market. The company has filed international and national non-provisional patents.

#### References

1. Kim D et al, *Expanded access to naloxone: Options for critical response to the epidemic of opioid overdose mortality*, Am J Public Health 99(3): pp402-7, 2013
2. Visit: [cordantsolutions.com/the-history-of-naloxone](http://cordantsolutions.com/the-history-of-naloxone)
3. Visit: [www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html](http://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html)



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