

FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder

Consider prescribing naloxone to those at increased risk of opioid overdose

7-23-2020 Drug Safety Communication

What safety concern is FDA announcing?

To reduce the risk of death from opioid overdose, the U.S. Food and Drug Administration (FDA) is making the following recommendations about the opioid reversal medicine, naloxone:

For all patients who are prescribed opioid pain relievers, health care professionals should discuss the availability of naloxone, and consider prescribing it to patients who are at increased risk of opioid overdose, such as patients who are also using [benzodiazepines](#) or other medicines that depress the central nervous system, who have a history of opioid use disorder (OUD), or who have experienced a previous opioid overdose. Health care professionals should also consider prescribing naloxone if the patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.

For all patients who are prescribed medicines to treat OUD, health care professionals should discuss the availability of naloxone and strongly consider prescribing it. For methadone and buprenorphine-containing products, health care professionals should also consider prescribing naloxone if the patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.

For other patients at increased risk of opioid overdose, health care professionals should consider prescribing naloxone, even if the patient is not receiving a prescription for an opioid pain reliever or medicine to treat OUD. This may include people with a current or past diagnosis of OUD or who have experienced a previous opioid overdose.

Opioid pain relievers are medicines that can help manage pain when other treatments and medicines are not able to provide enough pain relief. Certain opioids are also used to treat OUD. Opioids have serious risks, including misuse and abuse, addiction, overdose, and death. Naloxone can help reverse opioid overdose to prevent death.

What is FDA doing?

Increased access to the opioid reversal medicine, naloxone, may help save lives by preventing opioid overdose deaths. We are requiring the drug manufacturers for all opioid pain relievers and medicines to treat OUD to add new recommendations about naloxone to the prescribing information. This will help ensure that health care professionals discuss the availability of naloxone and assess each patient's need for a naloxone prescription when opioid pain relievers or medicines to treat OUD are being prescribed or renewed. The patient [Medication Guides](#) will also be updated.

In addition, we recommend that health care professionals consider prescribing naloxone to patients at increased risk of opioid overdose, regardless of whether they are receiving a

prescription for an opioid pain reliever or medicine to treat OUD. These may include people with a current or past diagnosis of OUD or who have experienced a previous opioid overdose.

What is naloxone and how can it help me?

Naloxone is an emergency treatment for an opioid overdose. An overdose can happen when someone takes too much of an opioid or takes it with certain other medicines or substances, such as alcohol. Opioid overdose is a medical emergency that can result in death. Naloxone works quickly to block the effects of opioids and temporarily reverses the breathing problems caused by the overdose, which can help prevent death. Naloxone is a temporary treatment so repeat doses may be required. Even when naloxone is given to someone, it is critical to call 911 or get emergency medical help right away in all cases of known or possible opioid overdose.

Naloxone can be given safely whenever you think an opioid overdose may have occurred. Giving naloxone to a person who has not taken an opioid medicine will not hurt them. Naloxone can be given safely to people of all ages, from infants to elderly adults. This includes a child who has or may have accidentally taken an opioid pain reliever or medicine to treat OUD.

Non-health care professionals, such as a family member, friend, or bystander can give naloxone for known or possible opioid overdoses. There are three FDA-approved forms of naloxone: a nasal spray, an injectable, and an auto-injector. Naloxone is sold under the brand names Narcan and Evzio, and also as generics. Depending on the [state](#) you live in, it may be available without a prescription. Naloxone may also be available from community-based distribution programs. All forms of naloxone can be provided by these programs and used by individuals with or without medical training to reverse the effects of an opioid overdose.

What should health care professionals do?

Routinely discuss the availability of naloxone with all patients when prescribing or renewing an opioid analgesic or medicine to treat OUD. Consider prescribing naloxone to patients prescribed medicines to treat OUD and patients prescribed opioid analgesics who are at increased risk of opioid overdose. Patients receiving medicines to treat OUD have a lower risk of opioid overdose than those with OUD who are not being treated; however, they are still at risk of relapse and opioid overdose. Also, consider prescribing naloxone when a patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.

Additionally, even if the patients are not receiving a prescription for an opioid analgesic or medicine to treat OUD, consider prescribing naloxone to them if they are at increased risk of opioid overdose.

Educate patients and caregivers on how to recognize respiratory depression and how to administer naloxone. Inform them about their options for obtaining naloxone as permitted by their [individual state](#) dispensing and prescribing requirements or guidelines for naloxone. Emphasize the importance of calling 911 or getting emergency medical help right away, even if naloxone is administered.

What should patients and caregivers do?

Talk to your health care professionals about the benefits of naloxone and how to obtain it. Your health care professional can give you a prescription for naloxone. Additionally, in most states and the District of Columbia, you can obtain naloxone from a pharmacy under a standing order that takes the place of an individual prescription. Some states also allow you to obtain naloxone without a prescription from a community-based program or pharmacy. Check with your [state Health Department](#) for more information.

Recognize the signs and symptoms of a possible opioid overdose. These include slowed, shallow, or difficult breathing, severe sleepiness, or not being able to respond or wake up. If you know or think someone is overdosing, give the person naloxone if you have access to it, and always call 911 or go to an emergency room right away. Naloxone is a temporary treatment, so repeat doses may be required. Even if you give naloxone, you still need to get emergency medical help right away.

If you have naloxone, make sure to tell your caregivers, household members, and other close contacts that you have it, where it is stored, and how to properly use it in the event of an overdose. When using opioid medicines away from home, carry naloxone with you and let those you are with know you have it, where it is, and how to use it. Read the Patient Information leaflet or other educational material and Instructions for Use that comes with your naloxone because it explains important information, including how to use the medicine. It is important to do this *before* an emergency happens, so you and others know what to do.

How do I report side effects from naloxone or opioids?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving naloxone, opioids, or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Facts about Naloxone

- Naloxone is an FDA-approved medicine used to treat an opioid emergency such as an overdose or possible overdose. Signs of an opioid overdose include breathing problems, severe sleepiness, or not being able to respond or wake up.
- Naloxone works by blocking the effects of opioids and temporarily reverses the dangerous symptoms caused by the overdose, which can help prevent death. When an overdose is suspected, naloxone can be given safely to people of all ages, from infants to elderly adults.
- There are three FDA-approved forms of naloxone: a nasal spray, an injectable, and an auto-injector. All forms of naloxone can be provided by community-based distribution programs and used by individuals with or without medical training to stop or reverse the effects of an opioid overdose. Naloxone is sold under the brand names Narcan and Evzio, and also as generics.
- In patients who have been using opioids regularly, the use of naloxone may cause symptoms of opioid withdrawal, including feeling nervous, restless, or irritable; body aches; dizziness or weakness; diarrhea, stomach pain, or nausea; fever, chills, or goose bumps; or sneezing or runny nose.

Additional Information for Patients and Caregivers

- FDA is recommending that patients taking opioid pain relievers or medicines to treat opioid use disorder discuss with their health care professionals the availability of the opioid reversal medicine, naloxone, to treat an opioid overdose. An overdose is a medical emergency that must be treated quickly and having patient or home access to naloxone can help prevent death.
- Talk to your health care professional about options for obtaining naloxone according to your [state's](#) requirements or guidelines. This may include access by a prescription from your health care professional, without a prescription directly from a pharmacist, or as part of a community-based program.
- If you have naloxone, keep it in a place where family, friends, and close contacts can easily access it in an emergency. Also, advise them:
 - that you have it, and where you keep it
 - to call 911 or get emergency medical help right away in all cases of known or suspected overdose, even if naloxone is administered
 - how to recognize the signs and symptoms of an overdose, including serious slowed, shallow, or difficult breathing, severe sleepiness, or not being able to respond or wake up
 - how to administer naloxone in the event of an overdose
 - to read the Patient Information leaflet or other educational material and Instructions for Use that come with naloxone *before* an opioid emergency happens, so everyone knows what to do.
- When using opioids away from home, carry naloxone with you and let those you are with know you have it, where it is, and how to administer it.
- In patients who have been using opioids regularly, the use of naloxone may cause symptoms of opioid withdrawal, including feeling nervous, restless, or irritable; body aches; dizziness or weakness; diarrhea, stomach pain, or nausea; fever, chills, or goose bumps; or sneezing or runny nose.
- Always take opioids as prescribed. Do not take more doses or take them more often than prescribed. Opioids carry serious risks including [misuse and abuse](#), addiction, overdose, and death.
- It is important to lock up opioids and to [dispose](#) of them properly to keep them from being taken accidentally by children or being stolen.
- Do not store your naloxone with your opioids. Opioids should be locked up, but naloxone should be accessible in an emergency.
- To help FDA track safety issues with medicines, report side effects from naloxone, opioids or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals

- FDA recommends discussing naloxone with all patients and/or their caregivers when prescribing opioid analgesics or medicines to treat opioid use disorder (OUD). Assess the

potential need for patient or home access to naloxone, both when initiating and renewing treatment with opioid analgesics and medicines to treat OUD.

- Consider prescribing naloxone to patients prescribed medicines to treat OUD and patients prescribed opioid analgesics who are at increased risk of opioid overdose, such as those who are also using [benzodiazepines](#) or other CNS depressants, who have a history of OUD, or who have experienced a previous opioid overdose. Additionally, consider prescribing naloxone to patients who have household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.
 - The existence of a risk factor for opioid overdose should not prevent the proper management of pain in any given patient. Patients at increased risk of overdose may be prescribed opioid analgesics, if other options for pain management are inadequate and opioid treatment is indicated. However, use in such patients necessitates intensive counseling about the risks and proper use of these products, along with intensive monitoring.
- Consider prescribing naloxone to other patients at increased risk of opioid overdose, even if they are not receiving a prescription for an opioid analgesic or medicine to treat OUD. These include people with a current or past diagnosis of OUD or who have experienced a previous opioid overdose. Patients receiving medicines to treat OUD have a lower risk of overdose than those not being treated, however they are still at risk of relapse and overdose.
- Familiarize yourself with the options for patients to obtain naloxone as permitted by your [individual state](#) dispensing and prescribing requirements or guidelines (e.g., by prescription, directly from a pharmacist, or as part of a community-based program) for naloxone. Inform patients and caregivers of these options.
- Educate patients and caregivers that taking an opioid other than how it is prescribed or with alcohol or certain other medicines or drugs could increase the risk of overdose and how to recognize the signs and symptoms of an overdose.
- Explain to patients and caregivers that naloxone's effects are temporary, and that they must call 911 or get emergency medical help right away in all cases of known or suspected opioid overdose, even if naloxone is administered.
- If naloxone is prescribed, educate patients and caregivers on the proper use of naloxone in the event of an overdose. Advise them to tell their family and friends that they have it, and to keep it in a place where their family and friends can easily access it in an emergency.
- Encourage patients and caregivers to read the Patient Information leaflet or other educational material and Instructions for Use that come with naloxone *before* an opioid emergency happens.
- Educate patients and caregivers on proper storage and [disposal](#) of opioids.
- To help FDA track safety issues with medicines, report adverse events involving naloxone, opioids, or other medicines to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of this page.

Background Summary

The misuse and abuse of illicit and prescription opioids and the risks of addiction, overdose, and death are a public health crisis in the United States. In 2018, an estimated 1.7 million Americans

had a substance use disorder involving prescription pain relievers and 0.5 million had a substance use disorder involving heroin.¹ From 1999 to 2018, nearly 450,000 people died from an overdose involving any opioid, including prescription and illicit opioids.² Opioids were involved in 46,802 deaths in 2018.³

As a result, FDA is committed to encouraging health care professionals to raise awareness of the availability of naloxone when they are prescribing and dispensing opioid pain relievers or medicines to treat opioid use disorder (OUD) through the new actions described in this communication. FDA held discussions about naloxone availability with the [Anesthetic and Analgesic Drug Products and the Drug Safety and Risk Management Advisory Committees](#), which recommended that all patients being prescribed opioids for use in the outpatient setting would benefit from a conversation with their health care professional about the availability of naloxone.

References

1. Substance Abuse and Mental Health Services Administration. (2019). *Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health* (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.
2. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2020. Available at: <http://wonder.cdc.gov>.
3. Hedegaard H, Miniño AM, Warner M. Drug Overdose Deaths in the United States, 1999–2018. NCHS Data Brief, no 356. Hyattsville, MD: National Center for Health Statistics; 2020. Available at: <https://www.cdc.gov/nchs/data/databriefs/db356-h.pdf>

Related Information

[Information about Naloxone](#)

[State Health Departments](#)

[Opioid Medications](#)

[Opioid Overdose](#)

[Naloxone Access by State](#)

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)

[Advisory Committees: Critical to the FDA's Product Review Process](#)