NALOXONE ACCESS: A Practical Guideline for Pharmacists

College of Psychiatric and Neurologic Pharmacists

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Background

Drug overdoses are occurring at an alarming rate in the United States. Most overdoses have been linked to opioid analgesics, which may have been obtained from community pharmacies. One potential solution is to offer take-home naloxone.

Patient Selection

Naloxone should be considered for all patients exposed to opioids regardless of the source. The risk of a potentially fatal opioid overdose is a hazard of the drug and the drug combinations that are used. This applies to those who take opioids for pain and to those who misuse them.

Additional overdose risk factors include the following:

- Concurrent use of benzodiazepines or alcohol
- History of opioid addiction or other substance use disorder
- Comorbid mental illness
- Receiving prescriptions from multiple pharmacies and prescribers
- Daily opioid doses exceeding 100 mg of morphine equivalents
- Receiving a methadone prescription
- Recent emergency medical care for opioid poisoning/intoxication/overdose
- Recent release from incarceration/prison/jail
- Comorbid renal dysfunction, hepatic disease, or respiratory diagnoses (smoking/COPD/emphysema/asthma/sleep apnea/other)

Naloxone is a bystander-administered drug, and the request for naloxone may come from caregivers.

How It Is Supplied

Naloxone for take-home use can be supplied as an intramuscular (IM) injection or as an intranasal (IN) spray. Both formulations are effective. The nasal spray tends to be preferred by patients and caregivers, while the components of the IM kit are more readily available in pharmacies. There is also a recently available IM auto-injector, which is convenient to prescribe and dispense but costly.

Intranasal Spray

IN kits should contain: 2 naloxone 2 mg/2 ml prefilled syringes, 2 atomizers, step-by-step instructions for responding to an opioid overdose, and directions for naloxone administration.

Intramuscular Injection

IM kits should contain: 2 naloxone 0.4 mg/ml vials, 2 IM syringes, step-by-step instructions for responding to an opioid overdose, and directions for naloxone administration.
Prescribing and Dispensing

**Intranasal**
Naloxone 2 mg/2 ml prefilled syringe, 2 syringes
NDC No. 76329-3369-01
SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat ×1.
Atomizer No. 2
SIG: Use as directed for naloxone administration

**Intramuscular**
Naloxone 0.4 mg/ml single dose vial, 2 vials
NDC No. 00409-1215-01
SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat ×1.
Syringe 3 ml 25G ×1 inch No. 2
SIG: Use as directed for naloxone administration

**Intramuscular Auto-injector**
Naloxone 0.4 mg/0.4 ml
No. 1 twin pack
SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat ×1.

Acquisition and Reimbursement
The single-dose vial, prefilled syringe, and IM syringes are available from pharmacy wholesale distributors. The atomizers for IN administration are available from medical supply vendors, and in some cases, can be purchased directly from the pharmacy wholesaler, or obtained from point persons within the pharmacy corporation.

<table>
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<th>Vendor</th>
<th>Item No.</th>
<th>Contact</th>
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<tbody>
<tr>
<td>Professional Hospital Supply</td>
<td>392322</td>
<td>707-429-2884</td>
</tr>
<tr>
<td>Cardinal</td>
<td>MAD 300</td>
<td>800-964-5227</td>
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<td>Healthcare Logistics</td>
<td>17474</td>
<td>800-848-1633</td>
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<td>MAD 300</td>
<td>919-544-8000</td>
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To cover the cost of the atomizer, some pharmacies are charging patients directly. The cost is about $10 for 2. In other cases, the atomizers are included with the drug at no additional charge. New Mexico provides a reimbursement code for the entire kit, including the pharmacist’s time.

Naloxone Storage Information
- Store naloxone in the original package at room temperature. Avoid light exposure.
- The shelf life of naloxone is generally 12 to 18 months. If stored properly, naloxone should be effective until at least the expiration date on the packaging.
- Do not insert naloxone into the prefilled syringe until ready to use. Once inserted it expires within 2 weeks.
- Monitor the expiration date on naloxone and replace before it expires. When there are no other alternatives, expired naloxone can be administered but may not be as effective.

Supporting Laws and Regulations
State laws to support naloxone access fall under three categories:
- Good Samaritan: Protects individuals who call for help at the scene of an overdose from being arrested for drug possession.
- Liability protection/third party administration: Protects both the prescriber and the bystander who may be administering the naloxone. It also allows bystanders to be prescribed naloxone for use on opioid overdose victims.
- Collaborative practice agreement: Allows pharmacists to prescribe naloxone to at-risk individuals. It may be done with individual physicians or on a statewide basis.

Medicaid, Medicare, and many private insurance companies will pay for naloxone. However, at present, health plans do not have a viable way to pay for the atomizer, which lacks any unique identifier, such as a NDC number.

The Network for Public Health Law has an updated summary of state laws supporting access to naloxone.11

Examples of Successful State and Local Models
New Mexico: In 2001, New Mexico enacted legislation to protect third parties who administer naloxone to an overdose victim. This was followed by a Good Samaritan statute in 2007 and pharmacist prescribing in 2014. To obtain prescribing authority, pharmacists need to complete a 2-hour certification course every 2 years. The State Medicaid program pays for naloxone, the
atomizer, and the consultation time via a specific NDC number for the entire naloxone kit.

California: San Francisco’s Department of Public Health expanded naloxone access by making the atomizer and education brochures available in primary care clinics. Naloxone was co-prescribed with opioid analgesics and picked up at community pharmacies. Patients were trained both at the primary care clinic and the community pharmacy. Pharmacist training and outreach was done by the Public Health Department. Pharmacists also make naloxone available to methadone and buprenorphine maintenance patients at a specialty mental health pharmacy run by the Department of Public Health under a collaborative practice agreement.

Rhode Island: All Walgreens and CVS Pharmacies in Rhode Island make IM and IN naloxone available without a prescription under a collaborative practice agreement. The pharmacy chains have secured atomizer access through their supply systems, and the collaborative drug therapy agreement is signed by one physician for the state. The University of Rhode Island offers continuing education training.

Collaborative Practice Agreements
- New Mexico
- Washington State
- San Francisco Department of Public Health
- Providers’ Clinical Support System for Opioid Therapies (PCSS-O): Description of collaborative practice with focus on Rhode Island

Frequently Asked Questions

What are signs of opioid overdose?
- Skin is pale and/or clammy to the touch.
- Body is limp.
- Fingernails or lips have a blue or purple cast.
- Patient is vomiting or making gurgling noises.
- Patient is unarousable.
- Breathing is very slow or stopped.

What is rescue breathing?
Rescue breathing involves essentially breathing for someone else. By providing rescue breathing during an opioid overdose, the rescuer can potentially prevent the patient from developing organ damage. See the patient information sheets for details on how to administer rescue breaths.

How quickly does naloxone work?
Naloxone works within 2 to 5 minutes, depending on how naloxone has been administered.

How long should a bystander remain with the overdose victim after naloxone has been administered?
Bystanders should remain with the overdose victim until help arrives. Naloxone only has a 30- to 90-minute duration of action. Patients who have overdosed on a long-acting opioid may initially respond and then succumb to overdose symptoms again. It is important to remain with the patient to continue to provide support and additional doses of naloxone (if required) until help arrives.

Is naloxone effective in treating other types of overdoses?
No, naloxone is only effective in reversing an opioid overdose. At times, it may be difficult to distinguish opioid overdose symptoms from other overdoses or illnesses. Therefore, it is important to immediately seek medical help.

What happens if you administer expired naloxone?
Naloxone’s full efficacy cannot be guaranteed beyond the expiration date. However, in urgent situations without alternatives, it will not hurt the patient to administer expired naloxone and may provide some benefit.

Can the intranasal naloxone be assembled in advance?
The shelf life of the assembled prefilled syringe is only 2 weeks; therefore, it is recommended that the atomizer is attached to the syringe but the naloxone is not inserted until ready to administer.

Can naloxone be administered to pregnant women?
Yes, in an opioid overdose, naloxone can and should be administered to a pregnant woman. However, there is risk for opioid withdrawal.

For More Information
- www.prescribetoprevent.org
- Overdose_rescue/naloxone_long-format_training_August 23, 2012
- SAMHSA Opioid Overdose Prevention Toolkit
Intranasal Naloxone Patient Information Sheet
Common brand names: Narcan

Uses: This medication is used to treat an opioid overdose. Naloxone works by reversing the effects of opioids.

Patients should be instructed to tell family/friends where naloxone is stored and how to administer it in case of an overdose.

Signs of an opioid overdose
Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

How to Use IN Naloxone
If you suspect someone is suffering from an opioid overdose:

Step 1. Call 911.

Step 2. Give naloxone.

Step 3. Give a second dose of naloxone in 2 to 3 minutes if there is no response to the first dose.

Step 4. Follow the 911 dispatcher’s instructions or perform rescue breathing if comfortable doing so.

Rescue Breathing
The key components of rescue breathing include the following:

Step 1. Make sure nothing is in the individual’s mouth.

Step 2. Tilt the head back, lift chin, and pinch nose shut.

Step 3. Give one slow breath every 5 seconds; chest should rise.

Side effects
Anxiety, sweating, nausea/vomiting, or shaking. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.
Intramuscular Naloxone Patient Information Sheet

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Signs of an opioid overdose
Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

How to Use IM Naloxone
If you suspect someone is suffering from an opioid overdose,

Step 1. Call 911.

Step 2. Give naloxone.

Step 3. Give a second dose of naloxone in 2 to 3 minutes if there is no response to the first dose.

Step 4. Follow 911 dispatcher’s instructions or perform rescue breathing if comfortable doing so.

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References


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