

Personally Furnishing Naloxone Pursuant to a Protocol Standing Orders

Canton City Public Health

Contact Person	Amanda Archer, MPH
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Clinical Pharmacology of Naloxone

Naloxone hydrochloride (naloxone), aka Narcan[®], prevents or reverses the effects of opioids, including respiratory depression, sedation and hypotension.

Naloxone is an essentially pure opioid antagonist, i.e., it does not possess the “agonistic” or morphine-like properties characteristic of other opioid antagonists. When administered in usual doses and in the absence of opioids or agonistic effects of other opioid antagonists, it exhibits essentially no pharmacologic activity.

Naloxone has not been shown to produce tolerance or cause physical or psychological dependence. However, in the presence of opioid dependence, opioid withdrawal symptoms may appear within minutes of naloxone administration and subside in about 2 hours.

Naloxone may not reverse overdose in all cases, such as when high doses of opioids or particularly potent opioids (e.g., fentanyl or carfentanil) have been consumed.

Indications for Use of Naloxone

Naloxone is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids.

Indications for Personally Furnishing Naloxone

1. Previous opioid intoxication or overdose
2. History of nonmedical opioid use
3. Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment.
4. Higher dose (≥ 50 mg morphine equivalent/day) opioid prescription.
5. Receiving any opioid prescription plus:
 - a. Rotated from one opioid to another because of possible incomplete cross-tolerance.
 - b. Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection or other respiratory illness.
 - c. Renal dysfunction, hepatic disease, cardiac illness or HIV/AIDS.
 - d. Known or suspected concurrent alcohol use.
 - e. Concurrent benzodiazepine or other sedative prescription.

- f. Concurrent antidepressant prescription.
 - g. Patients who may have difficulty accessing emergency medical services (distance, remoteness).
6. Voluntary request from a family member, friend, peace officer or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

If staff believe that a person is currently experiencing an opioid overdose, emergency medical assistance must be summoned immediately.

Precautions, Contraindications, and Adverse Reactions

- Precautions
 - Use in Pregnancy:
 - Teratogenic Effects: no adequate or well controlled studies in pregnant women.
 - Non-teratogenic Effects: Pregnant women known or suspected to have opioid dependence often have associated fetal dependence. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms.
 - Nursing mothers: caution should be exercised when administering to nursing women due to transmission in human milk. Risks and benefits must be evaluated.
- Contraindications
 - Contraindicated in patients known to be hypersensitive to it or to any of the other ingredients in naloxone hydrochloride.
- Adverse reactions
 - Adverse reactions are related to reversing dependency and precipitating withdrawal and include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgia, diaphoresis, abdominal cramping, yawning and sneezing.
 - These symptoms may appear within minutes of naloxone administration and subside in approximately 2 hours.
 - The severity and duration of the withdrawal syndrome is related to the dose of naloxone and the degree of opioid dependence.
 - Adverse effects beyond opioid withdrawal are rare.

Authorization to Dispense Naloxone

Pursuant to section 4731.941 of the Ohio Revised Code (ORC), the following individuals are authorized to dispense naloxone without a prescription in accordance with this protocol:

- Please refer to [Appendix A](#) for updated list

Upon completion of required overdose prevention and response training, naloxone may be dispensed to the following individuals:

- An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose; or
- A peace officer as defined in section 2921.51 of the Ohio Revised Code.

This protocol authorizes the individuals listed above to dispense the following doses of intranasal formulations of naloxone:

- Two (2) naloxone 2 mg/2 mL prefilled syringes used with mucosal atomization devices
- Two (2) NARCAN® Nasal Spray 4mg/0.1 mL FDA-approved nasal spray device

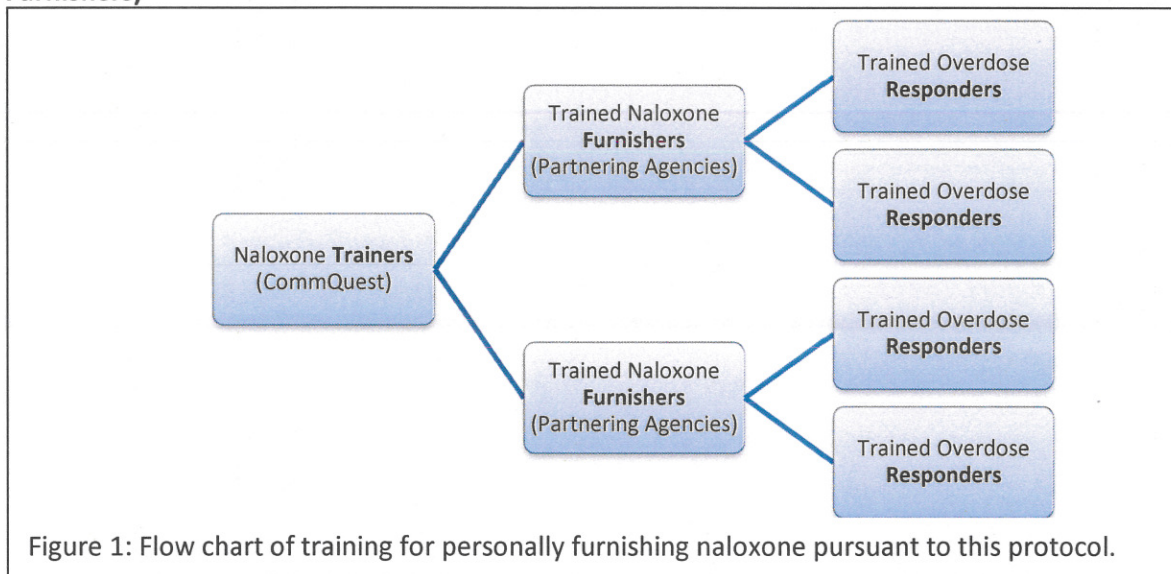
Variation in dosage and/or formulation are permissible under the following circumstances:

- When high doses of opioids or particularly potent opioids (fentanyl, fentanyl analogues or carfentanil) are suspected that may require more than the standard dose of naloxone, extra doses may be distributed.

The authorized individual shall do all of the following in accordance with rule 4729-5-17 of the Ohio Administrative Code:

- Prepare, package and appropriately label the naloxone.
- Conduct the final check of the naloxone prior to personally furnishing on behalf of the prescriber.
- Keep and maintain all records in accordance with OAC 4729-9-22.
- Conduct patient counseling, including training on the use of the naloxone, as specified in this protocol.

Training of Individuals Authorized to Furnish Naloxone (Naloxone Trainers and Trained Naloxone Furnishers)



CCPH has a partnership agreement with CommQuest Services for their Naloxone Trainers to provide ‘Train-the-Trainer’ instruction to increase naloxone distribution. Prior to furnishing naloxone, individuals authorized to furnish naloxone (Trained Naloxone Furnishers) must first complete the ‘Train-the-Trainer’

course provided by CommQuest. The training will be arranged by CCPH with CommQuest for individuals of approved agencies. Upon successful completion of the training, the individual will receive a *Certificate of Completion as a Trained Naloxone Furnisher* and will provide a copy to Canton City Public Health to be added to this protocol. At this time, individuals who are trained to personally furnish naloxone must be associated with a partnering agency. Partnering agencies must sign a partnership agreement that defines the agreed-upon roles and responsibilities of the agency.

Training to become a furnisher includes an educational session on overdose prevention, and response (through PowerPoint or Project DAWN training DVD per CommQuest's procedure). Training components will include the following:

1. Risk factors for opioid overdose
2. Signs and symptoms of opioid overdose
3. Response to opioid overdose, including calling 911 and performing rescue breathing
4. Procedures for assembling and administering naloxone
 - a. Trainees will practice assembling naloxone doses with demo doses when available
5. Information on naloxone, including possible adverse reactions
6. Proper storage of naloxone
7. Expiration date of the medication
8. Procedures for refilling/replacing naloxone doses
9. Information on referrals for substance abuse treatment for program participants

Training of Individuals to Whom Naloxone May be Furnished (Trained Overdose Responders)

Prior to furnishing naloxone, Trained Naloxone Furnishers will engage each Overdose Responder in an educational session on overdose prevention and response. Training components will include the following:

1. Risk factors for opioid overdose
2. Strategies to prevent opioid overdose
3. Signs and symptoms of opioid overdose
4. Response to opioid overdose, including calling 911 and performing rescue breathing
5. Procedures for assembling and administering naloxone
6. Information on naloxone, including possible adverse reactions
7. Proper storage of naloxone
8. Expiration date of the medication
9. Procedure for reporting an overdose reversal
10. Procedure for obtaining a replacement dose of naloxone
11. Information on where to obtain a referral for substance abuse treatment

All individuals to whom naloxone is dispensed must be specifically instructed to summon emergency services as soon as practicable either before or after administering naloxone.

Labeling, Storage, Record-Keeping, and Administrative Requirements

Each dose of naloxone received and dispensed, including refill doses, will be recorded in a dispensing log as per OAC 4729-9-22.

Records of receipt shall include:

- Description of naloxone received
- Kind and quantity of naloxone received
- Name and address of the person from whom naloxone is received

Records of inventory shall include:

- Number/Count of naloxone added/subtracted to agency inventory
- Date that naloxone is added/subtracted to agency inventory
- Lot # of naloxone kits that are added/subtracted from agency inventory
- Expiration date of kits that are added/subtracted from agency inventory
- Signature of naloxone furnisher who is adding/subtracting from agency inventory
- Total naloxone kit balance in inventory

Records of distribution shall include:

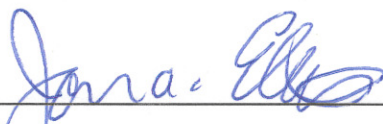
- Description of the kind and quantity of naloxone dispensed
- Name and address of the person to whom, or for whose use, the naloxone was dispensed

Each box of naloxone distributed must be labeled, pursuant to OAC 4729-5-17, with the following:

- Name and address of the prescriber (i.e. the physician authorizing this protocol)
- Full name of the person to whom the naloxone is furnished
- Strength and formulation of naloxone
- Date that naloxone is dispensed
- Directions for use ([Appendix B](#))

Each box of naloxone will be securely stored in a locked cabinet at the partnering agency's choice of site and in a manner consistent with the manufacturer's guidelines, including storing at controlled room temperature, 59°F to 77°F (15°C to 25°C). Excursions permitted between 39°F to 104°F (4°C to 40°C). Do not freeze. Protect from light.

This protocol for dispensing naloxone was reviewed and approved by Jon A. Elias, MD on 9/25/19.
[Date]



Jon A. Elias, MD
Medical Director
Canton City Public Health



Personally Furnishing Naloxone Pursuant to a Protocol Standing Orders Appendix A

Canton City Public Health

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This list will be updated as Canton City Public Health and partnering agencies train Naloxone Furnishers to enhance distribution in Stark County.

Authorization to Dispense Naloxone

Pursuant to section 4731.941 of the Ohio Revised Code (ORC), the following individuals are authorized to dispense naloxone without a prescription in accordance with this protocol:

- Canton City Public Health Staff – 420 Market Ave N, Canton, OH 44702
Contact: Amanda Archer, MPH – 330.438.4646

<i>Employee</i>	<i>Division/Position</i>	<i>Date Trained</i>

- OhioCAN (Change Addiction Now) - 2298 Comet Circle NW, North Canton, OH 44720
Contact: Cindy Koumoutzis – 330.327.5911 or Ron Stromsky – 330.280.6500

<i>Employee/Volunteer</i>	<i>Division/Position</i>	<i>Date Trained</i>

- ICAN Housing – 1214 Market Ave N, Canton, OH 44714
Contact: Aaron Wagster – 330.455.9100 Ext. 127

<i>Employee/Volunteer</i>	<i>Division/Position</i>	<i>Date Trained</i>



1 Identify Opioid Overdose and Check for Response



ASK person if he or she is okay and shout name.

Check for signs of opioid overdose:

- Will not wake up or respond to your voice or touch
- Breathing is very slow, irregular, or has stopped
- Center part of their eye is very small, sometimes called "pinpoint pupils"

Lay the person on their back to receive a dose of NARCAN® Nasal Spray.

2 Give NARCAN® Nasal Spray



Remove NARCAN® Nasal Spray from the box.



Peel back the tab with the circle to open the NARCAN® Nasal Spray

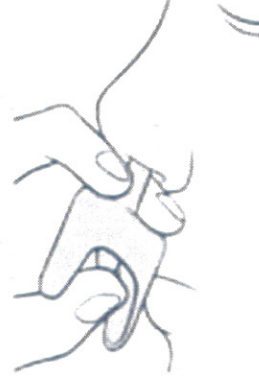


Hold the NARCAN® Nasal Spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.



Gently insert the tip of the nozzle into either nostril.

- Tilt the person's head back and provide support under the neck with your hand.
- Gently insert the tip of the nozzle into one nostril, until your fingers on either side of the nozzle are against the bottom of the person's nose.



Press the plunger firmly to give the dose of NARCAN® Nasal Spray.

- Remove the NARCAN Nasal Spray from the nostril after giving the dose.

3

Call for emergency medical help, Evaluate, and Support



Get emergency medical help right away.

Move the person on their side (recovery position) after giving NARCAN Nasal Spray.

Watch the person closely.

If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available.

Repeat Step 2 using a new NARCAN Nasal Spray to give another dose in the other nostril. If additional NARCAN®

Nasal Sprays are available, repeat step 2 every 2 to 3 minutes until the person responds or emergency medical help is received.