University of Toledo Medical Center

Department of Psychiatry Service Guidelines

Title: Naloxone (Narcan) in the Clinic

Purpose: This guideline aims to ensure that staff are familiar with the procedure for administration, documentation, and storage for emergency use Naloxone (Narcan) in the event of a suspected Opioid overdose as well as protocol to dispense Naloxone to individuals enrolled and receiving services in the Outpatient Recovery Services Program.

Related Polices: 3364-100-06-07 Medical Assistant Roles in Ambulatory Services

Accountability: This guideline applies to all employees who have been trained and found competent to utilize Naloxone. It is the clinical team's responsibility to provide assistance in the event of a suspected Opioid overdose.

Clinical Pharmacology of Naloxone

Naloxone hydrochloride (naloxone) 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 Dispensing 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.

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:

- Any University of Toledo Medical Center employee who has completed appropriate training and feels competent to provide necessary naloxone education

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
- Two (2) Kloxxado® Nasal Spray 8mg/0.1mL FDA- approved nasal spray device

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

- If intranasal naloxone is unavailable from Project Dawn, then intramuscular naloxone or naloxone intramuscular Auto-injector can be distributed
    - Two (2) naloxone 0.4 mg/ml single dose vials
    - Two (2) naloxone 0.4 mg/0.4 ml Auto-injectors

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:

- Completion of an in person training session
- Passing score on competency test after completion of training session

Training of Individuals to Whom Naloxone May be Furnished

Prior to dispensing naloxone, Project DAWN staff will engage each program participant 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 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

Procedure for Emergency Administration:

1. All staff, when appropriate will participate in Naloxone (Narcan training). Naloxone Training will at minimum cover;
    a. Location of where Naloxone will be stored
    b. Identification of a patient at risk of overdose
    c. Recognizing signs of an overdose
    d. Recognizing when to administer Naloxone
    e. Medical Management of an overdose
        i. The administration of the medication
        ii. Initiating CPR when indicated
        iii. Calling 911

2. All staff who are Naloxone trained will at minimum maintain Basic Life Support Certification
3. All staff who have completed Naloxone training and have a current BLS certification are authorized to administer Naloxone when clinically indicated
4. Any trained staff who believe that a person is currently experiencing an opioid overdose, emergency medical assistance must be summoned immediately.

Resources:

SAMHSA Guidance for Law Enforcement and First Responders Administering Naloxone – May 8, 2020
Toledo Lucas County Health Department

SAMHSA Opioid Overdose Prevention Toolkit – Five Essential Steps for First Responders

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Reviewed: 12/2/2022
Revised: