

PROTOCOL: PERSONALLY FURNISHING NALOXONE

Section 4731.941 of the Ohio Revised Code permits a physician to authorize one or more individuals to personally furnish a supply of naloxone pursuant to a protocol. This protocol describes the clinical pharmacology of naloxone; precautions and contraindications; individuals to whom naloxone may be furnished; naloxone dosage, labeling, storage, record-keeping and administrative requirements; training requirements for authorized personnel and individuals to whom naloxone may be furnished; program design.

Clinical Pharmacology

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. In the presence of physical dependence on opioids, naloxone will produce withdrawal symptoms. However, in the presence of opioid dependence, opioid withdrawal symptoms may appear within minutes of naloxone administration and subside in about 2 hours.

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. It may be delivered intranasally with the use of a mucosal atomizer device (MAD) or intramuscularly with use of a needle or auto-injector.

Naloxone can be dispensed by a pharmacist, or a pharmacy intern under the direct supervision of a pharmacist without a prescription in accordance with this protocol to all the following:

- 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 Revised Code.

Indications for dispensing naloxone are:

1. Previous opioid intoxication or overdose.
2. History of nonmedical opioid use.
3. Initiation of 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.
6. Patients who may have difficulty accessing emergency medical services (distance, remoteness).
7. 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 and Contraindications

Precautions

Use in Pregnancy:

- Teratogenic Effects: no adequate or well controlled studies have been completed 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: naloxone is transmitted through breast milk.

Contraindications

- Contraindicated in individuals known to be hypertensive to naloxone hydrochloride or to any of the other ingredients in it.

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, sneezing.
 - 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 withdrawal are rare.

Individuals to whom naloxone may be furnished

The Ohio Revised Code Section 4731.941 permits a physician to authorize one or more individuals to personally furnish a supply of naloxone pursuant to a protocol to either of the following:

1. An individual who there is reason to believe is experiencing or is at risk of experiencing an opioid-related overdose;
2. 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.

Many individuals work in environments where they may assist an individual experiencing an overdose, including, but not limited to, the following:

1. Colleges (residence life staff) and schools (school nurses, administrators, teachers, etc.)
2. Substance abuse treatment programs (residential and nonresidential)
3. Halfway houses
4. Homeless shelters
5. Home healthcare agencies
6. Probation officers
7. Social workers and home visitors

Note: Each county's authorizing physician will specify in their protocol the individuals to whom naloxone may be furnished, and will be available to be directly consulted if there are any questions. The authorizing physician will specify in protocol how many naloxone kits may be furnished by refill to a single individual.

See Project DAWN Criteria of An Individual At Risk of Opioid Overdose.

Naloxone dosage to be furnished

Naloxone will be furnished in intranasal form in a kit that contains:

- Naloxone 2 mg/2 ml prefilled syringe, 2 syringes
- NCD No. 76329-3369-1
- SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1
- Two mucosal atomization devices (MAD300)
- SIG: Use as directed for naloxone use

Labeling, storage, record-keeping, and administrative requirements

Labeling – Pursuant to Ohio Administrative Code (OAC) 4729-5-17 each naloxone kit will be labeled with the following information:

- The name and address of the prescriber ***[Each county must have its own authorizing physician.]***
- The name of the individual receiving the kit
- The name and strength of the drug
- Directions for use
- Date furnished

Storage

Entities must have an Unlimited Category II or III Terminal Distributor of Dangerous Drugs license in order to store naloxone on-site. **Copies of current TDLs must be provided to Morrow County Project DAWN.**

Naloxone must be stored at room temperature (between 68 and 77 degrees Fahrenheit), and away from bright light. Doses must be checked periodically (before training and distribution) to ensure the naloxone has not been adulterated: is beyond the manufacturer's or distributor's expiration date; and/or shows signs of discoloration or particulate matter in the naloxone solution. Adulterated doses must be discarded and documented. Naloxone has a shelf life of two years.

Record Keeping

Clients who participate in an approved training and receive a naloxone kit must complete the required registration form that will be stored and protected as personal health information at each county program site. **It is essential that clients complete the entire registration form.** Each client will be assigned a Client ID Number. **Each completed registration form will have both a Site Number (see County Code Map) and a Client ID Number.** Clients seeking a refill will complete the required refill form. The same Client ID Number will be used for registration and refill forms.

The **Site Number** will consist of the Morrow County Code and the Participating County Code separated by a hyphen. For example, 59-00, will refer to Morrow County (59) as the Program Manager and X County as the Program Site (00).

The **Client ID Number** will refer to the number assigned to the kit at the time it is furnished to a client. The Client ID Number will consist of the county code and another number separated by a hyphen. This Client ID Number will be used for each kit (including refills) furnished to a client.

Each county program site will electronically submit to ODH the information from registration forms by the 5th day of each month. Also on the 5th of each month, county programs will report to Morrow County, Project Manager, the number of kits and refills distributed, training dates, trainer names, any overdose reversals reported, and EMS calls. A reporting form will be provided.

Administrative Requirements

The Morrow County Health Department, as Program Manager, will provide a Memorandum of Understanding, Policies & Procedures, Protocols, Standards of Guidance, sample Standing Orders, a sample Letter of Commitment, required registration and refill forms, Train-the-Trainer training, community-based training materials, a specified number of Naloxone kits, prescription labels template, information card template (to be inserted in each kit at time of training), reporting form.

The Morrow County Health Department, as Program Manager, will provide regularly scheduled conference calls for information sharing and guidance. MCHD will submit a marketing plan to the Ohio Department of Health by June 1, 2016 for FY16; and October 1, 2016 for FY17. MCHD will report data to ODH by July and October 15, 2016; January and March 15, 2017; and a program evaluation report on June 30, 2017.

The Morrow County Health Department and participating counties commit to providing community-based training and naloxone kits to 600 individuals by June 30, 2017.

Training Requirements for Authorized Personnel

Individuals who will be authorized to furnish naloxone must complete Train-the-Trainer training through a Project DAWN Program that includes the following:

- Risk factors for opioid overdose
- Prevention strategies
- Signs of an overdose
- Calling 911
- Rescue breathing
- Administering intranasal naloxone
- Completion of proper documentation
- Proper storage of naloxone

- Post-overdose care
- Refill procedure
- Program design and materials
- Program requirements

Training Requirements for Individuals Receiving Naloxone

- Overdose prevention techniques
- Recognizing signs and symptoms of overdose
- Calling 911
- Airway and breathing assessment/Rescue breathing/Recovery position
- Naloxone storage, carrying, and administration in an emergency situation
- Reporting of overdose and refill procedures
- Post-overdose follow-up care

Program Design

In order to store naloxone on-site and provide opioid overdose education and naloxone kit distribution, each participating county entity must complete and/or provide copies of the following documents to Morrow County Health Department, Project DAWN Program Manager:

- Memorandum of Understanding between MCHD and county entity/project site
- Name, address, and contact phone number for project site and proposed hours of operation – may include regularly scheduled hours for individual walk-ins and/or group trainings
- Copy of TDDDL
- Name of medical director/authorizing physician
- Letter of commitment from medical director/authorizing physician
- Names of authorized personnel who attend Train-the-Trainer training, provide community-based opioid overdose education, and furnish naloxone kits

Policies and Procedures

1. Morrow County Project DAWN (MCPD) Policies and Procedures
2. MCPD Protocol
3. Standard Operating Guideline for Naloxone Storage, Handling, and Administration
4. Standard Operating Guideline for PD Training for Overdose Prevention Educators and Opioid Overdose Responders
5. Standard Operating Guideline for PD Program Administration
6. PD Criteria of An Individual At Risk of Opioid Overdose
7. Memorandum of Understanding
8. Sample Letter of Commitment
9. Sample Standing Order

Forms

1. Training Sign-in Sheet
2. Prescription Labels
3. Instruction Cards
4. Registration and Refill Forms
 - Paper
 - Project DAWN (PD) Registration final 4-28-16
 - PD Refill final 4-28-16
 - PD Data Collection form for agencies
 - Electronic Data Submission
 - PD data collection tool_registration_intake form_distributed
 - PD data collection tool_refill form_distributed
 - PD data entry form for agencies_distributed

5. Morrow County PD Reporting Form

Training Materials

1. Overdose Prevention Educator (train-the-trainer) Training
 - Power Point Presentation
 - ODH Training Video
 - Understanding Addiction Video
2. Opioid Overdose Responder (community-based) Training
 - Power Point Presentation
 - ODH Training Video