

This policy serves as a standing order for Point Defiance Aids Projects staff and volunteers to administer naloxone to clients who are experiencing an opioid overdose. It also serves as a standing order to provide overdose prevention education and naloxone kits to syringe exchange clients who are at risk of having or witnessing an opioid overdose.

II. POLICY STATEMENT

The objective is to authorize persons, other than a licensed health care professional permitted by law to administer an opioid antagonist, to administer naloxone to another person if: (1) he/she, in good faith, believes the other person is experiencing an opioid drug overdose; and (2) he/she acts with reasonable care in administering the drug to the other person. Further, this policy shall provide recommended guidelines to prevent opioid overdose death.

Naloxone is a specific opioid antagonist drug that rapidly reverses the effects of opiate drugs, including heroin. Respiratory depression and arrest is the primary reason for death due to an opioid overdose. Naloxone is often effective in reversing an opioid/heroin overdose death if administered no more than three to five minutes after the person who has overdosed has stopped breathing, though Naloxone should be viewed as one of several tools and skills that can be taught and employed to prevent an opioid/heroin overdose death. Training Injection Drug Users (IDU) to prevent and/or properly respond to an overdose makes this population the primary target of this intervention since they are likely to be the people at the scene of an overdose. This training helps to provide them with the skills to function as peer educators within their drug using communities, which will ultimately decrease overdose deaths by spreading prevention education. Trained Targeted Responders (TTR) are non-medical first responders (e.g. law enforcement or volunteer fire fighters) are also included as a target population, since they may be the first to arrive at a medical emergency call, especially in rural areas of the state. Overdose Prevention Training Programs should include discussion of strategies for reducing the likelihood of overdose, the importance of providing rescue breathing to a person who is overdosing, the importance of quickly contacting professional medical help in the event of an overdose, and the appropriate use of Naloxone to reverse the effects of opiate overdose. Naloxone is a prescription medication. Naloxone is not a DEA-scheduled drug. The Naloxone prescription may be provided directly to the opiate user, family members, friends, or domestic partners of the active opiate user for the purpose of ensuring greater community access to Naloxone and decreasing opiate overdose fatalities statewide.

STANDING ORDER

Naloxone is indicated for reversal of opioid overdose in the setting of respiratory depression or unresponsiveness.

1. Naloxone may be given intramuscularly (IM) or intranasally (IN) by trained PDAP staff and volunteers (Overdose Prevention Educators) to a person who is experiencing a drug overdose.
2. Supplies of Naloxone Hydrochloride Injection shall be maintained for distribution as part

of the PDAP Opioid Antagonist Administration Program for the purpose of reducing opioid-related overdose deaths.

3. Trained Overdose Prevention Educators shall possess and distribute take-home naloxone kits to Overdose Responders who have completed the Overdose Prevention and Naloxone Training.
4. Overdose Responders, trained by Overdose Prevention Educators, who are trained employees and volunteers of PDAP's OAAP, shall be authorized to possess and administer naloxone to a person who is experiencing a drug overdose.
5. Pregnancy & Nursing Mothers: Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women and it is not known whether naloxone is excreted in human milk. Naloxone should only be given to pregnant and nursing mothers if clearly needed.
6. Over-dosage: There is no clinical experience with naloxone over-dosage in humans.

III. PDAP Procedure:

2. The PDAP OAAP Coordinator under direction of the Health Officer, shall be responsible for training staff and volunteers on overdose prevention and naloxone use. PDAP Staff and volunteers who have completed training shall be qualified as Overdose Prevention Educators. The Health officer does not need to be present for training or distribution services.

1. PDAP OAAP Staff shall be responsible for receiving shipments, monitoring inventory, and maintaining log details of dispensed kits and client enrollment forms.
2. All Overdose Prevention Educators (including staff and volunteers) shall be authorized to deliver the Overdose Prevention and Naloxone Training, and distribute take-home naloxone kits.
3. All Overdose Prevention Educators will be eligible for additional training with the OAAP Coordinator to recognize overdose and administer naloxone to clients experiencing overdose in the presence of PDAP staff.
4. Overdose Prevention Educators shall identify syringe exchange clients at least 14 years of age, at risk of experiencing or witnessing opioid overdose as eligible Overdose Responder candidates, who fulfill the following criteria:
 - Current opioid users, individuals with a history of opioid use, or someone with frequent contact with opioid users, age 14 years or older
 - Risk for overdose or likelihood of contact with someone at risk, by report or history

- Able to understand and willing to learn the essential components of overdose prevention, management, and naloxone administration

3. Opiate users who have participated in a PDAP-sanctioned Overdose Prevention Training Program are eligible to receive Naloxone from a local public health office or agency. The opiate user who is eligible to receive Naloxone will hereafter be referred to as the “participant”. PDAP-sanctioned Overdose Prevention Training Programs include those conducted by PDAP and PDAP Contractors. Contractors must be trained and certified by the Harm Reduction Program to provide overdose education and Naloxone prescription and use the training guidelines and best practices provided by PDAP.

4. Prior to distributing Naloxone, the Overdose Prevention Educator and the participant must discuss in person the indications, contraindications, potential adverse reactions and administration of the medication. Refer to Appendix A

5. If medically indicated, the Overdose Prevention Educator is authorized to distribute to the participant two (2) pre-filled 2.0 mg doses of Naloxone. Three (3) doses, or more, may be provided depending on the conditions indicated by the participant, such as lengthy travel or limited hours of availability. Each box containing the Naloxone must be labeled with a PDAP Pharmacy label indicating the name of the participant, the name of the prescribing clinician, the date and the instruction for the use of the medication. Other Community Based Organizations (CBO’s) providing the same service must also follow these guidelines.

6. The Overdose Prevention Educator should inform the participant about the expiration date of the medication and instruct the participant to return for a new prescription before the currently prescribed syringes expires, and not to use the drug if the solution is cloudy. Naloxone should be stored in a relatively stable environment, avoiding direct sunlight or excessive freezing or heat. Recommended Naloxone storage consists of a room temperature of 59-86 degrees Fahrenheit.

7. The prescription of Naloxone must be documented in the approved PDAP short form record/chart, which will be maintained by PDAP. The written record will document the name of the participant, the name of the prescribing clinician, the medical indication for the prescription if Naloxone, and documentation that the participant has been informed and understands the indications, contraindications, potential adverse reactions, and proper administration of the drug.

8. “Enrollment/Record of Use” forms should be sent to the PDAP by the 10th of every month. PDAP does not receive or maintain the participant record/chart from partner or contracted agencies.

IV. Overdose Prevention Training Program

1. An Overdose Prevention Training Program should prepare a participant or Trained Targeted Responder to administer Naloxone as recommended by PDAP for the OAAP.

2. The program must provide overdose education; what is and what causes an overdose, how overdoses can be avoided, how to identify and properly respond to an opioid overdose, which must include universal safety precautions, rescue breathing, activating EMS, and the administration of Naloxone.

3. Due to the small nature of many of the rural public health offices (PHO) and where it is not uncommon for there to be only two or three PDAP staff available to provide all services, and that some CBO's do not have a medical component that allows them to store and distribute Naloxone, collaboration is essential. If cooperation can be proven and maintained, a CBO or PHO may provide the educational component to the participants and another CBO or PHO may provide the Naloxone prescriptions and subsequent refills.

V. Overdose Prevention Prescription Program Guidelines

1. A Program Director shall be identified who manages the overdose prevention program. The Program Director shall:

- a) Identify a Physician Medical Director to oversee the OAAP;
- b) Select and identify program participants;
- c) Maintain Naloxone administration training records for all program participants while they are active in the program, and for at least three (3) years thereafter;
- d) Maintain OAAP records including Naloxone inventory records, program participant training records, and Overdose Prevention Program usage records;
- e) Ensure that all program participants are trained by the Overdose Prevention Training Program approved by PDAP.
- f) Provide evidence of coordination of the OAAP with local Emergency Medical Services and emergency dispatch agencies, including 911 dispatch agencies;
- g) Report all administrations of Naloxone to PDAP using the required reporting format;
- h) PDAP staff shall ensure that all naloxone kits are securely stored at physical address under conditions consistent with the manufacture guidelines.

2. Each Overdose Prevention Program will identify a Consulting Pharmacist or Physician who will be responsible for maintaining PDAP/PHO licensure and compliance in accordance with WBOP requirements for the ordering, inventory, issuance, control and storage of medications.

3. Overdose Prevention Selection, Supplies, and Medication Storage/Control:

- a) Opioid Antagonist Selection: OAAP shall use Naloxone, as the opioid antagonist. The program shall select the specific injection or administration device. It is recommended that the 2 ml prefilled dose with an atomizer for intranasal delivery be used.

b) Response Kit Supplies: OAAP shall maintain at least the following minimum response equipment as selected by PDAP:

- 1) Medical exam gloves.
- 2) Mask or other barrier for use during rescue breathing.
- 3) If an injectable delivery method is recommended, an agent to prepare skin before injection. If an injectable delivery method is recommended, sharps disposal should be provided.

c) Medication Storage and Control: Medication storage and control shall be in accordance with the WBOP and Federal Food and Drug Administration (FDA) rules and regulations.

4. Record Keeping: The OAAP shall establish and maintain a record keeping system that is available for audit. It shall include the following information:

- a) List of program participants;
- b) Dates of training for program participants;
- c) Copy of medical director approved medical protocols;
- d) Copy of the medical director contract/agreement;
- e) Naloxone Administration usage reports/Data collection forms;
- f) Quality assurance review documentation; and,
- g) Naloxone purchase/order and maintenance records.

5. Participant Enrollment/Record of Use Report/Distribution Forms: Every person who receives overdose prevention training and/or is provided with Naloxone will have an Enrollment/Record of Use Form/Distribution Forms completed and signed by the trainer that will be sent to PDAP by the 10th of every month. Only forms for participants who have actually received Naloxone or reported an overdose reversal should be submitted. The report form shall be designated by PDAP, and shall include at a minimum:

- a) Name of the OAAP;
- b) Name of the trainer submitting the report;
- c) Name of the participant;
- d) If reporting the use of Naloxone and requesting a refill:
 - 1) Attempt to report approximate date of Naloxone use;
 - 2) Attempt to report amount of Naloxone administered;

3) On distribution form, document the amount of Naloxone replaced to the participant at the time of the report, document the reason for replacement;

4) If known, list the type of drugs (other than opioids) taken by the person to whom the Naloxone was administered; and,

5) Circumstances relating to overdose (if known):

1. Was EMS called, and if not, why;

2. Was the person transported to a clinical facility;

3. Was rescue breathing performed on the person who overdosed;

4. Distance from nearest emergency department (in road miles);

5. Clinical disposition of the incident (if known).

Note: It is recommended that participants be able to get unlimited refills, for any reason. It is not recommended that you require participants to bring back their old/used naloxone kit, or put a limit on refills they can receive in a given period of time.

6. Enrollment Cards/Distribution Forms: It is preferred to avoid having trained participant obtain their naloxone by referral. In certain cases, such as a training provided in a detention facility, or in rural areas, where it is not possible to provide the Naloxone to a participant at the time of the training, an enrollment card should be given to the participant, along with information on suggested locations where the participant may redeem the card for their Naloxone and related equipment. When the card is redeemed, the original trainer should then send in the participants enrollment form or training log. This card/log should have:

a. The individuals first and last name,

b. The date and location of the training,

c. The name and telephone number of the trainer (or the OAAP),

7. Notification: Local EMS agencies shall be notified of the activation and existence of the OAAP. The notification shall include the name of the OAAP Program Director, Physician Medical Director, location of the program, telephone number, and a copy of medical director approved protocols. The local EMS agencies shall also be notified if an existing OAAP stops or cancels the Overdose Prevention Program.

8. Applicability: This policy applies to all PDAP employees, volunteers, interns and contract providers who are certified to provide overdose prevention training with Naloxone prescription to both current and former injection drug users, their family members and friends, treatment providers, and other non-medical first responders, such as law enforcement personnel, who may encounter an overdose situation while performing their duties.

9. Responsibility:

- a) PDAP leadership has the ultimate responsibility for assuring this policy is enforced.
- b) PDAP is responsible for monitoring, reviewing and certifying both PDAP and contracted providers and the quality of the training being provided.

10. Definitions:

1. "Administration of Opioid Antagonist" means the administration of an opioid antagonist by a person authorized pursuant to this regulation.
2. "Emergency Medical Service (EMS)" means the services rendered by licensed Emergency Medical Technicians, certified Emergency Medical Services First Responders or Emergency Medical Dispatchers in response to a person's need for immediate medical care to prevent loss of life or aggravation of physical or psychological illness or injury.
3. "Medical Direction" means guidance or supervision for trained targeted responders provided by a physician for the administration of opioid antagonists. This includes overseeing training, emergency medical services coordination, protocol approval, quality assurance and reporting.
4. "Opioid" means containing or derived from opium, including but not limited to morphine, heroin, or pharmaceutical medications containing opiates, such as methadone, codeine, hydrocodone, and oxycontin.
5. "Opioid antagonist" means a drug that nullifies in whole or in part the administration of an opioid. The opioid antagonist is limited to Naloxone or other medications approved by the NMDOH, unless otherwise stated in this regulation and is limited to a dose less than or equal to 1.0mg by subcutaneous injection or a dose of 2.0mg by intramuscular injection, not to exceed a total overall dose of 2.0mg. (Need to clarify: separate out IM dose definition).
6. "Opioid Antagonist Administration Program (OAAP)" means an organized program to administer Naloxone in accordance with these regulations.
7. "Overdose Prevention Training Program" means a training program which teaches overdose prevention information and practices, and prepares a person to administer an opioid antagonist as recommended by the agency for an OAAP.
8. "Participant" is any qualified individual who has been trained and enrolled in the program.
9. "Physician" means a doctor of medicine or doctor of osteopathy who is licensed or otherwise authorized to practice medicine or osteopathic medicine in Washington.
10. "Physician Medical Director" means a physician who is responsible for oversight of an Opioid Antagonist Administration Program, including providing for or ensuring the medical control of

trained targeted responders; the development, implementation, and evaluation of medical protocols; oversight of quality assurance activities, and compliance with the WBOP requirements.

11. “Protocols” means predetermined, written medical care plans and includes standing orders.

12. “Provider” means a person or entity contracted to deliver services.

11. References:

1. WA State Law. *RCW 69.50.315 (911 Good Samaritan Drug Overdose Law)*. 2010 Retrieved from <http://apps.leg.wa.gov/RCW/default.aspx?cite=69.50.315>
<http://apps.leg.wa.gov/billinfo/Summary.aspx?bill=5516&year=2009>.
2. Washington State Department of Health, *Washington State Injury and Violence Prevention Guide*, Injury and Violence Prevention Program, Editor. 2013.
3. Control Centers for Disease and Prevention, *Community-based opioid overdose prevention programs providing naloxone - United States, 2010*. MMWR Morb Mortal Wkly Rep, 2012. **61**(6): p. 101-5.
4. APHA Policy Statement LB-11-03 – Reducing Unintentional Prescription Drug Overdoses, *Preventing Overdose Through Education and Naloxone Distribution*, American Public Health Association, Editor. 2012.
5. P. O. Coffin and S. D. Sullivan, *Cost-effectiveness of distributing naloxone to heroin users for lay overdose reversal*. Ann Intern Med, 2013. **158**(1): p. 1-9.
6. Dykes, Pam. *Clark County Policy and Standing Order*. CCPH. 2014.

APPENDIX A. NALOXONE PACKAGE INSERT

Naloxone - Clinical Pharmacology

Complete or Partial Reversal of Opioid Depression

Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation and hypotension. Also, Naloxone can reverse the psychotomimetic and dysphoric effects of agonist-antagonists, such as pentazocine.

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 will subside in about 2 hours. The severity and duration of the withdrawal syndrome are related to the dose of Naloxone and to the degree and type of opioid dependence.

While the mechanism of action of Naloxone is not fully understood, *in vitro* evidence suggests that Naloxone antagonizes opioid effects by competing for the mu, kappa, and sigma opioid receptor sites in the CNS, with the greatest affinity for the mu receptor.

When Naloxone hydrochloride is administered intravenously, the onset of action is generally apparent within two minutes; the onset of action is slightly less rapid when it is administered subcutaneously or intramuscularly. The duration of action is dependent upon the dose and route of administration of Naloxone hydrochloride. Intramuscular administration produces a more prolonged effect than intravenous administration. Since the duration of action of Naloxone may be shorter than that of some opioids, the effects of the opioid may return as the effects of Naloxone dissipate. The requirement for repeat doses of Naloxone, however, will also be dependent upon the amount, type and route of administration of the opioid being antagonized.

Indications and Usage for Naloxone

Naloxone Hydrochloride Injection is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids including propoxyphene, methadone, and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine, butorphanol and cyclazocine. Naloxone hydrochloride is also indicated for the diagnosis of suspected or known acute opioid overdose.

Contraindications

Naloxone hydrochloride injection is contraindicated in patients known to be hypersensitive to Naloxone hydrochloride or to any of the other ingredients contained in the formulation.

Warnings

Drug Dependence

Naloxone hydrochloride injection should be administered cautiously to persons, including newborns of mothers, who are known or suspected to be physically dependent on opioids. In such cases, an abrupt and complete reversal of opioid effects may precipitate an acute withdrawal syndrome.

The signs and symptoms of opioid withdrawal in a patient physically dependent on opioids may include but are not limited to, the following: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In the neonate, opioid withdrawal may also include: convulsions, excessive crying, and hyperactive reflexes.

Repeat Administration

The patient who has satisfactorily responded to Naloxone should be kept under continued surveillance and repeated doses of Naloxone should be administered, as necessary, since the duration of action of some opioids may exceed that of Naloxone.

Respiratory Depression Due to Other Drugs

Naloxone is not effective against respiratory depression due to non-opioid drugs and in the management of acute toxicity caused by levopropoxyphene. Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher doses of Naloxone. If an incomplete response occurs, respirations should be mechanically assisted as clinically indicated.

Precautions

General

In addition to Naloxone, other resuscitative measures such as maintenance of a free airway, artificial ventilation, cardiac massage, and vasopressor agents should be available and employed when necessary to counteract acute opioid poisoning.

Drug Interactions

Large doses of Naloxone are required to antagonize buprenorphine since the latter has a long duration of action due to its slow rate of binding and subsequent slow dissociation from the opioid receptor.

Buprenorphine antagonism is characterized by a gradual onset of the reversal effects and a decreased duration of action of the normally prolonged respiratory depression. The barbiturate methohexital appears to block the acute onset of withdrawal symptoms induced by Naloxone in opioid addicts.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies in animals to assess the carcinogenic potential of Naloxone have not been conducted. Naloxone was weakly positive in the Ames mutagenicity and in the *in vitro* human lymphocyte chromosome aberration test but was negative in the *in vitro* Chinese hamster V79 cell HGPRT mutagenicity assay and in the *in vivo* rat bone marrow chromosome aberration study.

Reproduction studies conducted in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day (when based on surface area or mg/m²), demonstrated no embryotoxic or teratogenic effects due to Naloxone.

Use in Pregnancy

Teratogenic Effects: Pregnancy Category C

Teratology studies conducted in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day (when based on surface area or mg/m²), demonstrated no embryotoxic or teratogenic effects due to Naloxone. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Naloxone hydrochloride should be used during pregnancy only if clearly needed.

Non-teratogenic effects

Risk-benefit must be considered before Naloxone is administered to a pregnant woman who is known or suspected to be opioid-dependent since maternal dependence may often be accompanied by fetal dependence. Naloxone crosses the placenta, and may precipitate withdrawal in the fetus as well as in the mother. Patients with mild to moderate hypertension who receive Naloxone during labor should be carefully monitored as severe hypertension may occur.

Nursing Mothers

It is not known whether Naloxone is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Naloxone hydrochloride is administered to a nursing woman.

Geriatric Use

Clinical studies of Naloxone hydrochloride injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Adverse Reactions

Opioid Dependence

Abrupt reversal of opioid effects in persons who are physically dependent on opioids may precipitate an acute withdrawal syndrome which may include, but not limited to the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and tachycardia.

Drug Abuse and Dependence

Naloxone hydrochloride injection is an opioid antagonist. Physical dependence associated with the use of Naloxone hydrochloride injection has not been reported. Tolerance to the opioid antagonist effect of Naloxone is not known to occur.

Naloxone Dosage and Administration

Naloxone Hydrochloride Injection, USP may be administered intravenously, intramuscularly, or subcutaneously. The most rapid onset of action is achieved by intravenous administration and it is recommended in emergency situations. Since the duration of action of some opioids may exceed that of Naloxone, the patient should be kept under continued surveillance. Repeated doses of Naloxone should be administered, as necessary.