Cleveland State University
Emergency Naloxone Cabinet Procedures

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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.

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.

Limitations on Administration of Naloxone to Certain Individuals

- Alcohol intoxication
    - Naloxone is not effective in treating alcohol intoxication or poisoning.
- Benzodiazepines and stimulants
    - Naloxone is not effective in treating benzodiazepine or stimulant overdoses

Authorization to Administer Naloxone

- Authorization to administer Naloxone
    - Pursuant to Section 4729.515 of the Ohio Revised Code and Section 4729:5-3-19 of the Ohio Administrative Code, the following are authorized to administer naloxone in accordance with this protocol:
        - Any capable and knowledgeable member of the Cleveland State University community when there is reason to believe a person is experiencing an opioid-related overdose.
    - The above authorized individuals may administer the following doses of intranasal formulations of naloxone:
        - 4 mg Generic Naloxone Nasal Spray
        - 4 mg Narcan Nasal Spray
    - Variation in dosage or formulation are permissible based on availability of naloxone through Recovery Ohio, the Ohio Department of Higher Education, the Ohio Department of Health, or Project Dawn.

Labeling, storage, record-keeping, and administrative requirements

- Labeling
    - Each emergency naloxone cabinet will be labelled with the Department of Health Services telephone number to facilitate notification of use or restock needs.
- Storage
    - Each dose of naloxone received and dispensed, including refill doses, will be recorded by the Department of Health Services in a dispensing

log in accordance with Ohio Administrative Code Section 4729-9-22.
    - Naloxone must be stored in a location accessible to authorized Department of Health Services and Cleveland State University Police Department personnel in accordance with the manufacturer's or distributor's labeling.
    - All doses should be checked periodically to ensure that the naloxone is not adulterated. Naloxone shall be considered adulterated when it is beyond the manufacturer's or distributor's expiration date.
    - Adulterated naloxone shall be stored at the Department of Health Services in the Expired and Adulterated Medication Disposal Cabinet.
- Record-keeping
    - The Department of Health Services shall maintain a complete list where emergency naloxone cabinets are located on campus, which shall include:
        - Complete address of the location where cabinets are located
        - A description of the location where cabinets are located
        - The list maintained under this section shall be immediately available for inspection upon request of an employee of the State of Ohio Pharmacy Board.
    - The Department of Health Services shall maintain a record of all naloxone stored in an emergency use naloxone cabinet, which shall include:
        - The name of the drug
        - Strength
        - Dosage form
        - National drug code
        - Expiration date for any Naloxone stored in an emergency cabinet.
        - The records maintained under this section shall be produced within three business days upon request by an employee of the State of Ohio Pharmacy Board.

Training

- The Department of Health Services will make instructions available to The Cleveland State University community regarding the emergency administration of naloxone to any individual who might access naloxone, to include:
    - Specific instructions to summon emergency services pursuant to Ohio revised Code Section 4729.515(D)(2),
    - Procedures for administering naloxone contained with the kit, including possible administration of multiple doses,
    - Performing rescue breathing and use of a face shield or other rescue breathing barrier device, which shall be provided with the naloxone, and
    - Proper method for placing an individual into the recovery position.

Reporting and Maintenance

- Any access to an emergency naloxone cabinet shall be reported to the

Department of Health Services within a reasonable time of such access.

- Contact information for the Department of Health Services shall be posted on each emergency Naloxone cabinet to facilitate such notification.
- A Department of Environmental Health employee shall inspect each naloxone cabinet on campus at least once every thirty days to monitor whether the cabinets have been accessed or need replenished.
- Any reported use or discovered missing naloxone or accompanying components will be replaced by the Department of Health Services within 48 hours of any such reported use or discovered missing components.
- Any necessary repairs to an emergency use naloxone cabinet will be reported to The Cleveland State University Department of Physical Facilities
- Cabinet Keys
    - One set of keys to emergency use naloxone cabinets shall be maintained by the Department of Health Services
    - One spare set of keys to emergency use naloxone cabinets shall be maintained by The Cleveland State University Police Department.