Naloxone Access: Expanding the Role of the Pharmacist

Victoria Tutag-Lehr BS Pharm, Pharm D
Associate Professor, Department of Pharmacy Practice
Eugene Applebaum College of Pharmacy & Health Sciences
Wayne State University, Detroit, MI vtlehr@med.wayne.edu

Pharmacist Objectives:

1. Identify clinical signs and symptoms of opioid overdose.
2. List dosage and common adverse effects of naloxone.
3. Develop a monitoring plan for an individual who has received naloxone for overdose with caregiver education.
4. Select an appropriate formulation of naloxone for a person in a given clinical situation.
5. Discuss implications of the naloxone standing order protocol on practice (2016 PA 383).

Technician Objectives:

1. Identify clinical signs and symptoms of opioid overdose.
2. List available formulations and dosage of naloxone for overdose.
3. Describe the mechanism of action and common adverse effects of naloxone.
4. Select an appropriate formulation of naloxone for an individual in a given situation.
5. Discuss implications of the naloxone standing order protocol for technicians.

I. The Opioid Epidemic in Michigan:

A. Trends in mortality-opioids
B. Contributors to opioid over-use/misuse
C. Risks for overdose
D. Identification of opioid overdose-signs/symptoms
   1. History of current opioid use
   2. Unresponsive or unconscious
   3. Not breathing or slow/shallow respirations
   4. Snoring or gurgling sounds
   5. Blue lips and/or nail beds
   6. Pinpoint pupils
   7. Clammy skin

II. Naloxone:

A. Why naloxone?
   1. Safe/Easy to administer
   2. Stigma
   3. Prevents death from opioid overdose-data
B. Naloxone mechanism of action
   1. Opioid antagonist
      a. Reverses respiratory depression, sedation, hypotension (clinical/toxic effects of prescription + illicit opioids)
      b. Monitor for withdrawal symptoms or pain crisis
      c. Adverse effects: transient, usually limited-rarely severe
         i. Nausea, vomiting, arrhythmia, ↑ blood pressure, shivering, tremor, seizures, hot flashes
         ii. Pulmonary edema (rare in outpatient setting)
   d. Pharmacokinetics/Pharmacodynamics:
Onset: 2-3 minutes
Duration: < 90 minutes:

**Most opioids especially sustained or extended release products > duration-must monitor/stay with individual until EMS arrives**

2. Dose: FDA comparator adult dose 0.4 mg IM
   a. Initial adult dose: 0.4 to 4 mg in available dosage forms (Intranasal (IN), Intramuscular (IM), Subcutaneous (SubQ))

3. Formulations:
   a. Naloxone injection - 0.4 mg/mL; 1.0 mg/mL (must provide a needle and syringe for IM or Intra Nasal Device adapter (IND) for administration-unreliable delivery, recall)
   b. Naloxone auto-injector 4 mg/0.4 mL 2 pack with English language with microchip trainer unit *(FDA approved for layperson use)* AWP ≈ $3000.00 +
   c. Naloxone nasal spray unit 2 mg or 4 mg single use-2 pack, respray in 2 min *(FDA approved for layperson use)* AWP ≈ $75.00

5. Formulation selection?
   a. Ease of use, liability (unapproved product) vs cost
   b. Other factors? Insurer formulary?
   c. Statewide protocol
   d. Clear and effective training essential (4-minute video by Dr W Morrone DO):
      Please review https://m.youtube.com/watch?v=yKmOZR6WefU

III. Overdose Response Education:

A. Call 911
B. Administer Naloxone, repeat dose if no effect in 2-3 minutes
C. Rescue Breaths
D. CPR-Recovery Position
E. Stay with the Person

Figure 1: Naloxone Access in Michigan

IV. Avenues for Access Naloxone in Michigan
A. Historical Perspective:
   1. Poor uptake by primary care physicians
   2. Limited collaborative practice prescribing by pharmacists
   3. Access points in community depends on location
   4. Good Samaritan
   5. 39 states Naloxone legislation

B. Standing Order Naloxone Prescription for Opioid Overdose Prevention—Michigan
   1. PA 383: Target implementation date April 1\textsuperscript{st} 2017
   2. Allows pharmacists to give individuals at risk of opioid overdose and their support persons naloxone without an individual prescription
   Prescriptive authority MI Chief Medical Executive: Dr Eden Wells MD

C. Challenges and Opportunities for Pharmacists
   1. Consistent practice and support of standing order
   2. Professional education and training
   3. Education and counseling of individuals:
      i. How naloxone works
      ii. How to identify an overdose
      iii. How to respond in an overdose
      iv. How to administer naloxone (Intranasal (IN) or IM (Intramuscular)
      v. What to do and what to expect after naloxone administration
      vi. How to identify and avoid risk overdose situation

   4. Consistent formulation selection and availability
   5. Billing and reimbursement
   6. Integration into practice and workflow-space for consultation and training
   7. Documentation of dispensing, education, administration of dose, outcomes
   8. Referral to treatment?
   9. Limits on prescriptions
   10. Technician collaboration and support
   11. Individuals without funds or 3\textsuperscript{rd} party insurance or Medicaid
   12. Persistent stigma
   13. Others? Opportunity for inter-professional collaboration with Addiction Medicine community

V. Summary
   A. Michigan is experiencing a deadly opioid epidemic and naloxone the opioid antagonist can prevent death from opioid overdose
   B. Naloxone uptake and access in Michigan requires improvement—citizens are dying!
   C. The Michigan Standing Order Naloxone Prescription for Opioid Overdose Prevention ensures Michigan residents at risk of an opioid overdose or those that can assist a person at risk of experiencing an opioid overdose, the ability to obtain naloxone from a pharmacist under the authority of the Chief Medical Executive
   D. Pharmacists are well positioned to increase availability of naloxone in the community via the standing order
   E. Technicians can assist pharmacists by improving workflow and product availability in addition to identifying individuals at risk for overdose
F. The pharmacist will educate and verify the knowledge of all individuals to make sure they understand the steps to identify an overdose, and naloxone administration and overdose prevention

G. Pharmacists and technicians will require training and education

H. Consistent and effective education will be available from the State of Michigan for individuals seeking naloxone

I. The Standing Order for Naloxone Prescription protocol under development for April 1, 2017

Self-assessment #1: A young woman is found in the restroom by a pharmacy technician, lethargic, unresponsive to verbal stimuli. Her pulse is difficult to palpate, breaths are shallow and slow, pupils are pinpoint. An empty vial for morphine sustained release tablets labeled for a male patient is in her pocket.

This individual’s condition is most likely caused by:

- a. Sepsis from infected needle sites
- b. Hypoglycemia
- c. Opioid overdose
- d. Post ictal state from seizure

Self-assessment #2: The most appropriate rationale for instructing support persons to remain with individuals after naloxone reversal until EMS arrives is?

- a. Naloxone administration always causes seizures
- b. Naloxone administration may induce withdrawal symptoms
- c. Individuals taking long-acting opioids may lapse back into respiratory depression
- d. Not necessary for caregiver to remain with an adult

Self-assessment #3: Your accountant stops by your pharmacy and confides that he is very worried about his 25-year-old, a student at a local university. His son has been misusing fentanyl for the past year and just stopped medication assisted therapy (MAT) at a local clinic with Suboxone. The son decided to taper fentanyl “on his own”. His son spends the weekends at the family home and dad is concerned his son may overdose.

The following questions refer to the above case scenario.

3A. Which factor places the individual’s son at high risk for an opioid overdose:

- a. Student status
- b. Male gender
- c. Living away from home
- d. Recent discontinuation of MAT

3B. The most appropriate intervention you can make for this individual and his son is:

- a. Contact the son’s physician to obtain a prescription for a naloxone nasal spray 4 mg and dispense it to the father.
- b. Inform the individual that you cannot dispense naloxone to him for his son. In the event of overdose he should call 911 and they will administer naloxone.
c. Offer to contact the individual’s primary care provider to obtain a prescription for naloxone 0.4 mg vials and a IM syringe for his son.

d. Dispense naloxone nasal spray 4 mg to the individual under a standing order protocol or collaborative practice plan. Provide appropriate counseling and education on naloxone administration and opioid overdose response.

Self-assessment #4:
Select all of the naloxone formulations that are FDA approved for use in the community based on ease of use and effective plasma concentrations after administration:

a. Naloxone 0.4 mg/mL vial and syringe for intramuscular injection
b. Naloxone 4 mg/0.4mL auto-injector unit
c. Naloxone 2 mg/2 mL syringe and nasal adapter device
d. Naloxone nasal spray 2 mg or 4 mg/0.1 mL

Self-assessment #5:
The first step after identifying a possible opioid overdose is to instruct the support person to:

a. Place the individual in the rescue position
b. Call 911
c. Transport them to the ED
d. Administer naloxone

Selected References and Resources


Get Naloxone now www.getnaloxonenow.org

Harm Reduction Coalition www.harmreduction.org

Prescribe to Prevent www.prescribetoprevent.org

Project Lazarus www.projectlazarus.org

StopOverdose.org www.stopoverdose.org

Naloxone education 4 min video William Morrone, DO MS MPH FACOFP DAAPM ASAM
https://m.youtube.com/watch?v=yKmOZR6WefU