Increasing Naloxone Access in Kentucky: Implementation of SB 192 by Pharmacists

137th KPhA Annual Meeting & Convention
Bowling Green, Kentucky
June 28, 2015
Learning Objectives

• At the end of the session the participant should be able to:

  • Explain the epidemiology of opioid addiction and overdose
  • Identify risk factors for opioid abuse and overdose
  • Explain how to recognize and respond to opioid overdoses in the community
  • List the indications and contraindications for use of naloxone as rescue therapy
  • Demonstrate the administration of naloxone in the setting of opioid overdose in the community
  • Describe adverse effects associated with naloxone rescue therapy
Learning Objectives, Cont’d.

• At the end of the session the participant should be able to:
  • Explain provisions of SB 192 and the associated Board of Pharmacy regulations that authorize pharmacists to initiate dispensing of naloxone
  • Identify persons that meet criteria for provision of naloxone via protocol
  • Educate persons receiving naloxone via protocol regarding the use of naloxone for rescue therapy
  • Identify the required elements of a protocol that can be used to initiate the dispensing of naloxone
  • Define the required documentation when initiating dispensing of naloxone
Program Outline

- Introduction and history of naloxone access policy in US 5 mins.

- Epidemiology, risk factors, signs and symptoms of opioid overdose, pharmacology of naloxone 40 mins.

- SB 192 and associated KAR 10 mins.

- Developing a protocol, identifying and educating patients, dispensing and documentation 30 mins.

- Questions 5 mins.
Introduction

• SB192 passed in the 2015 legislative session

• Effective date March 25, 2015
• Authorizes pharmacists to initiate the dispensing of naloxone under a physician-approved protocol to prevent opioid overdose
• This program designed to meet the educational requirements set forth by the Board of Pharmacy in administrative regulations (201 KAR 2:360) promulgated on May 14, 2015
History of Naloxone Access Policy in US

- First efforts to institute take-home naloxone started in Chicago in the 1990s
- First naloxone access law implemented in NM in 2001
- Project Lazarus in NC showed great results from increased access in reducing overdose death rates
- As of May 8, 2015, 33 other states and DC have some form of naloxone access policy
- Pharmacists role more recently a focus in several states
  - WA (2012)
  - NM (2014)
  - RI (2013)
  - CA (2014)
  - NY (2014)
  - KY (2015)
Status of Naloxone Access Policy in US 5/8/15

APhA policy on controlled substances and other medications with the potential for abuse and use of opioid reversal agents (2014)

1. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.

2. APhA supports recognition of pharmacists as health care providers who must exercise professional judgement in the assessment of a patient’s conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.

3. APhA supports pharmacists’ access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.

4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.

5. APhA supports the pharmacists’ role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.
Epidemiology of Overdose

Emma Palmer, PharmD, BCPS, BCPP
Background
DSM-5: Defining a Substance Use Disorder

• Pathological pattern of behaviors noted as it relates to the use of a substance
  • Impaired control
    • Larger amounts over a longer period of time; unsuccessful attempts to quit/cut down; spends a large amount of time obtaining substance; cravings present
  • Social impairment
    • Failure to fulfill work, school, or home obligations; use despite interpersonal problems; giving up other activities
  • Risky use
    • Use in hazardous situations; use despite persistent psychological or physical harm
  • Pharmacological criteria
    • Presence of tolerance and withdrawal
Tolerance

• Tolerance
  • An adaptive state characterized by:
    • Diminished response to the same quantity of drug
    • Need to use larger doses to produce the original effect
  • Drug tolerance may develop without a substance use disorder present

• Cross-tolerance
  • Tolerance to a drug produced by the repeated administration of another drug
Withdrawal

- Unpleasant physical & psychological effects produced by discontinuation of or administration of a receptor antagonist to a psychoactive drug upon which a person has developed a physical dependence

- Causes clinically significant distress and/or impairment in functioning

DSM-5
Substance Intoxication

- Reversible substance-induced maladaptive behavioral or psychological changes after recent ingestion of substance
- Signs and symptoms present, are not due to a medical or psychiatric illness
- Does not always co-occur with a substance use disorder

“This one time in college…”

“Occasional glass of wine with dinner…”
Addiction in the US

• Negatively effects productivity, health, and crime

• Major public health and social problem
  • Cancer, heart disease, and HIV/AIDS cases cite substance abuse as ~ 30% of causality
  • Drugged/drunk driving attributed to up to 22 % of crashes
  • Violence and child abuse additionally impacted by drug abuse

http://www.drugabuse.gov/publications/drugfacts/drugged-driving
Opioid Overdose Deaths: A Frightening Trend

Opioid Addiction in KY

Occurrences of Specific Drugs among the Contributing Causes for Kentucky Resident Drug Overdose Deaths, 2011-2012


Total Number

Opioid Addiction in KY

Kentucky Resident Drug Overdose Deaths by Intent, 2000-2012

Drug Abuse: The Stigma

- “Moral failure”
- Junkies
- Drunks
- Crackheads
- “The war on drugs”

Multiple roadblocks to recovery

- Failure to seek or receive appropriate treatment
- Caught up in the legal system, treated with suspicion, challenging to get jobs/benefits/etc.

People can’t seek recovery if they don’t survive
Source Where Pain Relievers Were Obtained 2012-2013

- One Doctor (21.2%)
- More than One Doctor (2.6%)
- Free from Friend/Relative (53.0%)
- Other¹ (4.3%)
- Bought on Internet (0.1%)
- Drug Dealer/Stranger (4.3%)
- Bought/Took from Friend/Relative (14.6%)

¹ The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

Note: The percentages do not add to 100 percent due to rounding.

ABUSE OF PRESCRIPTION PAIN MEDICATIONS
RISKS HEROIN USE

In 2010 almost 1 in 20 adolescents and adults—12 million people—used prescription pain medication when it was not prescribed for them or only for the feeling it caused. While many believe these drugs are not dangerous because they can be prescribed by a doctor, abuse often leads to dependence. And eventually, for some, pain medication abuse leads to heroin.

1 IN 15

PEOPLE WHO TAKE NON MEDICAL PRESCRIPTION PAIN RELIEVERS WILL TRY HEROIN WITHIN 10 YEARS.

Number of People Who Abused or were Dependent on Pain Medications and Percentage of Them that Use Heroin

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>1.4 million</td>
<td>5%</td>
</tr>
<tr>
<td>2010</td>
<td>1.9 million</td>
<td>14%</td>
</tr>
</tbody>
</table>

Heroin users are 3X as likely to be dependent
14% of non medical prescription pain reliever users are dependent
54% of heroin users are dependent.

Heroin Emergency Room Admissions Are Increasing

<table>
<thead>
<tr>
<th>Year</th>
<th>Admissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>200K</td>
</tr>
<tr>
<td>2008</td>
<td>230K</td>
</tr>
<tr>
<td>2011</td>
<td>260K</td>
</tr>
</tbody>
</table>
Opioid Overdoses

What to Do?
Who is More Likely to Develop a Use Disorder?

• Major considerations
  • Personal or family history of abuse or dependence
  • Other mental health comorbidities
  • Pain conditions

• Other factors
  • Males
  • Younger age
  • Socioeconomic status

http://cpnp.org/guidelines/naloxone
Who is More Likely to Overdose?

<table>
<thead>
<tr>
<th>Drug Exposure</th>
<th>Other Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Concurrent use of other CNS depressants</td>
<td>• Personal history of substance use disorder</td>
</tr>
<tr>
<td>• Benzodiazepines</td>
<td>• Recent overdose or intoxication</td>
</tr>
<tr>
<td>• Alcohol</td>
<td>• Recent discharge from an abstinent environment</td>
</tr>
<tr>
<td>• High-dose opioids</td>
<td>• Comorbidities</td>
</tr>
<tr>
<td>• ≥ 100 mg morphine equivalents</td>
<td>• Respiratory disease</td>
</tr>
<tr>
<td>• Polypharmacy</td>
<td>• Renal dysfunction</td>
</tr>
<tr>
<td>• Methadone use</td>
<td>• Hepatic dysfunction</td>
</tr>
<tr>
<td>• Opioid rotation</td>
<td></td>
</tr>
</tbody>
</table>

Physiologic Effects of Opioid Overdose

• Opioid overdoses result in:
  • Reduced sensitivity to changes in O2 and CO2
  • Decreased tidal volume
  • Decreased respiratory frequency
  • Respiratory failure and death due to hypoventilation
Opioid Overmedication

- Risk of worsening condition
  - Monitor patient closely
- Sleepiness or difficulty staying awake “nodding off”
- Confusion, slurred speech
- Behaviors consistent with intoxication
- Reduced respiratory rate
- Bradycardia
- Miosis

Opioid Overdose

- Nonresponse to sternal rub
- Infrequent, shallow respirations, “death rattle”
- Dusky/cyanotic skin, lips, and/or fingernails
- Hypotension and bradycardia
- Coma, death


Overdose Triad

Pinpoint pupils

Respiratory depression

Unconsciousness

World Health Organization, *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence*
General Considerations for Suspected Overdose

• Call 911

• Support respiration
  • Ideally, oxygen administration
  • Anoxic brain injury
  • Acute lung injury following naloxone administration

• “Rescue breathing”
  • Clear airway
  • Chin tilt
  • Two breaths, then once every five seconds

Naloxone Rescue for Opioid Overdoses
Naloxone

https://pbs.twimg.com/media/BtPSd7JCIAASOw4.png
Naloxone

- Pure opioid antagonist
- Competes for mu, kappa, and sigma opiate receptor sites within the CNS
- When administered alone, has no pharmacological activity


# Naloxone – Routes of Administration

<table>
<thead>
<tr>
<th>Route</th>
<th>Dose</th>
<th>Onset</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous</td>
<td>0.4 – 2 mg</td>
<td>Rapid</td>
<td>T ½ 30 – 81 min</td>
</tr>
<tr>
<td></td>
<td>Max 10 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intramuscular</td>
<td>0.4 mg</td>
<td>2 – 5 min</td>
<td>T ½ ~ 1.36 hrs</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>0.4 mg</td>
<td>2 – 5 min</td>
<td>0.5 – 2 hrs</td>
</tr>
<tr>
<td>Intranasal</td>
<td>2 mg (1 mg per nare)</td>
<td>8 – 13 min</td>
<td>Up to 120 min</td>
</tr>
</tbody>
</table>

Lexicomp Online®, Lexi-Drugs®
Naloxone – Indications

• Complete or partial reversal of opioid toxicity and depression

• Emergency reversal of known or suspected opioid overdose
  • Respiratory depression
  • CNS depression

• Emergency administration in settings where opioids may be present

Administration of Naloxone

• Intranasal

Administration of Naloxone

- Intramuscular

1. Remove cap from naloxone vial and uncover the needle.
2. Insert needle through rubber plug with vial upside down. Pull back on plunger and take up 1 mL.
3. Inject 1 mL of naloxone at a 90 degree angle into a large muscle (upper arm/thigh, outer buttocks).


Administration of Naloxone

• Intramuscular Auto-Injector

Storage and Handling

- Avoid exposure to light
- Store at room temperature
- Approximate expiration ~ 12 – 18 months
- Not dangerous to give expired naloxone
- Auto-injector should be stored in outer case as supplied

http://cpnp.org/guidelines/naloxone

Naloxone – Contraindications and Precautions

• Hypersensitivity to naloxone
• Risk of incomplete reversal
  • Partial agonists or mixed agonist/antagonist
    • Buprenorphine
    • Pentazocine
  • Multiple substance overdose / intoxication
• Precipitation of severe acute withdrawal syndrome
• Effect is limited in duration

Naloxone – Safety and Tolerability

- Severe opioid withdrawal syndrome
  - Body aches
  - Diaphoresis, rhinitis
  - Yawning
  - Tremor, anxiety, irritability
- GI effects
  - N/V/D
  - Abdominal cramps
- Autonomic instability

Naloxone Use in Special Populations

- **Pregnancy**
  - Category B agent
  - No toxic/teratogenicity noted in animal models
  - Monitoring of fetus for s/sx of distress in opioid-dependent mothers

- **Geriatric use**
  - May experience higher systemic exposure to opioids and naloxone
  - Clinical trials insufficient to determine difference in response vs general adult population

The Effects of Bystander-Administered Naloxone

• Saved by the nose!
  • Trained bystanders can be similarly skilled and successful with opioid reversal
  • We trust bystanders to administer other lifesaving medication - why not naloxone?

• Does it change opioid use?
  • Not thoroughly studied in US
  • European studies of heroin abusers describe concerns as unfounded


SB 192 and KAR 201 KAR 2:360

Steve Hart, RPh
SB 192

- Comprehensive legislation passed in 2015 session commonly known as the “Heroin Bill”
- Available at http://www.lrc.ky.gov/record/15rs/SB192.htm
- Many facets of legislation
  - Increased access to treatment
  - Prohibits discrimination and action against pregnant women who have substance abuse problems
  - Needle exchange program
  - Medical education and continuing education on substance abuse and addiction
  - Increased access to naloxone for overdose prevention
SB 192, CCR: Pharmacist Provisions

KRS 217.186 is amended to read as follows:

(1) A licensed health-care provider who, acting in good faith, directly or by standing order, prescribes or dispenses the drug naloxone to a [person or agency] patient who, in the judgment of the health-care provider, is capable of administering the drug for an emergency opioid overdose, shall not, as a result of his or her acts or omissions, be subject to disciplinary or other adverse action under KRS Chapter 311, 311A, 314, or 315 or any other professional licensing statute.

As used in this subsection, "licensed health-care provider" includes a pharmacist as defined in KRS 315.010 who holds a separate certification issued by the Kentucky Board of Pharmacy authorizing the initiation of the dispensing of naloxone under subsection (5) of this section.
201 KAR 2:360

- Promulgated May 14, 2015
- Available at http://www.lrc.state.ky.us/kar/201/002/360E.htm
- Outlines the:
  - Requirements for certification Section 1
  - Procedures for dispensing naloxone Section 2
  - Protocol minimum requirements Section 3
  - Education to be provided to person receiving naloxone prescription under protocol Section 4
  - Pharmacist education and training required for certification Section 5
APPLICATION FOR PHARMACIST CERTIFICATION
FOR NALOXONE DISPENSING

Incomplete or illegible applications will be returned to applicant for correction.

Name ___________________________________________ RPh License No _____________

Street ___________________________ Home Phone _______________________

City ___________________________ County ___________ State ________ Zip ________

E-mail Address ___________________________ Birthdate _______ Social Security Number XXX-XX-____

Primary Place of Employment: [Please provide secondary places of employment on additional sheet and attach.]

Pharmacy/Business Name _____________________________________________

Kentucky Pharmacy Permit Number ___________________________ Phone No. ________________

INCLUDE WITH YOUR APPLICATION IS PROOF OF EDUCATION AND TRAINING IN THE USE AND DISPENSING OF NALOXONE SET FORTH IN 201 KAR 2:360.

THE APPLICATION MUST BE DATED AND SIGNED.

_________________________  _______________________
DATE                        SIGNATURE
Procedures for Dispensing Naloxone

• A pharmacist is authorized to initiate the dispensing of naloxone under the following conditions:
  • The pharmacist has met the requirements for certification and has applied for and received his or her certification from the Board
  • The pharmacist has a physician-approved protocol that meets the minimum requirements
  • The pharmacist documents the dispensing event in the pharmacy management system including:
    • Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and
    • Documentation that the individual receiving naloxone was provided with the required training and education
Protocol Minimum Requirements

• A physician-approved protocol authorizing a pharmacist to initiate the dispensing of naloxone shall contain:
  • Criteria for identifying persons eligible to receive naloxone under the protocol
  • Naloxone products authorized to be dispensed including name of product, dose, and route of administration
  • Specific education to be provided to the person to whom the naloxone is dispensed
  • Procedures for documentation of naloxone dispensation, including procedures for notification of the physician authorizing the protocol
  • The length of time the protocol is in effect
  • The date and signature of the physician approving the protocol
  • The names and work addresses of pharmacist(s) authorized to initiate dispensing of naloxone under the protocol
Required Elements of Patient Education

- A pharmacist dispensing naloxone to a person shall provide verbal counseling and written educational materials, appropriate to the dosage form of naloxone dispensed, including:
  - Risk factors of opioid overdose
  - Strategies to prevent opioid overdose
  - Signs of opioid overdose
  - Steps in responding to an overdose
  - Information on naloxone
  - Procedures for administering naloxone
  - Proper storage and expiration of naloxone product dispensed
Pharmacist Education and Training Required for Certification

A pharmacist who applies for certification to initiate dispensing of naloxone shall have received education and training related to the safe dispensing of opioids and use of naloxone as rescue therapy for opioid overdose, including:

- Risk factors for opioid abuse and overdose
- Opioid overdose prevention
- Recognizing and responding to opioid overdoses
- Indications for use of naloxone as rescue therapy
- Contraindications for use of naloxone
- Administration of naloxone
- Adverse effects associated with naloxone rescue therapy
- Identification of a patient who meets the criteria for provision of naloxone
- Required education to provide to persons receiving naloxone
- Required elements of protocol to initiate dispensing of naloxone
- Required documentation when initiating dispensing of naloxone
Implementing a Naloxone Dispensing Program at Your Practice

Trish Freeman, RPh, PhD
Developing a Protocol

- Must contain minimum requirements per BoP regulations
- Elements should be edited and agreed upon by authorizing physician
- If physician requests notification, must make sure to follow through with that subsequent to dispensing naloxone
- Protocol template available on flash drive
Protocol to Initiate Dispensing of Naloxone for Opioid Overdose Prevention and Response

Purpose: This protocol specifies the criteria and procedures for eligible pharmacists, who have met the requirements and received certification from the Board of Pharmacy, to initiate the dispensing of naloxone.

Criteria: Persons eligible to receive naloxone under this protocol include:

1) Persons with history of receiving emergency medical care for acute opioid poisoning or overdose
2) Persons with a suspected history of substance abuse or nonmedical opioid use
3) Persons receiving high-dose opioid prescriptions (>100 mg morphine equivalent)
4) Persons who are opioid naïve and receiving a first prescription for methadone
5) Persons starting buprenorphine or methadone for addiction treatment
6) Persons on opioid prescriptions for pain in combination with:
   a. smoking, COPD, emphysema, sleep apnea, or other respiratory illness
e  b. renal dysfunction, hepatic disease, or cardiac disease
   c. known or suspected alcohol use
d. concurrent benzodiazepine or other sedative prescription
e. concurrent antidepressant prescription
7) Persons who may have difficult accessing emergency medical services
8) Voluntary request
Medication: For patients meeting the above criteria, this protocol authorizes the pharmacist(s) to initiate the dispensing of naloxone as follows:

For intranasal administration:

Naloxone HCl 0.4 mg per mL
2mL Carpujet syringes with MAD nasal drug delivery device
Dispense #2
Administer 1 mL in each nostril at signs of overdose
May repeat in 3 minutes if no or minimal breathing and responsiveness

For parenteral administration:

Naloxone HCl 0.4mg per 0.4 mL autoinjector (Evzio)
Dispense #1
Administer into the anterolateral aspect of the thigh, through clothing if necessary
May repeat in 3 minutes if no or minimal breathing and responsiveness

Education: Pharmacist will provide and document in the pharmacy management system that persons receiving naloxone under this protocol were education on the following:

1) Risk factors for opioid overdose, strategies to prevent opioid overdose
2) Signs of opioid overdose
3) Steps in responding to an overdose
4) Information about naloxone
5) Procedures for administering naloxone
6) Proper storage procedures and expiration date of naloxone product dispensed
Documentation: Pharmacists will document via prescription record each person who receives a naloxone prescription under this protocol. In addition to standard information required in the prescription record, documentation will include name and title of person providing education to recipient of naloxone.

[If directed by the authorizing physician] The pharmacist shall provide written notification via fax to the authorizing physician of persons receiving naloxone under this protocol within 7 days of initiating dispensing.

Terms: This protocol is in effect until rescinded or for 2 years after the effective date as indicated on this protocol.

Signatures:

________________________________________  ________________
Physician  Date

________________________________________  ________________
Pharmacist  Date

________________________________________
Pharmacy Address

________________________________________  ________________
Pharmacist  Date

________________________________________
Pharmacy Address
Identifying At-Risk Individuals

- During DUR
  - Multiple CNS depressants
  - Multiple prescribers
  - High dose Rx

- Upon new Rx presentation

- Reports from medication management system based on at-risk drug combinations/disease states

- KASPER Reports

- Signage which alerts family and friends to availability of take-home naloxone
Identifying At-Risk Individuals

- Ask patients about overdose history
  - Have you overdosed?
  - Witnessed an overdose?
  - Used strategies to prevent overdose?
  - Do you have a plan for responding to an overdose?
Education of Persons Receiving Naloxone via Protocol

- Must contain all elements as outlined in BoP regulation
- Education must be provided orally as well as written materials for take-home
- Many educational resources available
  - [http://prescribetoprevent.org/pharmacists/pharmacy-basics/](http://prescribetoprevent.org/pharmacists/pharmacy-basics/)
Education: Overdose Prevention Strategies for Patients

• Take prescription opioids only as directed
• Don’t mix opioids with other drugs or alcohol
• Store medication in safe and secure place
• Dispose of unused medication
• Make sure healthcare providers know all medications being taken
• Not taking opioids for a period of time (abstinence) can change tolerance
Education: Recognizing an Overdose

• Check breathing
  • If not breathing or struggling to breathe call out name and perform sternal rub

• Look for signs of drug use

• Look for other signs of overdose
  • Pinpoint pupils
  • Blue/gray lips and nails
Education: Signs of Opioid Overdose

- Extreme sleepiness, inability to awaken verbally or upon sternal rub
- Breathing problems can range from slow to shallow breathing in a patient who cannot be awakened
- Fingernails or lips turning blue/purple
- Extremely small “pinpoint” pupils
- Slow heartbeat and/or low blood pressure
Education: Signs of Overmedication / Intoxication

- Signs of **OVERMEDICATION**, which may progress to overdose, include:
  - Unusual sleepiness, drowsiness, or difficulty staying awake despite loud verbal stimulus or vigorous sternal rub
  - Mental confusion, slurred speech, intoxicated behavior
  - Slow or shallow breathing
  - Extremely small “pinpoint” pupils; although normal size pupils do not exclude opioid overdose
  - Slow heartbeat, low blood pressure
  - Difficulty waking the person from sleep
Education: Responding to Overmedication / Overdose

- If overmedicated/intoxicated
  - Stimulate and observe

- If overdosed
  - Call 911
  - Initiate rescue breathing
  - Administer naloxone
  - Stay until help arrives
Education: Rescue Breathing

- Involves essentially breathing for someone else
- Providing rescue breathing during an opioid overdose potentially prevents end-organ damage

**Procedure:**
- Be sure the person's airway is clear (check that nothing inside the person's mouth or throat is blocking the airway)
- Place one hand on the person's chin, tilt the head back and pinch the nose closed
- Place your mouth over the person's mouth to make a seal and give 2 slow breaths
- The person's chest should rise (but not the stomach)
- Follow up with one breath every 5 seconds

Two fingers under the chin and one hand on the forehead.

Tilt the head back gently and open the mouth.

Pinch the nose and create a seal with your mouth around the other person’s mouth.

Give the person 2 SMALL breaths first. Then, continue by giving one breath every 5 seconds.
Education: Administer Naloxone

VIDEOS

http://prescribetoprevent.org/patient-education/videos/
Intranasal Naloxone Patient Information Sheet

Common brand names: Narcan

Uses: This medication is used to treat an opioid overdose. Naloxone works by reversing the effects of opioids. Patients should be instructed to tell family/friends where naloxone is stored and how to administer it in case of an overdose.

Signs of an opioid overdose
Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

How to Use IN Naloxone
If you suspect someone is suffering from an opioid overdose:

Step 1. Call 911.

Step 2. Give naloxone.

Step 3. Give a second dose of naloxone in 2 to 3 minutes if there is no response to the first dose.

Step 4. Follow the 911 dispatcher’s instructions or perform rescue breathing if comfortable doing so.

Rescue Breathing
The key components of rescue breathing include the following:

Step 1. Make sure nothing is in the individual’s mouth.

Step 2. Tilt the head back, lift chin, and pinch nose shut.

Step 3. Give one slow breath every 5 seconds; chest should rise.

Side effects
Anxiety, sweating, nausea/vomiting, or shaking. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.

Intramuscular Naloxone Patient Information Sheet

Common brand names: Narcan

Uses: This medication is used to treat an opioid overdose. Naloxone works by reversing the effects of opioids.

Patients should be instructed to tell family/friends where naloxone is stored and how to administer it in case of an overdose.

Signs of an opioid overdose
Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

How to Use IM Naloxone
If you suspect someone is suffering from an opioid overdose,

Step 1. Call 911.
Step 2. Give naloxone.

1. Remove cap from naloxone vial and uncover the needle
2. Insert needle through rubber plug with vial upside down
   Pull back on plunger and take up 1 mL
3. Inject 1 mL of naloxone at a 90 degree angle into a large muscle (upper arm/thigh, outer buttocks)

Step 3. Give a second dose of naloxone in 2 to 3 minutes if there is no response to the first dose.
Step 4. Follow 911 dispatcher’s instructions or perform rescue breathing if comfortable doing so.

Rescue Breathing
The key components of rescue breathing include the following:

Step 1. Make sure nothing is in the individual’s mouth.
Step 2. Tilt the head back, lift chin, and pinch nose shut.
Step 3. Give one slow breath every 5 seconds; chest should rise.

Side Effects
Anxiety, sweating, nausea/vomiting, or shaking. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.
Education: Naloxone Storage Information

• Store naloxone in the original package at room temperature. Avoid light exposure.
• The shelf life of naloxone is generally 12 to 18 months. If stored properly, naloxone should be effective until at least the expiration date on the packaging.
• Do not insert naloxone into the prefilled syringe until ready to use. Once inserted it expires within 2 weeks.
• Monitor the expiration date on naloxone and replace before it expires. When there are no other alternatives, expired naloxone can be administered but may not be as effective.

Education: Stay Until Help Arrives

• Do not leave person alone after giving naloxone
• Continue rescue breathing (1 breath every 5 sec) until EMS arrives
• Repeat dose of naloxone after 3 – 5 min if person still unresponsive with slow or no breathing
• If must leave for any reason, place person in rescue position
Dos and Don’ts in Responding to Opioid Overdose

• DO support the person’s breathing by administering oxygen or performing rescue breathing

• DO administer naloxone

• DO put the person in the “recovery position” on the side, if he or she is breathing independently

• DO stay with the person and keep him/her warm
Dos and Don’ts in Responding to Opioid Overdose

• DON'T slap or try to forcefully stimulate the person — it will only cause further injury. If you are unable to wake the person by shouting, rubbing your knuckles on the sternum (center of the chest or rib cage), or light pinching, he or she may be unconscious.

• DON'T put the person into a cold bath or shower. This increases the risk of falling, drowning or going into shock.

• DON'T inject the person with any substance (salt water, milk, “speed,” heroin, etc.). The only safe and appropriate treatment is naloxone.

• DON'T try to make the person vomit drugs that he or she may have swallowed. Choking or inhaling vomit into the lungs can cause a fatal injury.
Dispensing and Documentation

• Must initiate Rx for naloxone and atomizers or kit just as would any other prescription

• Patient education is MANDATORY on all Rx for naloxone initiated via protocol and education must be documented in pharmacy management system

• Prescription records must be kept for 5 years as per usual record-keeping requirements
Dispensing Naloxone: Routes/Products

• **Intranasal**
  - Naloxone 2 mg/2 ml prefilled syringe, 2 syringes NDC No. 76329-3369-01
  - SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat ×1.
  - Atomizer No. 2; MAD 300
  - SIG: Use as directed for naloxone administration

• **Intramuscular**
  - Naloxone 0.4 mg/ml single dose vial, 2 vials NDC No. 00409-1215-01
  - SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat ×1.
  - Syringe 3 ml 25G ×1 inch No. 2
  - SIG: Use as directed for naloxone administration

• **Intramuscular Auto-injector**
  - Naloxone 0.4 mg/0.4 ml No. 1 twin pack
  - SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat ×1

Reimbursement

• Medicaid reimbursement variable
  • Is on formulary, but dummy claims came back as non-formulary
• Some third-party insurance companies are paying for naloxone injection, but not atomizer
• In NM, will pay for “kit” which includes both as well as RPh time in counseling
• The coalition is working on these issues in KY
## Comparative Costs

<table>
<thead>
<tr>
<th>Product</th>
<th>Average Wholesale Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naloxone HCL 0.4 mg/ml injection (1ml)</td>
<td>$18.71 per unit</td>
</tr>
<tr>
<td>Naloxone HCL 1 mg/ml injection (2ml)</td>
<td>$39.60 per unit</td>
</tr>
<tr>
<td>Naloxone solution Auto-injector 0.4 mg/0.4 ml (0.4 ml)</td>
<td>$345.00 per unit</td>
</tr>
<tr>
<td>Intranasal atomizer with syringe</td>
<td>$5.95 per unit</td>
</tr>
</tbody>
</table>

Lexicomp Online®, Lexi-Drugs®

# Does Insurance Cover It?

<table>
<thead>
<tr>
<th>Product</th>
<th>Humana Medicaid</th>
<th>Passport Medicaid</th>
<th>Humana Exchange</th>
<th>Wellcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naloxone HCL 0.4 mg/ml injection</td>
<td>+</td>
<td>-</td>
<td>Tier 2</td>
<td>-</td>
</tr>
<tr>
<td>Naloxone HCL 1 mg/ml injection</td>
<td>+</td>
<td>-</td>
<td>Tier 2</td>
<td>+</td>
</tr>
<tr>
<td>Naloxone solution Auto-injector</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>0.4 mg/0.4 ml</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Naloxone syringe</td>
<td>+</td>
<td>-</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
Legal/Liability Issues

• State law to support naloxone access falls under three categories:
  • Initiation of dispensing via protocol as discussed today
  • Good Samaritan
    • Protects individuals who call for help at the scene of an overdose from being arrested for drug possession
  • Liability protection/third party administration
    • Protects both the prescriber and the bystander who may be administering the naloxone
    • Allows bystanders to be prescribed naloxone for use on opioid overdose victims
Legal/Liability Issues

• When initiating dispensing of naloxone via protocol, must ensure that:
  • Protocol and certification are up to date
  • Criteria and procedures for dispensing outlined in protocol are followed
  • Documentation is complete
Questions?