Role of the Pharmacist: Naloxone Training

Kathleen Besinque, Pharm.D., MSEd., FASHP, FCPhA
Loma Linda University School of Pharmacy
Disclosure

• Kathleen Besinque
  • Nothing to disclose.
Objectives:

After attending the presentation participants will be able to:

1. Identify appropriate candidates to receive naloxone rescue products

2. Describe opioid overdose risk factors, prevention strategies, symptoms of an overdose, and overdose treatment with naloxone

3. Compare the different administration methods of naloxone

4. Counsel a person receiving naloxone regarding how and when to use the product.

5. Apply the California Board of Pharmacy protocol for furnishing naloxone
Pharmacists Roles

• Corresponding responsibility
• Pain Management (CDTM)
• Take Back programs
• Referral resource
• Education
• Naloxone furnishing
Pharmacists and Naloxone

• In 2013 the pharmacy practice act was amended to authorize pharmacists to furnish naloxone under a protocol to be developed by the Board of Pharmacy.

• The protocol requires pharmacists to:
  • Receive training (1 hour CE is required) Note CME is accepted by the CABOP
  • Screen potential recipients
  • Provide education to the “recipient”
  • Provide referral and drug treatment information
Utilizing Pharmacists to Increase Naloxone Access

Based on data collected by NASPA (updated February 2016)

**Broad** - Allow initiation of therapy, community pharmacists authorized to participate, no drug restrictions (may need to specify within the agreement), laws/regulations silent regarding the relationship between the prescriber and the patient.
• Naloxone is a life-saving medication.
• Naloxone is not a controlled substance and it should not be confiscated by law enforcement
• A.B. 1535: authorizes pharmacists to furnish naloxone
• A.B. 472, 635: Good Samaritan Laws
  - provide protection from civil and criminal liability for lay persons who respond to an overdose
  - provide limited protection from drug charges for people who call 911 re: an overdose
  - provide protection from civil and criminal liability for medical providers who establish standings orders to distribute naloxone
Welcome to the California State Board of Pharmacy

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist’s care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.

What's New

- Self-Administered Hormonal Contraception Protocol Information
- DEA National Prescription Drug Take-Back Day
- CDC Approves Final Opioid Guidelines
- Nicotine Replacement Therapy Protocol Information
- Naloxone Protocol Information
- Recall Notices
- Information for CURE2 (Updated 7/29/16)
Who are the appropriate recipients for naloxone?

- Persons who take opioids or associates of persons who take opioids are all potential recipients for naloxone.
- Pharmacists screening for patients and/or recipients
- Self-identification by patients

Patient vs recipient
Who is at risk for overdose?

- History of substance use, dependence or addiction
- Potential for accidental exposure
  - Children, other members of household
- Being alone while using opioids
- Dose of opioid
  - Taking MED >20mg/day
- Chronic renal or hepatic insufficiency

- Changes in Tolerance
  - short periods of reduced use or abstinence followed by resumed use
- Changes in Substance Used
  - unpredictable with illicit substances
  - change in prescribed opioid
- Sleep apnea
- Mixing medications
  - CNS depressants
  - alcohol
**Pharmacological Effects of Opioids**

- Depressed central nervous system
  - Sedation, drowsiness (“nodding”)
  - Slow/slurred speech
  - Euphoria, pain relief
- Respiratory depression
  - Shallow and/or infrequent breathing
  - Constricted breathing; choking sounds, gasping
- Dilated pupils
- Nausea/Vomiting
- Flushed skin; itching
Mechanics of an Opioid Overdose

Breathing Stops → Heart Stops → Brain Dies

Intervene with naloxone
Assessing for Overdose: ABC

1) Awake
   Can you wake the person up?
   Sternum Rub: rub knuckles on sternum/breastbone- HARD
   Trapezius Pinch: Pinch muscle that connects shoulder to neck

2) Breathing
   Is breathing normal?
   Are breaths more than 8-10 seconds apart?
   Do you hear choking or gurgling sounds?

3) Color
   Is color changing?
   Are face, lips, fingernails turning blue or purple?
Naloxone

Temporary opioid blocker that causes complete or partial reversal of respiratory and/or CNS depression.

- only impacts opioid receptors (mu, kappa, delta)
- does not eliminate opioids from brain/body
- overdose symptoms can return
- onset 2-5 minutes, peaks in 15-20 minutes, duration of action 20-90 minutes
Effects of Naloxone

- Temporary opioid blocker
  - takes effect in 2 to 5 minutes; lasts 20 to 90 minutes
  - cannot be abused
  - no dosage limit; more naloxone = more receptors blocked
  - no drug interactions beyond opioids

- Precipitated withdrawal
  - pain
  - nausea/vomiting
  - anxiety
Recipient Training: Overdose Prevention

• Encourage buddy system
  - Tell friends/family/caregivers where naloxone is kept and how to use it

• Educate on polysubstance use
  - Mixing sedatives makes overdose more likely
  - Mixing stimulants with sedatives does not reduce overdose risk

• Educate on tolerance changes
<table>
<thead>
<tr>
<th><strong>Recipient Training: Responding to an Overdose</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S</strong></td>
</tr>
<tr>
<td>Stimulation: assess for responsiveness with sternum rub or trapezius pinch</td>
</tr>
<tr>
<td><strong>C</strong></td>
</tr>
<tr>
<td>Call 911: follow dispatcher's instructions</td>
</tr>
<tr>
<td><strong>A</strong></td>
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<tr>
<td>Airway: Lay person flat and check mouth for food/objects</td>
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<tr>
<td><strong>R</strong></td>
</tr>
<tr>
<td>Rescue Breathing: tilt head back, pinch nose and breathe into mouth; give 2 breaths every 5 seconds</td>
</tr>
<tr>
<td><strong>E</strong></td>
</tr>
<tr>
<td>Evaluate for change</td>
</tr>
<tr>
<td><strong>M</strong></td>
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<tr>
<td>Medicine: administer naloxone; wait 2-3 minutes; continue rescue breathing</td>
</tr>
<tr>
<td><strong>E</strong></td>
</tr>
<tr>
<td>Evaluate for change; administer more naloxone if needed</td>
</tr>
</tbody>
</table>
Recipient Education: After an Overdose

- Overdose symptoms can return;
  - encourage person who overdosed to go to hospital
- Withdrawal symptoms cannot be treated with opioids after an overdose
- Recovery position
- Return for more naloxone if it gets used or lost
Opioid withdrawal symptoms

- Anxiety
- Sweating
- Irritability
- Flu-like symptoms
- “goose-bumps”
- Nausea, vomiting and/or diarrhea
- Rapid heart rate or hypertension
Requirements for furnishing naloxone

1. Conduct Screening (3 questions)
2. Provide training & consultation *(required)*
   a. Risk factors and prevention
   b. Assessing for overdose
   c. Responding to overdose emergency
   d. Naloxone consultation
   e. Legal protection
3. Naloxone is a bystander administered drug; instruct patients to tell a potential caregiver where naloxone is kept and how to use it
4. Patients can self-refer and request naloxone
Naloxone Information

- Naloxone News Release
- Naloxone Protocol
- Sample Naloxone Labels

Fact Sheets

- Naloxone Fact Sheet - English
- Naloxone Fact Sheet - Spanish
- Naloxone Fact Sheet - Traditional Chinese
- Naloxone Fact Sheet - Korean
- Naloxone Fact Sheet - Russian
- Naloxone Fact Sheet - Tagalog
- Naloxone Fact Sheet - Vietnamese

Screening Questions

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- Naloxone Screening Questions - Korean
- Naloxone Screening Questions - Russian
Documentation

- Medication label:
  
  http://pharmacy.ca.gov/licensees/naloxone_labels.shtml

- Notifications
  
  - If recipient is also the person at risk of overdose, they are considered the patient
  - Primary care provider will be notified if the patient gives consent
  - If primary care provider cannot be notified, refer the patient to a primary care provider and complete a written record of items furnished

- Document each product in medication record/profile
Furnishing Naloxone

1. Conduct Screening
2. Provide training & consultation (required)
3. Provide resources

Naloxone Fact Sheet:

Referrals for drug treatment:
SAMHSA’s National Helpline: 1-800-662-HELP (4357) 1-800-487-4889 (TDD)
Community Assessment Service Centers: (888) 742-7900
Screening questions for naloxone furnishing

1. Does the potential recipient currently use or has a history of using illicit or prescription opioids?
   If the recipient answers yes, the pharmacist may skip question 2

2. Is the potential recipient in contact with anyone who uses or has a history of using illicit or prescription opioids?
   If the recipient answers yes, the pharmacist may continue.

3. Does the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone.
   If the recipient answers yes, the pharmacist should not provide naloxone.
   If the recipient responds no, the pharmacist may continue.
Naloxone Consultation

• Advise on product choice
  - price
  - comfort with devices

• Dosing
  - depending on product
  - multiple doses may be needed to be effective

• Expiration dates

• Storage
  - protect from sunlight, extreme temperatures

• Adverse effects
  - risk of cardiovascular effects
  - overdose symptoms can return
  - withdrawal symptoms.

• Recipient cannot waive consultation
Naloxone Information

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What is an opioid overdose?

Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can’t handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone...
Tell someone where it is and how to use it.

Common opioids include:

<table>
<thead>
<tr>
<th>GENERIC</th>
<th>BRAND NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>Vicodin, Lortab, Norco, Zohydro</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Percocet, OxyContin, Percodan</td>
</tr>
<tr>
<td>Morphine</td>
<td>MSContin, Kadian, Embeda, Avinza</td>
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<tr>
<td>Codeine</td>
<td>Tylenol with Codeine, TyCo, Tylenol #3</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Duragesic</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Dilaudid</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>Opana</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Demerol</td>
</tr>
<tr>
<td>Methadone</td>
<td>Dolophine, Methadose</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Suboxone, Subutex, Zubsolv, Bunavail, Butrans</td>
</tr>
</tbody>
</table>

Opioid safety and how to use naloxone

For patient education, videos and additional materials, please visit www.prescribetoprevent.org
How to identify an opioid overdose:

Look for these common signs:
- The person won’t wake up even if you shake them or say their name
- Breathing slows or even stops
- Lips and fingernails turn blue or gray
- Skin gets pale, clammy

How to give naloxone:
There are 3 ways to give naloxone. Follow the instructions for the type you have.

Nasal spray naloxone
1. Take off yellow caps.
2. Screw on white cone.
3. Take purple cap off capsule of naloxone.
4. Gently screw capsule of naloxone into barrel of syringe.
5. Insert white cone into nostril; give a short, strong push on end of capsule to spray naloxone into nose: **ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.**
6. Push to spray.

Injectable 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 into an upper arm or thigh muscle.
4. If no reaction in 3 minutes, give second dose.

Auto-injector
The naloxone auto-injector is FDA approved for use by anyone in the community. It contains a speaker that provides instructions to inject naloxone into the outer thigh, through clothing if needed.

In case of overdose:

1. **Call 911 and give naloxone**
   If no reaction in 3 minutes, give second naloxone dose
2. **Do rescue breathing or chest compressions**
   Follow 911 dispatcher instructions
3. **After naloxone**
   Stay with person for at least 3 hours or until help arrives
Naloxone Formulations

• Naloxone formulations allowed:
  • Any FDA-approved formulation
  • May advise recipient on product selection
  • May recommend other items
    • Alcohol pads
    • Gloves
    • Rescue breathing masks

• May provide in advance (obvious)
• May refill orders
# Naloxone Formulations Compared

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>Other notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intramuscular (IM)</td>
<td>Fastest onset&lt;br&gt;May be least expensive</td>
<td>Potential exposure to blood&lt;br&gt;Requires user to have injection training</td>
<td>Lowest cost</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Intranasal</td>
<td>Onset fast (similar to IM)&lt;br&gt;Easy to administer&lt;br&gt;No blood exposure</td>
<td>May require assembly&lt;br&gt;May not work as well as IM (especially if nasal passages are clogged)&lt;br&gt;May need repeat doses</td>
<td>Intermediate cost</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Auto-injector device</td>
<td>Easy to use (voice directed instructions)&lt;br&gt;Trainers devices are available to train users</td>
<td>Expensive</td>
<td>Highest cost</td>
</tr>
</tbody>
</table>
Naloxone injection (kit)

Injectable Naloxone:
1. Remove orange cap from vial
2. Draw up all liquid (single dose vial)
3. Insert needle into skin at a 90° angle
4. Inject in muscle: upper arm or thigh
5. Push down on plunger slowly
Administration:
IM injection
Intranasal Naloxone

Amphastar® Luer Lock Prefilled Syringe: 2 mg per 2 mL single dose syringe or vial
1. Remove protective caps from vial and syringe
2. Insert vial into syringe
3. Affix nasal device
4. Spray ½ of solution into each nostril
Administration: nasal

1. Take off yellow caps.
2. Screw on white cone.
3. Take purple cap off capsule of naloxone.
4. Gently screw capsule of naloxone into barrel of syringe.
5. Insert white cone into nostril; give a short, strong push on end of capsule to spray naloxone into nose: ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.
6. Push to spray.

If no reaction in 3 minutes, give second dose.
Intranasal Naloxone

Adapt Pharma Narcan® Device:
4 mg per 1 mL single dose device
1. Place tip of device in either nostril until your fingers touch the bottom of the patient’s nose
2. Press plunger to release medication into nose
Administration: nasal

https://fpdl.vimeocdn.com/vimeo-prod-skyfire-std-us/01/238/6/151191919/463598027.mp4?token=579ffd9c_0x90a46edf2eb198b8d77d7c035b12eb279c891020&download=1&filename=NARCAN%C2%AE+Nasal+Spray+4mg+Instructions+for+Use.mp4
Naloxone Auto-injector

EVIZIO® Naloxone Auto-injector:
1. Remove from outer case
2. Pull out red safety tab
3. Press black end firmly into thigh muscle & hold down for 5 seconds
4. OK to inject through clothing
Administration: Auto-injector

A Trainer is Included for Practice

Each EVZIO prescription comes with a black-and-white Trainer that can be used for practice. Unlike EVZIO, the Trainer:

- Does not have a needle
- Does not have an expiration date
- Does not contain medicine or any liquid
- Can be reused (more than 1000 times)

To be prepared in an opioid overdose emergency, patients, family members, caregivers, and other individuals who may have to administer EVZIO should practice using the Trainer to become familiar with the injection process. After practicing with the Trainer, the electronic voice system should be reset by:

- Replacing the red safety guard
- Sliding the Trainer all the way back into the outer case

The Trainer should be left in its outer case for at least 5 seconds between each practice interval to allow the electronic voice system to read properly. For more information on the Trainer, view the Trainer Information.

How to Use EVZIO

Visual and voice instructions help guide the way

EVZIO is designed to be easy to use for patients, their family members, and other caregivers who do not have medical training. It contains the Intelligent Prompt System (IPS™) with visual and voice instructions that help guide the user through the injection process.

Administration steps

1. Pull EVZIO from the outer case.

Do not go to Step 2 (do not remove the red safety guard) until you are ready to use EVZIO. If you are not ready to use EVZIO, put it back in the outer case for later use.

2. Pull off the red safety guard.

To reduce the chance of an accidental injection, do not touch the black base of the auto injector, which is where the needle comes out. If an accidental injection happens, get medical help right away.

Note: The red safety guard is made to fit tightly. Pull firmly to remove.

Do not replace the red safety guard after it is removed.

3. Place the black end against the middle of the patient’s outer thigh, through clothing (shorts, jeans, etc.) if necessary, then press firmly and hold in place for 5 seconds.

If you give EVZIO to an infant less than 1 year old, pinch the middle of the outer thigh before you give EVZIO and continue to pinch while you give EVZIO.

Note: EVZIO makes a distinct sound (click and hiss) when it is pressed against the thigh. This is normal and means that EVZIO is working correctly. Keep EVZIO firmly pressed on the thigh for 5 seconds after you hear the click and hiss sound. The needle will inject and then retract back up into the EVZIO auto-injector and is not visible after use.

4. After using EVZIO, the user should immediately seek emergency medical attention whether or not they think the injection worked.
Referral information

http://www.dhcs.ca.gov/provgovpart/Pages/SUD-Directories.aspx
Additional resources/sources

• California Board of Pharmacy
• College of Psychiatric and Neurologic Pharmacists
• Managing Pain Safely (MPS): Pharmacy Toolkit
• Homeless Health Care Los Angeles Overdose Prevention and Response Training
Prescription Drug Abuse is one of the fastest growing public health concerns in the U.S.

The United States is in the midst of an epidemic of prescription drug abuse fueled by unsafe prescribing practices, lack of addiction treatment options, and limited safe drug disposal options, among other important contributing factors.

Given that the causes of prescription drug abuse are multifaceted, the solution to this problem will require a comprehensive and coordinated approach.
Safe Prescribing Pharmacy Practice Action Team

Priority Area I: Education and Training

**KEY OBJECTIVE 2:**
EDUCATE AND TRAIN HEALTH CARE PROFESSIONALS, INCLUDING PHYSICIANS AND PHARMACISTS, ON BEST PRACTICE GUIDELINES FOR SAFE PRESCRIBING AND IDENTIFYING PRESCRIPTION DRUG MISUSE THROUGH SCREENINGS

In addition to educating the community, education and training for health care professionals is also critical given their pivotal role in limiting prescription drug abuse by following safe prescribing practices and better recognizing misuse and addiction.

The Safe Prescribing Pharmacy Practice Action Team and the Safe Prescribing Medical Practice Action Team will:

- Engage key providers and organizations in order to expand the adoption of safe prescribing practices for controlled medications, such as limiting
# Formulary Naloxone Products

<table>
<thead>
<tr>
<th>Health Plan</th>
<th>Line of Business (LOB)</th>
<th>Covered Products</th>
<th>Limits/Comments*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actra</td>
<td>Commercial</td>
<td>Naloxone nasal spray</td>
<td>N/A</td>
</tr>
<tr>
<td>Aetna</td>
<td>Medicare</td>
<td>Naloxone auto-injector, nasal spray, and nasal sprays</td>
<td>N/A</td>
</tr>
<tr>
<td>Anthem Blue Cross</td>
<td>Commercial</td>
<td>Naloxone vials and syringes, Naxos nasal spray</td>
<td>Not preferred, requires step therapy with preferred agents. Quantity limit of 6 sprays/vials per 3 months, 6 nasal sprays (3 cartons) per 3 months or 6 auto injectors per 3 months.</td>
</tr>
<tr>
<td>Anthem Blue Cross</td>
<td>Medicare</td>
<td>Naloxone vials and syringes, Naxos nasal spray</td>
<td>N/A</td>
</tr>
<tr>
<td>Blue Shield of California</td>
<td>Commercial</td>
<td>Naloxone nasal spray, vials and syringes</td>
<td>Quantity limit of 2 vials or sprays per month; for nasal spray quantity limit of 2 doses/month.</td>
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<tr>
<td>Blue Shield of California</td>
<td>Medicare</td>
<td>Naloxone solution and syringes</td>
<td>Quantity limit of 2 mi. per month for the solution.</td>
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<tr>
<td>Care1st</td>
<td>Medicare</td>
<td>Naloxone nasal spray</td>
<td>Quantity limit of 2 mi. per day.</td>
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<tr>
<td>CofinMutual</td>
<td>Medicare</td>
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<td>Canceled for Medi-Cal members.</td>
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<tr>
<td>Contra Costa Health Plan</td>
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<tbody>
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<td>Naloxone nasal spray</td>
<td>Curved out to fee for service.</td>
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<td>Naloxone sprays and boli</td>
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*Prior authorization may be required, check individual benefit plans.

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Disclaimer: Verification of individual plans and benefits may be required for formulary status. This information reflects formulary status as of March 2017 based on information available at the health plan websites.
Resources
Summary

• There are multiple roles for the pharmacist in the arena of pain management and opioid use.

• Collaborative practice enhances patient safety.