Overcoming Barriers to Improve Access to Naloxone in the Community Pharmacy Setting

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The speakers in this presentation report no actual or potential conflicts of interest associated with this presentation.
Objectives

1. To describe the symptoms and prevalence of opioid use disorder and opioid overdose
2. To identify patients at risk for opioid overdose in a systematic manner in order to recommend naloxone where indicated
3. To effectively communicate treatment strategies for opioid use disorder and overdose with patients and caregivers
4. To discuss how to improve access to naloxone in the community setting by overcoming challenges related to:
   – State specific logistical implementation
   – Third party reimbursement
   – Public awareness and acceptance
Introduction
Opioid Use Disorder (OUD)

- Terminology
- DSM-V criteria
- Symptoms of opioid use disorder
Scope of the Problem
Symptoms of Opioid Overdose

Opioid Overdose Triad

<table>
<thead>
<tr>
<th>Symptom</th>
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<tbody>
<tr>
<td>Central nervous system (CNS)</td>
</tr>
<tr>
<td>Depression</td>
</tr>
<tr>
<td>Respiratory depression</td>
</tr>
<tr>
<td>Pupillary miosis</td>
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</tbody>
</table>

Patient Counseling

<table>
<thead>
<tr>
<th>Symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue lips and/or nails</td>
</tr>
<tr>
<td>Slow/shallow/erratic breathing</td>
</tr>
<tr>
<td>Lack of responsiveness</td>
</tr>
<tr>
<td>Gurgling/choking sounds</td>
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<tr>
<td>Limpness</td>
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</table>

If someone is making unusual sounds when “sleeping” try to wake them up!
Risk Factors for Opioid Overdose

- Combinations with benzodiazepines, alcohol and/or other sedatives
- Alternate routes of administration
- MME $\geq 50$mg per day
- Recent relapse after period of abstinence
- Long-acting formulations
- Using alone (increased risk from overdose)
- History of substance use disorder
Identifying Patients at Risk

- Prescription Drug Monitoring Programs
- Co-prescriptions and Chronic Disease States
- Screening Tools
Naloxone Counseling

• How to identify an overdose
• Call 9-1-1
• Rescue breathing
• How to administer naloxone (either IM or IN)
• What to do and expect after naloxone administration (withdrawal, rescue position)
Symptoms of Opioid Withdrawal

- Unlike alcohol withdrawal, opioid withdrawal is not potentially fatal
- Patients going through withdrawal often feel anxiety, insomnia and low energy that may last several weeks to months
- Supportive care
- Detoxification versus rehabilitation
Active Learning

The risk of opioid overdose is highest in which of the following patient populations?

a) African American men
b) Hispanic women
c) White non-Hispanic men
d) Asian women
Active Learning

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c) **White non-Hispanic men**
d) Asian women
Barriers to OUD Treatment and Overdose Prevention

- Time
- Education
- Resources
- Access
- Awareness
- Confidence
- Biases
- Compensation
Myths Regarding OUD

- Use is voluntary
- People need to hit “rock bottom”
- Lack of willpower or character flaw
- Treatment is not effective
- Relapse indicates failure
Stereotypes and Biases

<table>
<thead>
<tr>
<th>Assumptions about opioid users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race/Ethnicity</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Socioeconomic Status</td>
</tr>
<tr>
<td>Age</td>
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<tr>
<td>Education</td>
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</tbody>
</table>

Beliefs that naloxone only prolongs time to next overdose
Which of the following factors can increase the stigmatization of patients with an opioid use disorder?

a) Using derogatory language such as “junkie,” “addict,” or “abuser” to describe patients

b) Using the Prescription Drug Monitoring Program to identify patients with potential opioid dependence or opioid use disorder

c) Strongly advising patients who have developed an opioid use disorder to quit and explaining the risks of continued use

d) Advising all patients on the risks of long-acting opioids
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c) Strongly advising patients who have developed an opioid use disorder to quit and explaining the risks of continued use

d) Advising all patients on the risks of long-acting opioids
Treatment and Recovery

- Recognize risk factors for OUD and overdose
- Recommend recovery options
- Methadone, naltrexone and buprenorphine
- Cognitive behavioral therapy
- SBIRT
Approach to the Patient with OUD

- Have a universal approach
- Language matters!
- Adopt principles of motivational interviewing
- Assess patients readiness to change
- Use analogies “fire extinguisher”
- Involve family and caregivers
- Provide supportive materials
- Understand cycle of misuse and recovery
Opportunities for Pharmacists

- Screening Tools for OUD
- PDMP
- Drug Take-Back Programs
- Needle Exchange
- Lock Boxes
- Involvement with Medication Assisted Therapy
- Recommend Naloxone
- Create a Supportive Environment
Resources

Centers for Disease Control and Prevention: http://www.cdc.gov/drugoverdose/index.html


Substance Abuse and Mental Health Services Administration: http://www.samhsa.gov/medication-assisted-treatment/treatment/opioid-overdose

National Institute on Drug Abuse: https://www.drugabuse.gov/drugs-abuse/opioids
Overcoming Challenges to Implement a Naloxone Program
Barriers to Implementation

- State Regulations
- Pharmacist and Patient Training and Education
- Reporting Requirements
- Types of Products Available
- Patient Identification
- Third Party Reimbursement
State Regulations

- State laws and regulations vary and can impact implementation of a national naloxone program
- State Departments of Health, Boards of Pharmacy and other governing bodies may provide guidance on how to implement the program
- Pharmacist’s Authority to Dispense Naloxone:
  - Standing Order/ Collaborative Practice Agreement
  - Prescriptive Authority
  - Prescription Only
- Training requirements vary by state
- Types of naloxone products
- Good Samaritan Laws
States that have made Naloxone available without a prescription at pharmacies

States that have limitations or have not passed Naloxone regulations
## Standing Order (Protocol) vs Prescriptive Authority

<table>
<thead>
<tr>
<th>Standing Order, Collaborative Practice Agreement (CPA), or Statewide Order</th>
<th>Prescriptive Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requires a prescriber to sign a protocol</td>
<td>Pharmacist is allowed to dispense the medication under independent authority without a prescriber’s order</td>
</tr>
<tr>
<td>A patient can receive naloxone from a pharmacy without ever seeing the prescriber</td>
<td>Pharmacist is the prescriber and uses own NPI to dispense the prescription</td>
</tr>
<tr>
<td>A statewide order can be beneficial if a prescriber is unwilling to sign a Standing Order or CPA</td>
<td>Circumvents difficulty in finding a supportive prescriber to sign a naloxone protocol</td>
</tr>
<tr>
<td>Duration of protocol can vary depending on state or prescriber requirements</td>
<td>Increases patient’s access to Naloxone</td>
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Training and other challenges

- States may require specific training for the pharmacists to be qualified to dispense or issue naloxone
- Specific training may be designated by the state
  - CA, CT, IL, KY, NV require CE
  - MA, NY and OH require approved training
- Some states restrict which naloxone products may be dispensed under Standing Orders or CPAs
- State regulations may protect pharmacists/prescribers from liability
- Good Samaritan laws protect persons administering naloxone to a patient
- Renewal interval of Standing Orders or CPAs with prescriber may vary
  - Yearly, have expiration date, or “evergreen”
Patient Education Requirements

- States have requirements to educate patients on when and how to use naloxone products
- Usually handled in the counseling portion of the fulfillment process
- Education can include both verbal and written training materials

### Naloxone Administration

1. **Naloxone Nasal Spray**
   1. Remove the nasal spray from the box. Peel back the tab with the thumb to open the nasal spray. 
   2. Hold the spray with your thumb on the bottom of the plunger and your index and middle fingers on either side of the nozzle.
   3. Gently insert the tip of the nozzle into either nostril. Tilt the person’s head back and provide support under the mask with your hand. Gently insert the tip of the nozzle into one nostril, until your fingers on either side of the nozzle are against the bottom of the person’s nose.
   4. Press the plunger firmly to give the dose of Naloxone nasal spray. Remove the plastic nasal spray from the nostril after giving the dose.

2. **Naloxone Inj**
   1. Remove the needle and needle guard. 
   2. Insert the needle into the upper arm or upper thigh muscle. 
   3. Press the plunger firmly to give the dose of Naloxone injection. Remove the Syringe from the needle after giving the dose.

### Signs of Withdrawal

- **Opioid Withdrawal**
  - Shaking and goose bumps
  - Diaphoresis
  - Stiff neck
  - Difficulty breathing
  - Irregular heart rate
  - Stomach cramps
  - Pounding pulse
  - Cold and clammy skin
  - Sweet or salty taste in mouth
  - Nausea or vomiting

### Resources

- **Importance of Resources**
  - Naloxone should be stored at room temperature and protected from light.

### References

1. Massachusetts Department of Public Health, Opioid Oversed Education and Naloxone Distribution.
State Departments of Health, Boards of Medicine, Boards of Pharmacy and collaborating physicians all require different information to be reported at varying intervals making compliance challenging.

- Number of units by dosage form
- New protocol requests or approvals
- De-identified patient information
- Dispensing store and/or pharmacist information
- Quarterly or Annually
- Prescription types (new or refill)
Naloxone Products Available

- Nasal (intranasal – IN)
- Autoinjector (intramuscular – IM)
- Injectable (IM or subcutaneous – SC)
Patient Identification

- We consider the person requesting naloxone to be the patient
- Ultimate recipient is anonymous to the pharmacy
- If a patient asks for naloxone, we dispense it
- There are no limitations to the number of units dispensed
- We do not monitor frequency of usage
Third Party Reimbursement

- Must be processed as a prescription
  - Billed for a specific patient
  - Billed under a specific NPI (Prescriber or Pharmacist)
- Most insurances, including Medicaid, cover one of the formulations available
- Medicaid / Government programs require specific patient information for billing
- Certain state practice acts allow prescriptions to be processed under lay person asking for the medication
- Some states may require the prescription to be processed under patient only. i.e.; Montana
Public Awareness

• Work with your State Health Department and other local organizations such as drug rehabilitation centers, pain management clinics, and hospitals to educate patients and help raise awareness.

• The National Institute on Drug Abuse (NIDA) has created a section on their website dedicated to resources about opioid overdose reversal and naloxone.
  – The NIDA page also includes links to pharmacies that offer naloxone.

• Naloxone is becoming more widely available.
  – Frequency of police and first responders carrying.
  – Availability at the pharmacies has increased.
Public Awareness
Value of a Pharmacist

As the practice of pharmacy continues to evolve, pharmacists will have a greater role in making potentially life saving medications such as naloxone more readily available to the public.