Pharmacy’s Role in Expanding Access to Naloxone in the Community

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Target Audience: Pharmacists
ACPE#: 0202-0000-18-046-L01-P
Activity Type: Application-based
Disclosures

Drs. Jacobson and Melton DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Learning Objectives

1. Describe validated tools and practice-based methods to assess the risk for opioid-induced respiratory depression.
2. Identify models for overdose education and naloxone distribution that are applicable to various practice settings.
3. Describe strategies to overcome some of the barriers to implementing overdose education and naloxone distribution.
5. Explain evolving state laws regarding options for pharmacists to prescribe or dispense naloxone under collaborative practice agreements, protocols or standing orders.
1. Assessment Question

Which of the following is a validated tool to evaluate risk of opioid overdose?

A. Opioid Risk Tool (ORT)
B. Drug Abuse Screening Test (DAST)
C. The Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)
D. Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIO SORD)
2. Assessment Question

The Commissioner of Health of your state declares a public health emergency related to the opioid overdose death rate. The Commissioner issues a directive that can be carried out by other health care workers when predetermined conditions have been met. What type of naloxone distribution model is described?

A. Protocol order
B. Standing order
C. Collaborative practice
D. Prescription distribution mandate
3. Assessment Question

Which of the following is a solution to workflow barriers in distribution of naloxone models?

A. Providing kits free of charge to laypersons
B. Integrating order sets into electronic medical records
C. Provision of comprehensive contact-based education programs
D. Acquiring naloxone products through patient assistance programs
4. Assessment Question

Which of the following is a key point of education about opioid overdose rescue with naloxone?

A. Naloxone takes approximately 5 minutes to reverse an overdose
B. To expedite naloxone rescue, ice packs should be placed under the victim’s arms
C. Rescue breaths and chest compressions should be performed before administration of naloxone
D. A person can return into an overdose situation after naloxone wears off after 30-45 minutes
5. Assessment Question

You need to determine if your state has provision of a standing order, protocol, or allows a collaborative practice agreement. Which of the following resources provides an interactive search method to answer your question?

A. National Institute on Drug Abuse
B. Prescription Drug Abuse Policy System
C. Prescription Drug Monitoring Program
D. Center for Disease Control and Prevention
Introduction and Overview
Scope of the Problem
From Prescription Opioids to Heroin
Symptoms of Opioid Use Disorder

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2801056/
https://www.samhsa.gov/disorders/substance-use
Data on Opioid Overdoses
Recognizing an Opioid Overdose
Symptoms of Opioid Overdose

- Pupillary Miosis
- Respiratory Depression
- Central Nervous System (CNS) Depression
- Depression

Source: http://www.who.int/substance_abuse/information-sheet/en/
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
Describe validated tools and practice-based methods to assess the risk for opioid-induced respiratory depression.
Practice-based Methods for Assessing Risk

- Obtain a history of the patient’s past use of drugs (either illicit drugs or prescribed medications with abuse potential)
  - “In the past 6 months, have you taken any medications to help you calm down, keep from getting nervous or upset, raise your spirits, make you feel better, and the like?”
  - “Have you been taking any medications to help you sleep? Have you been using alcohol for this purpose?”
  - “Have you ever taken a medication to help you with a drug or alcohol problem?”
  - “Have you ever taken a medication for a nervous stomach?”
  - “Have you taken a medication to give you more energy or to cut down your appetite?”

- The patient history also should include questions about use of alcohol and over-the-counter (OTC) preparations.

- Positive answers to any of these questions warrant further investigation.

Overdose Risk and Patient History

- Review medications
- Take a substance use history
- Check the prescription monitoring program
- Take an overdose history – *Ask your patient whether they have:*
  - Overdosed or had a bad reaction to taking opioid medications?
  - Witnessed an overdose?
  - Received training to prevent, recognize, or respond to an overdose or medication-related oversedation?

http://prescribetoprevent.org/prescribers/palliative/
The Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD)

- Estimates the likelihood of life-threatening respiratory depression or overdose among medical users of prescription opioids
- First validated in US veterans and then the general population
- Assessment in general population was a case-control analysis in a cohort of 18 million patients using prescription claims data
  - Authors identified 7234 cases of overdose or serious opioid-induced respiratory depression (OSORD) and compared them with 28,932 controls
  - Common risk factors associated with OSORD were assigned a score for each risk factor using multivariable logistic regression modeling
- This newer RIOSORD tool for the general population is a 16-question survey and has a total maximum score of 146 points

Case Study: Calculate the RIOSORD Score

- A 45-year-old patient presents to the pharmacy with a prescription for oxycodone ER 80 mg every 12 hours with 10 mg oxycodone IR every 6 hours for breakthrough pain for chronic hip disorder (200 morphine milligram equivalents/day – has been on this dose for past 8 months)

- 40-pack-year history of smoking

- MEDS: paroxetine 10 mg at bedtime, alprazolam 1 mg twice daily as needed for anxiety, and tiotropium 18 mcg handihaler once daily

- PMH: chronic obstructive pulmonary disease (COPD), depression, anxiety

- 3 Emergency Department visits in past year for hip pain, kidney stones, and pneumonia
<table>
<thead>
<tr>
<th>Risk Factor (Yes/No?)</th>
<th>RIOSORD Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the patient have any of the following conditions?</td>
<td></td>
</tr>
<tr>
<td>Opioid Dependence</td>
<td>15</td>
</tr>
<tr>
<td>Chronic hepatitis or cirrhosis</td>
<td>9</td>
</tr>
<tr>
<td>Bipolar or schizophrenia</td>
<td>7</td>
</tr>
<tr>
<td>Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis)</td>
<td>5</td>
</tr>
<tr>
<td>Chronic kidney disease with clinically significant renal impairment</td>
<td>5</td>
</tr>
<tr>
<td>An active traumatic injury, excluding burns (e.g., fracture, dislocation, contusion, laceration, wound)</td>
<td>4</td>
</tr>
<tr>
<td>Sleep apnea</td>
<td>3</td>
</tr>
<tr>
<td>Does the patient consume the following medications?</td>
<td></td>
</tr>
<tr>
<td>An extended-release or long acting (ER/LA) formulations of any prescription opioid or opioid with long and/or variable half-life (e.g., OxyContin, Oramorph-SR, methadone, fentanyl patch)</td>
<td>9</td>
</tr>
<tr>
<td>Methadone</td>
<td>9</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>3</td>
</tr>
<tr>
<td>A prescription anti-depressant</td>
<td>4</td>
</tr>
<tr>
<td>A prescription benzodiazepine</td>
<td>7</td>
</tr>
</tbody>
</table>

| What is the patient’s current maximum prescribed opioid dose (Oral Morphine Equiv.) |               |
| ≥ 100 mg                                                                             | 16            |
| 50 – 99 mg                                                                           | 9             |
| 20-49 mg                                                                             | 5             |

| In the past 6 months, has the patient:                                               |               |
| Had one or more emergency department visits                                          | 11            |
| Been hospitalized for one or more days                                               | 8             |
Evaluate the Score

<table>
<thead>
<tr>
<th>Risk index score</th>
<th>OIRD probability (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-24</td>
<td>3</td>
</tr>
<tr>
<td>25-32</td>
<td>14</td>
</tr>
<tr>
<td>33-37</td>
<td>23</td>
</tr>
<tr>
<td>38-42</td>
<td>37</td>
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<tr>
<td>43-46</td>
<td>51</td>
</tr>
<tr>
<td>47-49</td>
<td>55</td>
</tr>
<tr>
<td>50-54</td>
<td>60</td>
</tr>
<tr>
<td>55-59</td>
<td>79</td>
</tr>
<tr>
<td>60-66</td>
<td>75</td>
</tr>
<tr>
<td>≥67</td>
<td>86</td>
</tr>
</tbody>
</table>

Interventions in Case of Elevated Risk

- Education of the patient and caregivers
- Increased caution in opioid selection and dose escalation
- Consultation with pain management specialists
- Close monitoring for the emergence of OSORD or known risk factors for it
- **Prescription of naloxone** for administration by family members or caregivers as a rescue medication in the event of a suspected opioid emergency such as overdose
Identify models for overdose education and naloxone distribution that are applicable to various practice settings.
Pharmacy Naloxone Models

Patient or Other Authorized Recipient Sees Provider

<table>
<thead>
<tr>
<th>Pharmacist</th>
<th>Prescriber</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trained in overdose prevention</td>
<td>(MD, DO, NP, PA)</td>
</tr>
</tbody>
</table>

Screening for Risk Factors (prescription or medical history, protocol criteria, physical exam)

<table>
<thead>
<tr>
<th>Provides Nlx Via Collaborative Practice Agreement w/ Prescriber (e.g., WA, RI)</th>
<th>Provides Nlx Via Standing Order Issued by Prescriber (e.g., VA, GA)</th>
<th>Provides Nlx Via Protocol Order (e.g., CA, NV)</th>
<th>Prescribes Nlx (e.g., NM, ID)</th>
<th>Prescribes Nlx (all states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient/Other Authorized Recipient Consents to CPA</td>
<td></td>
<td></td>
<td></td>
<td>Rx filled by Pharmacist</td>
</tr>
</tbody>
</table>

Product Selection and Dispensing

Billing, Overdose Patient Education and Medication Counseling

Documentation of Medication Receipt Per Protocol, Agreement, Law


Nlx= naloxone
CPA=Collaborative Practice Agreement
WA= Washington
RI= Rhode Island
VA= Virginia
CA= California
NV= Nevada
NM= New Mexico
ID= Idaho
Health Systems

- Recommend appropriate use of opioids inpatient and at discharge
  - Assessment and monitoring
    - Prescription drug monitoring programs
- Institute and uphold diversion deterrent policies and procedures
- Educate staff and patients about non-opioid treatments for pain
- When opioids are prescribed, encourage co-prescribing of naloxone and perform bedside education with patients and family members

Describe strategies to overcome some of the barriers to implementing overdose education and naloxone distribution
Stereotypes and Stigma

Assumptions about opioid users

- Race/Ethnicity
- Gender
- Education
- Age
- Socio-economic Status

JUNKIE. ABUSER. ADDICT. HABIT. OXY BABY. GET CLEAN.

“Newborn babies are not born “addicted”... Portraying babies with neonatal abstinence syndrome as “victims” results in the vilification of their mothers, who are then viewed as perpetrators, and further perpetuates the criminalization of addiction.”

International Drug Policy Consortium 2013

- Beliefs that naloxone only prolongs time to next overdose
Responses to Myths

- Chemical and physical changes in the brain occur with use in susceptible individuals.
- People seek treatment for a variety of reasons, including self-motivation and a desire to protect family and career.
- Genetic and environmental components account for more than half of a person’s inherent risk of substance use disorder.
Responses to Myths

- The majority of people who quit using drugs successfully received assistance through treatment programs.

- Myths may prevent individuals from staying in treatment with methadone or buprenorphine long-term (including pressure from family and relatives to discontinue treatment)

- Substance use disorder is a chronic condition and successful cessation of use frequently requires multiple attempts.
Barriers to OUD Treatment and Overdose Prevention

<table>
<thead>
<tr>
<th>Time</th>
<th>Resources</th>
<th>Education</th>
<th>Access</th>
<th>Awareness</th>
<th>Confidence</th>
<th>Biases</th>
<th>Compensation</th>
</tr>
</thead>
</table>

![Image of a person tightrope walking over rocky terrain]
Identifying Barriers and Finding Solutions

Barriers

- Out of pocket cost of naloxone
- Stigma
- Liability concern
- Work flow and logistical issues

Solutions

- Federal and state grants, patient assistance program
- Social media campaigns, education of prescribers and law enforcement; contact-based education
- Good Samaritan protection and education about provisions
- Invested team members develop protocols that integrate in work flow and staff and personnel are trained
  - Integration in electronic medical record
  - Site champions

Myths Regarding Medication-Assisted Therapy (MAT) with Methadone or Buprenorphine

- MAT is substituting one addiction for another
- Methadone or buprenorphine are more dangerous than heroin
- Use of MAT will result in lifelong dependence
- MAT prevents functioning in society (job, driving, etc.)

https://www.crchealth.com/find-a-treatment-center/opiate-addiction-treatment-centers/additional-resources/debunking-myths-methadone-clinics/
Responses to Myths

- Addiction is a chronic condition (like diabetes). A person who is taking methadone is no more an “addict” than is a person whose diabetes is kept under control with insulin.

- All medications, including buprenorphine and methadone, can be dangerous when used improperly.

- Unlike heroin, methadone and buprenorphine are legal medications produced by licensed and approved pharmaceutical companies using quality control standards.
Responses to Myths

- As patients progress in recovery, they may opt to remain on methadone or buprenorphine for an extended period, or they may decide to be weaned under supervision.

- Patients may need to be on MAT for at least as long as they were using opioids recreationally or for maintenance.

- While taking MAT, patients are able to sort out the other aspects of their life (work, relationships, finances, legal matters and the rest) without suffering from withdrawal sickness or drug cravings and will not disqualify patients from driving a car or getting a job.
Summarize and demonstrate essential patient/caregiver overdose education elements for community and health care settings.
Offer Naloxone to Everyone

- Combination of opioid with benzodiazepines
- Methadone, buprenorphine
- Syringe purchasers
- Family and friends of those at risk
- High risk groups based on conditions, other medications and patient-related factors

ANY OPIOID PRESCRIPTION
Naloxone Basics

- Takes effect in 2-3 minutes
  - If patient is not responding in this time, a second dose may need be administered

- Wears off in 30-90 minutes
  - Patients can go back into overdose if long acting opioids were taken (fentanyl patch, methadone, extended release morphine, extended release oxycodone)
  - Patients should avoid taking more opioids after naloxone administration so they do not go back into overdose after naloxone wears off
  - Patients may want to take more opioids during this time because they may feel withdrawal symptoms

- Shelf-life is 12-24 months
  - Store at room temperature to minimize degradation
How to Respond in an Overdose

Steps to teach patients, family, friends, caregivers

1. Recognize overdose
2. Call/text 911 for help
3. Administer naloxone as soon as it is available
4. Rescue breaths/chest compressions per rescuer’s level of training
5. Stay until help arrives

- Multi-step nasal spray
- Intramuscular injection
- Auto-injector (EVZIO®)
- Single-step nasal spray (NARCAN®)

Stay until help arrives
Place in recovery position if breathing
Use of Motivational Interviewing for Opioid Use Disorder

RAPPORT

- People have to believe that you have heard their concerns or “side of the story” and that you validated them.
- Patients need to feel that they are being respected and cared for as an individual person with unique circumstances/beliefs/values/needs.
- Patients need to believe that you are willing to work with them to solve the problem and they are in charge.

**Key point:** patients/caregivers need to trust you, both your compassion and your skills as a healthcare professional.
Use of Motivational Interviewing for Opioid Use Disorder

**IMPORTANCE**

- People need to make sense of what is happening with their condition/risk, or why they need to make the change we are recommending

- If the information you provide does not make sense to the patient/caregiver in a way that they can connect to and believe, they will reject the information and not implement the recommendation

**Key point:** all human beings are sense-makers, we need to address how they make sense of health and wellness
Use of Motivational Interviewing for Opioid Use Disorder

CONFIDENCE

- People need to believe that they can make the change or implement the plan and be successful
- Patients/caregivers need to know exactly what to do if they have an adverse reaction with a medication
- Substance use disorders are frequently associated with relapse which can erode both the confidence of patients themselves and their family/loved ones
- Patients/caregivers need to make informed decisions about their health and wellness

**Key point:** we need to give patients real, actionable, and accurate information to be successful
Common Mistakes

- Discrediting inaccurate information or myths that a person believes, without first validating that you heard the information, and assuring the patient it is not “wrong” or “crazy” or “stupid”
  - Example: belief that naloxone is only for people who overdose on heroin (stigma)

- Not explaining in enough detail for people to really understand their condition/risk
  - Example: “I take my medications as prescribed, why would I be at risk for an overdose?”

- “Sugarcoating” or not stating the potential risk of overdose/other risks
  - Example: combination benzodiazepine + opioid is not “a little risky...”
Key Skills of MI

- First, discover and validate concerns or beliefs to avoid face loss; listen and avoid arguing with patient/caregiver
  - “I hear that from a lot of people”
  - “That is a common concern that people have about _____”
  - “It sounds like you have done a lot of research on ____”
  - “It seems that you are concerned about ______”
  - “It sounds like you had a bad experience with ______”

- Ask permission before giving information
  - “Would it be OK if I gave you some information about ______________?”
  - “Would it be OK if I talk to you about your ______?”

- Refer to overdose as a “breathing emergency” when someone is resistant to messages of their personal risk of overdose
Key Skills of MI

- Give the person accurate, specific, personalized information that makes sense to them, allow them to make “informed consent”
  - “Your ______ (medications/alcohol use/conditions/other factors) significantly increase your risk of a breathing emergency”

- Use analogies that are visceral and understandable
  - “Naloxone as a “fire extinguisher”, it does not cause you to start a fire, but is there if the fire starts accidentally”
Key Skills of MI

- Ask the patient/caregiver to help come up with solutions
  - “It sounds like you aren’t ready to seek a formal treatment and recovery program right now, and that is OK. Which of the things we talked about would you feel comfortable doing to decrease your risk of a fatal breathing emergency?”

- Get a conditional commitment
  - “It sounds like if we could find a formulation of naloxone that can be given as a nasal spray and is covered by your insurance you would be willing to have it in home just in case, can we go ahead and get that ready for you?”
Key Skills of MI

- Acknowledge that the patient is in “the drivers seat”, empower them to make change/monitor symptoms/make decisions
  - “We hope that by taking your medications as prescribed and avoiding alcohol you won’t experience a breathing emergency, but having naloxone available can save your life just in case.”

- Give a menu of options if possible

- Include effects on others where relevant
  - Include risk of breathing emergency to others visiting in the home (children/teens)
  - Always best to act if someone is not responsive- don’t just let them “sleep it off”

- Summarize and plan next steps
Example Patient Dialogue:

BH is a 68 year old patient who is being discharged home from an outpatient procedure with a prescription for oxycodone/acetaminophen 5/325 mg every 6 hours as needed #30.

He takes oxycodone extended release 20mg BID for chronic back pain s/p MVA with multiple fractures and clonazepam 1mg BID for generalized anxiety disorder. Other chronic medications include two medications for high blood pressure and three different inhalers for COPD.

- Pharmacist: I noticed on your prescription records that you are taking a long-acting pain medication, OxyContin, and a medication for anxiety, Klonopin, plus three inhalers for a respiratory condition, called COPD, is that correct?

- BH: Yeah, I have been taking all those for years with no problems. Why are you asking?
• Pharmacist: Unfortunately those medications in combination significantly increase your risk of having a breathing emergency, especially with your history of COPD. We recommend that you have a medication to reverse a breathing emergency, called naloxone, in your home in case this happens to you.

• BH: I know about naloxone, that is for drug abusers who overdose on heroin. Are you accusing me of abusing my meds? I only take them as prescribed by my doctor and I have never had a problem with them.
Pharmacist: You are right, we do use naloxone to help people who have overdosed on heroin. However naloxone is also helpful for people who have a breathing emergency from prescribed medications as well. It is great that you only take your medications as prescribed by your doctor and I am glad to hear you have not had any problems with them. Would it be okay if I give you some information about naloxone and why I think it might be important for you to consider having it at home?
BH: I guess so.

Pharmacist: Having naloxone in your home is like having a fire extinguisher to put out a fire. You still follow all the recommended safety procedures to prevent a fire, but you have the fire extinguisher available in case a fire starts accidentally. Having the fire extinguisher does not make it safe for children to play with matches, as an example, it just allows you to put a fire out if it happens despite all your fire safety efforts.

BH: That makes sense, but I don’t see why I would have a breathing emergency since I have been taking these medications as my doctor prescribed, he would know if they weren’t safe for me, right?
Pharmacist: I get that same question from a lot of my patients. Even when taken at prescribed doses pain medications can sometimes accidentally result in a breathing emergency. The reason you are at risk is the combination of oxycodone, and clonazepam with your history of COPD can cause your breathing to slow too much and you may become unconscious. It hasn’t happened to you yet, and I hope it never will, but the risk is there. I also find people feel safer having naloxone in their home in case they ever forget that they took their medication and take a second dose by accident, or if children visiting the home ever get into the medication and have a breathing emergency.
## Opportunities for Interventions

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify People at Risk for Overdose</td>
<td>Education</td>
</tr>
<tr>
<td>Drug Take-Back Programs</td>
<td>Needle Exchange</td>
</tr>
<tr>
<td>Lock Boxes</td>
<td>MAT</td>
</tr>
<tr>
<td>Have Naloxone</td>
<td>Create a Supportive Environment</td>
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</table>

Outreach Services needle exchange, on the alley, in back of University Methodist Temple, University District, Seattle, Washington. Photo by Joe Mabel May 2007
Explain evolving state laws regarding options for pharmacists to prescribe or dispense naloxone under collaborative practice agreements, protocols or standing orders.
Evolving State Laws Regarding Naloxone Distribution

PDAPS | Prescription Drug Abuse Policy System

A source of rigorous legal data for researchers and detailed policy information for the public.

PDAPS is funded by the National Institute on Drug Abuse to track key state laws related to prescription drug abuse. Click on any topic area to reach an interactive page where you can investigate the history and features of the law, or download data and other documentation for research.

Latest topics

**Expanded Access to Naloxone**
State laws authorizing third-party prescribing and lay administration of the standard antidote to opioid overdose.

**Good Samaritan 911 Immunity**
State laws providing protection from criminal sanctions to overdose victims or witnesses who seek emergency services.

http://pdaps.org

APhA2018
Annual Meeting & Exposition
Nashville, TN | March 16-19
Demonstration of PDAPS Prevention Laws

http://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139
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You need to determine if your state has provision of a standing order, protocol, or allows a collaborative practice agreement. Which of the following resources provides an interactive search method to answer your question?

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C. Prescription Drug Monitoring Program
D. Center for Disease Control and Prevention
Welcome to PrescribeToPrevent.org

Here you will find information you need to start prescribing and dispensing naloxone (Narcan) rescue kits, including some useful resources containing further information about this life-saving medicine. We are prescribers, pharmacists, public health workers, lawyers, and researchers working on overdose prevention and naloxone access. We compiled these resources to help health care providers educate their patients to reduce overdose risk and provide naloxone rescue kits to patients.

You may use and adapt any material on this site. Please include any attribution that documents may contain.

www.prescribetoprevent.org
Questions and Discussion