

Naloxone: Overview and Resources for Pharmacists

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Goal. The goal of this lesson is to provide pharmacists information on the opioid epidemic, with an emphasis on implementing naloxone distribution programs in Ohio.

Objectives. At the completion of this activity, the participant will be able to:

1. list key factors contributing to the opioid epidemic in the U.S.;
2. outline the history of naloxone used to treat opioid overdose, including legal and ethical issues;
3. identify key components for pharmacists to implement a naloxone distribution program;
4. demonstrate an understanding of effective communication skills for counseling patients on the use of naloxone; and
5. exhibit knowledge of the principles of overdose prevention and harm reduction.

Introduction

Opioid misuse and overdose have become a major public health crisis in the United States. Increased access to naloxone, the opioid antidote, is one way many states and health care providers have chosen to help combat this epidemic. This lesson provides pharmacists with tools to implement a naloxone distribution program. The information in this lesson is specific to dispensing naloxone in Ohio; other states

may have different requirements.

Prescription Opioid Epidemic

The rise of prescription opioid misuse is complex, but several key factors have culminated into what some call a “perfect storm” to form the opioid epidemic.

Treating Pain. It has become more prevalent in recent medical culture to treat pain more aggressively with medications. Since 1999, there has been no overall change in the amount of pain Americans have reported, yet the amount of prescription painkillers dispensed in the U.S. has quadrupled. In 2012, 259 million prescriptions were written for opioids, which is enough to medicate every American adult around the clock for one month.

Misperceptions about Safety and Legality. Many individuals believe that prescription drugs are safer to misuse than illicit “street” drugs and do not have the potential to cause addiction because they are prescribed by a doctor. This is especially true among teenagers, with 40 percent believing prescription drugs are safer than illicit drugs and 29 percent believing they are not addictive. In addition, the public is often not aware that possessing a controlled substance without a legitimate prescription is a felony offense.

Pharmaceutical Company Marketing. Strategic marketing by pharmaceutical companies has

contributed to an increase in pain medication prescribing. Industry representatives have aggressively targeted family practitioners, emergency departments, and hospitals to utilize new opioid pain medications such as oxycodone and hydrocodone rather than non-opioid alternatives. Practitioners have been misinformed at times of the addictive potential of these medications, and may not have been adequately trained in pain management.

Direct-to-Consumer Advertising. The United States is one of only two countries that allows direct-to-consumer advertising of prescription drugs, causing a normalization of prescription drug use which may cause patients to self-diagnose and self-prescribe.

Ease of Access. Some prescribers have operated high-volume pain clinics, or so called, “pill mills,” which provide an easy source for drug-seeking patients to obtain almost limitless supplies of opioids. Many individuals misuse opioids without ever receiving a prescription, as 70 percent of patients report obtaining them from a friend or relative, either for free, purchase, or by theft.

Lack of Treatment. Health insurance companies provide limited reimbursement for detoxification, rehabilitation or recovery counseling services. Patients who become addicted to prescription opioids are often left with limited resources and treatment options.

The Transition from Prescription Opioids to Heroin

This rise in prescription opioid misuse has led to an increase in heroin use. Reports show as many as 80 percent of new heroin users started out misusing prescription painkillers. Factors cited in causing individuals to switch from prescription opiates to heroin include: efforts to reduce inappropriate prescribing, states closing down “pill mills,” increased use of prescription drug monitoring programs, and the increased availability of relatively affordable heroin. With the even more addictive and devastating nature of heroin, the opioid epidemic is now even more cause for concern.

Opioid Overdoses

Overdoses from opioids have reached such magnitude that more Americans die of drug overdoses every year than from motor vehicle accidents. Every day, 44 people in the U.S. and almost five people in Ohio die from an opioid overdose. Overdoses from prescription opioids such as hydrocodone and oxycodone continue to make up the majority of opioid overdose deaths; however, fatal heroin overdoses more than tripled between 2010 and 2014.

A more recent alarming trend is that fentanyl-related overdoses have increased by 80 percent between 2013 and 2014. These overdose deaths are believed to be primarily due to heroin laced with illicitly-produced fentanyl, a small portion resulting from pharmaceutically-diverted fentanyl. This is especially concerning, as fentanyl is considered to be 30 to 50 times more potent than heroin, and thus puts individuals at an even higher risk of overdose.

Mechanism of Opioid Overdose and Naloxone

Opioids cause overdose by binding tightly to the mu opioid receptor and depressing respiration. Users become tolerant to the analgesic and euphoric effects of opioids, and must increase their dosage to

receive the same rewarding results. Unfortunately, users develop tolerance to the respiratory depression at a slower rate, thus paradoxically putting long-term users at more risk for opioid overdose. All opioids can cause overdose, regardless of their route of administration. Overdose from opioids can be unpredictable, but most overdoses take place over the course of one to three hours after use.

Naloxone is a mu opioid receptor antagonist, which binds at a higher affinity to these receptor sites than opioids. It displaces any opioids present and restores normal breathing. It also reverses most, if not all, of the opioid's euphoric effects, thus causing immediate withdrawal symptoms. Naloxone rarely produces adverse effects if administered to a person who is not on opioids. The onset of action occurs within two to five minutes, and typically lasts 30 to 90 minutes. It is important to note that most opioids have a duration of action of several hours, so once the naloxone wears off, the individual may re-overdose, requiring a second or sometimes third dose of naloxone.

History of Naloxone

Naloxone, often referred to by the brand name Narcan[®], was first approved by FDA in 1971 to treat opioid overdoses. It is now widely used by emergency departments, first responders, and intensive care units in patients who present with potential opioid overdoses. Since the 1990s, community-based programs have provided overdose education and naloxone distribution (OEND) to opioid users and their close contacts. In 2010, a report showed survey results from 188 OEND programs which distributed naloxone to 53,032 persons and received reports of 10,171 overdose reversals.

It is legal in all 50 states for pharmacists to dispense naloxone to an individual with a valid prescription. Following the rise of the opioid epidemic, several states have expanded their laws to allow

pharmacists, health departments, and other community-based programs to provide naloxone to patients, family members or friends without a prescription. Each state has its own unique rules and regulations with respect to pharmacist prescribing and dispensing. At the time of publication, 24 states allow pharmacists to provide naloxone under a specific protocol or collaborative practice agreement.

Ohio, for example, recognized the increase in fatal opioid overdoses, and has increased the options to expand access to naloxone. The following is a summary of legislation in Ohio.

House Bill 170. Signed into law on March 11, 2014. This law expanded access to naloxone by allowing physicians or other health care professionals to prescribe naloxone to friends, family members or others who may be in a position to assist those at risk of overdose.

House Bill 4. Signed into law on July 16, 2015. This law further expanded access to naloxone by allowing pharmacists and pharmacy interns to dispense naloxone to individuals without a prescription under a physician-approved protocol.

Good Samaritan Law.

Thirty-two states have passed “Good Samaritan” legislation which protects bystanders from being arrested for minor drug offenses when calling 911 during an overdose. Unfortunately, Ohio's current Good Samaritan Law does not explicitly protect individuals during drug overdoses. At the time of publication, Ohio House Bill 249, the 911 Good Samaritan Bill which would expand bystander protection around drug overdoses, was in the House Judiciary Committee.

Ethical Issues

Naloxone distribution programs are safe and effective; an estimated one in five naloxone kits result in an opioid reversal. However, there are many misconceptions surrounding its use. Pharmacists can help dispel prevalent myths about naloxone and advocate for the ex-

pansion of this vital service.

The most common concern regarding naloxone is whether expanding access will encourage drug misuse without fear of overdose. However, studies have shown an overall decrease in heroin use among drug users after naloxone distribution and overdose education. Not all drug users are ready for treatment; providing naloxone keeps patients alive and gives them access to medical professionals who can assist in finding treatment when they are ready. Overdoses can motivate users to seek treatment, as found in one study where one in four drug users sought treatment within 30 days of their overdose.

Another common concern relates to laypersons being unable to properly administer naloxone or recognize an overdose. However, a meta-analysis of bystander naloxone administration and education programs showed that administration of naloxone by lay persons is safe and effective, especially if proper training measures are in place. Drug users and their contacts are as skilled at recognizing and responding to opioid overdoses as medical professionals. Since naloxone does not harm a person who is not on opioids, it is relatively low-risk, but can be life-saving for a person experiencing an overdose.

Many myths exist surrounding the safety of naloxone. Literature that points to pulmonary edema and negative cardiovascular outcomes are all believed to be related directly to the sequelae of opioid overdose and not the naloxone itself. One common concern is related to pregnant women, in that naloxone does cross the placental barrier and may potentially induce an opioid withdrawal syndrome to the fetus. According to the American College of Obstetricians and Gynecologists, naloxone should be used only in the case of maternal overdose to save the woman's life. It is a complicated case of risk versus benefit, and individuals obtaining naloxone kits should be counseled on when administration is

appropriate in pregnant patients.

Finally, many believe addiction to drugs and alcohol occurs by choice, yet the American Medical Association, American Psychiatric Association and World Health Organization have defined addiction as a disease. The National Institute on Drug Abuse and American Society of Addiction Medicine describe addiction as a chronic, relapsing disease of the brain, associated with loss of control and continued abuse despite harmful consequences. Drug addiction needs to be better treated as a *disease*, rather than a *personal choice*, by insurance companies, health care providers, and society as a whole.

The initial decision to take a drug normally happens voluntarily. However, continued use may result from the addictive properties of the drugs which activate the brain's natural reward system. Chronic use depletes the brain of normal dopamine levels, leading to drug dependence and craving. Research findings using brain imaging techniques have identified changes in structure and function of the brain after chronic exposure to these drugs. These biochemical changes, along with multiple environmental and genetic contributions, lead to the complex disease of addiction.

Implementing a Naloxone Program

Target Populations. Naloxone can benefit all patients who use opiates or are in close contact with those using opiates. The following individuals are ideal candidates for naloxone distribution:

- caregivers, friends or families of an opiate user;
- patients on high doses of opiates (>100mg morphine equivalent per day);
- patients on methadone or buprenorphine;
- patients with concurrent benzodiazepine or alcohol use;
- patients with a history of addiction or mental illness;
- patients with a history of overdose;
- patients seen in an emergency

department for opiate overdose/intoxication;

- patients who are recently discharged from a treatment program or incarceration (lower tolerance);
- patients with concurrent poor physical health conditions (respiratory issues, renal or liver dysfunction, acute illness);
- staff who work with opiate users, such as homeless shelters, treatment centers and halfway houses.

How Supplied. Naloxone comes in both intranasal and intramuscular formulations. Both routes are effective, but the intranasal form is more common since it is preferred by those administering the drug. All naloxone dosage forms are available through most pharmacy wholesalers (Cardinal, McKesson, etc.). The following section will compare and contrast the various dosage forms with availability and pricing at time of publication.

Intranasal

Naloxone 2mg/2mL pre-filled syringes

This intranasal formulation is the most common dosage form used by naloxone distribution programs. The pre-filled syringes were originally intended for intravenous use, but a nasal adapter is used to convert them for use as a nasal spray. (Figure 1). Each nasal adapter is about \$5, and can be ordered from various wholesalers or suppliers as outlined in Table 1. It is important to note that the nasal adapters are not FDA-approved, and the device is usually not covered by insurance. However, the adapters are widely



Figure 1. Naloxone 2mg/2mL pre-filled syringe

Table 1
Selected nasal atomizer vendor contacts

Vendor	Item No.	Contact
Professional Hospital Supply	392322	707-429-2884
Cardinal	MAD 300	800-964-5227
Healthcare Logistics	17474	800-848-1633
Amazon	MAD 300	Amazon.com
American Medical	MAD 300	888-988-5350
Teleflex	MAD 300	919-544-8000

accepted and have been used with take-home naloxone effectively for decades. The cost for one intranasal naloxone kit is typically between \$80-120 without insurance. Figure 2 describes how to give nasal spray Narcan® using the nasal adapter.

Intranasal – Pre-filled

Naloxone 4mg/0.1 mL (Narcan® Nasal Spray)

A new intranasal formulation with two pre-assembled nasal sprays per package became available in early 2016. It is available at a higher dose than the other formulations (8 mg of naloxone per take-home kit versus 4 mg). At the time of publication, there was special contract pricing available through the manufacturer for certain programs which are not seeking reimbursement for the kits (e.g., free naloxone distribution programs, EMS, law enforcement).

Intramuscular

Naloxone 0.4 mg/mL single dose vial

The intramuscular vials are the cheapest option. The kit requires two intramuscular needles with syringes, which is beneficial compared to the nasal atomizer since they are readily available and billable through prescription insurance. Many patients do not feel comfortable drawing-up and measuring the dose, or they worry about an accidental needle stick. However, the cost of each kit is usually much lower.

Intramuscular Auto-Injector

Naloxone 0.4 mg/0.4 ml (Evzio® auto-injector)

The auto-injector device comes with two pre-filled pens and a training pen. The auto-injector device is similar to epinephrine pens, and there are automated voice instructions. The cost is over \$700 without insurance, and insurance coverage is limited. As of May 2016, there is a patient assistance program through the manufacturer for patients who do not qualify for Medicaid or Medicare.

Naloxone Kits

Naloxone is commonly distributed in community and ambulatory settings as a “naloxone kit.” Each kit should minimally include: two doses of naloxone, two adapters (nasal adapter or intramuscular needles with syringes), and a quick-reference insert with instructions on administering the drug and how to obtain a refill. Most kits also include a small CPR shield, and intramuscular kits often include gloves and alcohol swabs. The bags used to hold the components are generally small, zippered pouches. These bags can be ordered online or through local vendors, and many

programs print their logos along with words identifying the contents (e.g., “overdose prevention kit”). Alternatively, state naloxone programs may provide bags at little to no cost, such as through the Ohio Department of Health’s program, Project DAWN.

Dispensing: Prescriptions and Protocols

There are several ways for pharmacists to dispense naloxone to a patient: pursuant to a prescription from a prescriber, under a written protocol from a physician, and at a site which is part of a distribution program (i.e., “personally furnishing”).

Prescription. A prescription should be written in the name of the individual requesting the naloxone. This may not always be the opiate user, but rather a “third party” in a position to assist the opiate user, such as family or friends. Pharmacists should anticipate common questions from prescribers about logistics of writing the prescription, including dosage form selection, directions, refills and special instructions. Pre-printed prescription blanks may streamline the process for prescribers.

Pharmacy Protocols. Physician-approved protocols in Ohio, for example, allow pharmacists or pharmacy interns under the direct supervision of a pharmacist to dispense naloxone without a prescription. Pharmacists may bill prescription insurance under such a protocol. Ohio licensed physi-

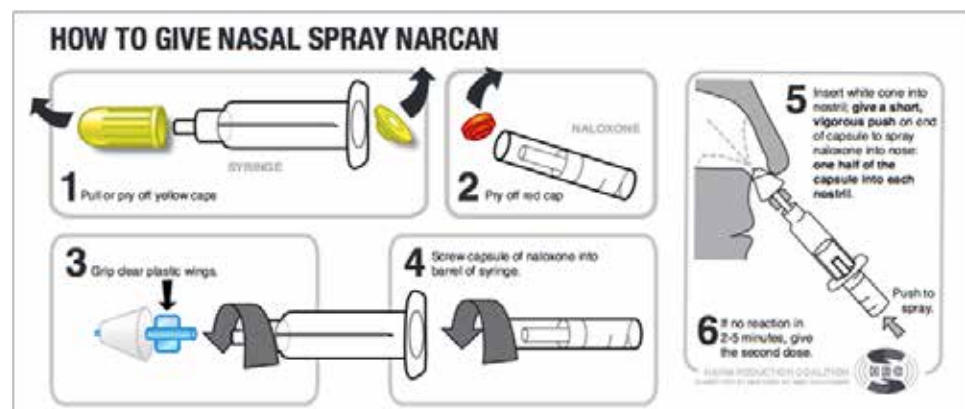


Figure 2. Harm Reduction Coalition (www.harmreduction.org)

cians must authorize the protocol and authorize if this service will be available in more than one location. The Ohio Board of Pharmacy has sample protocols available on their website, as well as a guidance document with sample prescriptions and naloxone information resources.

Personally Furnishing.

Physicians may also authorize staff to personally furnish naloxone to individuals under a protocol. This is a common model for community health centers, health departments and drug and alcohol treatment programs. Pharmacists may work in these locations and be named under the protocol as well. The Ohio Board of Pharmacy provides a guidance document to assist pharmacists in Ohio who are interested in this distribution model.

Billing and Reimbursement

Pharmacies can bill insurance of the individual who is requesting the naloxone at the pharmacy (i.e., not always the opiate user themselves). Medicaid, Medicare and many private insurance companies cover the intranasal or intramuscular naloxone at little to no cost. The intramuscular auto-injector Evzio® is usually non-formulary, but could be covered with a prior authorization. At the time of writing this lesson, insurance coverage of the Narcan® pre-assembled nasal spray was not known.

Unfortunately, the non-medication components of naloxone kits are not billable. Thus, the pharmacist must decide whether or not to absorb the non-billable components or pass the cost on to the patients. Some states have created an NDC number to cover the cost of the entire kit (naloxone, atomizer, CPR shields, and education materials) plus pharmacist consultation time. There are advocacy efforts in Ohio to approve a similar billing code.

Educational Component

Counseling points are reviewed in detail later in this article, but pharmacists should consider several logistical issues when implement-

ing a program. There are mandatory verbal and written counseling requirements that include ways to reduce overdose risk and referral to substance use treatment. Overdose prevention education is considered to be a critical component of the overall effectiveness of naloxone programs; however, this requires pharmacists to dedicate face-to-face time in a semi-private space.

Many programs use online training videos as referenced in Table 2. Videos can supplement part of the face-to-face time required of the pharmacist, and facilitate consistent patient education. In Ohio, pharmacy interns are legally allowed to counsel patients on naloxone under direct supervision of a pharmacist. Adequate time should be allotted for questions when counseling patients, and a summary and wrap-up provided. Many programs ask patients to repeat back and verify the information they have received. Also note that patients may have emotional responses to the training, and pharmacists may feel the need to spend extra time reassuring patients or referring them to counseling or support groups.

Educational tools are available from multiple sources, as outlined in Table 2. Most written resources are free, and the Ohio Board of Pharmacy will send free brochures upon request. Some programs use “placebo” training kits for patients to practice proper use of the devices. If using brand name naloxone (Evzio® auto-injector or Narcan® nasal spray), pharmacists may contact the manufacturer for training devices. Pharmacists can also make training kits by buying the intranasal vials and filling them with sterile water for demonstration purposes.

Staff Training

Pharmacies implementing a naloxone program should provide initial and ongoing training to all pharmacy staff members. Pharmacists should understand the requirements of their protocols, inventory management, reimburse-

Table 2 Resources for naloxone information and videos

Project DAWN (*Deaths Avoided With Naloxone*) was developed by the Ohio Department of Health and aims to provide naloxone resources and support to new or existing programs, along with a list-serve and conference calls for naloxone programs in Ohio. <http://www.healthy.ohio.gov/vipp/drug/ProjectDAWN.aspx>

Harm Reduction Coalition provides extensive resources and information on overdose prevention, naloxone training materials, sample brochures, and policy initiatives on harm reduction efforts. <http://harmreduction.org>

ExchangeSupplies.org includes a 10-minute video demonstrating a pharmacist counseling on naloxone. <https://www.youtube.com/watch?v=BaOUCo1M2mk>

NaloxoneInfo.org provides multiple training videos targeting different populations, tools to help run a program, and a bibliography of harm reduction citations. <http://www.naloxoneinfo.org/>

College of Psychiatric and Neurologic Pharmacists provides continuing education courses and guidance documents. www.cpnpp.org

Prescribe To Prevent Multiple resources and links to training videos, including a “Staying Alive on the Outside” video targeting incarcerated individuals approaching release. www.prescribetoprevent.org

ment options, and documentation. Interns should be familiar with the same information as pharmacists, and given guidance as to when to defer to the supervising pharmacist. Technicians should be aware of eligible patients, billing and documentation, and when to refer patients to the pharmacists. All staff should be introduced to the concept of harm reduction, which is outlined below.

Naloxone Counseling

Prior to dispensing naloxone, it is

Table 3
Patient counseling pearls for use of naloxone in opioid overdose

Risk Factors for Overdose

- Using alone, not in the presence of others
- Obtaining multiple prescriptions from multiple providers
- Mixing prescription opioids with other drugs (e.g., alcohol, benzodiazepines, cocaine or “speed”)
- Switching dealers or using new types of opioids
- Increased doses: patients self-titrating without discussing with a medical provider
- Decreased tolerance: patients leaving opioid detox centers, lengthy inpatient hospital stay, released from incarceration, or long period of enforced sobriety
- History of overdose, history of mental illness

Effect of Opioid Overdose

- Opioids slow down breathing, and when a person uses too many opioids, it causes them to stop breathing altogether.

Signs of Opioid Overdose

If not sure it is opioid overdose, give naloxone, call 911, perform CPR

- Unconscious or unresponsive despite shouting, shaking, or “sternal rub” (rubbing the breast bone with knuckles)
- Slow breathing (less than 1 breath every 5 seconds) or no breathing
- Pale or blue lips, face, fingertips, or toes (due to lack of oxygen)
- Slow, erratic, or no pulse
- Shallow or raspy breathing including snoring or gurgling noises while asleep or nodding out
- Pale, clammy face or skin feels cold to touch
- Pinpoint pupils
- Vomiting or foaming at the mouth

Naloxone Drug Information

- Mechanism: Naloxone is a “blocker,” meaning it has a stronger affinity than opioids for the opioid receptor. When given in the nose or in the muscle, it immediately reverses the opioid, allowing the person to breathe again.
- It only works if a person has opioids

- in their system, but even if you are not sure if the overdose is from opioids, give naloxone anyway.
- Duration: Naloxone may only last up to 30-90 minutes. Since opioids typically last longer, patients may require a second and sometimes third dose of naloxone.
- Storage: Should be stored at room temperature in a dark/dry area that is easily accessible to others.
- Expiration: Expired naloxone will not hurt the patient but may not be as effective; encourage patients to exchange expired naloxone for a new supply.

How to Respond to Overdose

1. Check for responsiveness: Call their name, shake them, rub knuckles over their sternum (breastbone).
2. Call 911: Indicate the person has stopped breathing or is struggling to breathe (avoid saying the words “drugs” or “overdose”).
3. Make sure nothing is in the person’s mouth that could be blocking their breathing.
4. If breathing has stopped, begin rescue breathing; Or, if you know CPR, you can begin CPR.
5. Assemble and administer naloxone.
6. Resume rescue breathing or CPR, and if no response after 2-3 minutes, give the second dose of naloxone.

Withdrawal and Aftercare

- Naloxone produces no adverse effects in opioid-naïve or non-dependent patients.
- Rapid reversal of opioid overdose may precipitate signs and symptoms of withdrawal.
- Possible withdrawal symptoms include: agitation, irritability, sweating, fever, body aches, shivering, nausea/vomiting, shaking, tachycardia, or elevated blood pressure.
- Since naloxone only lasts for 30-90 minutes, the person may re-overdose once naloxone wears off.
- Counsel individuals on this re-overdose risk, encourage them to go and stay at the hospital for monitoring, and do not allow them to use more drugs.

important for pharmacists or other health care providers to provide education to patients, family members, and/or friends. In Ohio, there are mandatory verbal and written counseling requirements for naloxone dispensing under a protocol as outlined in the Ohio Revised Code Section 4729.44, including, but not limited to, all of the following: (1) Risk factors of opioid overdose; (2) Strategies to prevent opioid overdose; (3) Signs of opioid overdose; (4) Steps in responding to an overdose; (5) Information on naloxone; (6) Procedures for administering naloxone; (7) Proper storage and expiration of the naloxone product dispensed; and (8) Information on where to obtain a referral for substance use disorder treatment.

It is imperative that friends and family know where the naloxone will be stored in case of overdose. It is valuable for them to understand what opioids are and that naloxone will not work on combination drug overdoses including alcohol and benzodiazepines. Despite the inability to reverse the action of all drugs, it is important to encourage patients to use naloxone even if they are not sure what substances have been used. Table 3 describes key counseling points in detail, and Table 4 provides information for referring patients to treatment services and naloxone distribution sites.

Various educational materials may have utility in patient counseling such as videos, verbal instructions, use of diagrams or pictures, or by directly handling a dosage form (Table 2).

The following communication techniques are suggested.

- 1) Use simple non-medical language and use common descriptive words.
- 2) Focus on 3-5 key messages; prioritize what needs to be discussed and understood.
- 3) Use teach back: verify patient understanding by having them demonstrate the proper use of naloxone.
- 4) Encourage patient participation; solicit questions (e.g., “what

Table 4 Addiction, recovery and support services

Addiction Treatment Services

- Substance Abuse Mental Health Services Administration (SAMHSA)
<https://findtreatment.samhsa.gov/>
1-800-662-HELP (referral helpline)
1-800-487-4889 (for hearing impaired)
- Buprenorphine physician and treatment program locator (SAMHSA)
<http://www.samhsa.gov>

Naloxone Distribution Program

- The Ohio State Board of Pharmacy keeps an updated list of pharmacies currently dispensing naloxone
<http://pharmacy.ohio.gov/Licensing/NaloxonePharmacy.aspx>

Syringe Exchange

- North American Syringe Exchange Network (NASEN)
<https://nasen.org/directory/>

Support Group Locator

- Narcotics Anonymous (For Addicts)
<https://www.na.org/meetingssearch/>
- Nar-Anon (For Families)
<http://www.nar-anon.org/find-a-meeting>

Free or Low-cost Health Services

- Community Health Center locator
www.findahealthcenter.hrsa.gov

questions do you still have?”).

5) Utilize patient-friendly handouts: this helps to reinforce the teaching and can be a useful resource for patient understanding (e.g., pictures, “how to” instructions).

Harm Reduction

Harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use. Harm reduction acknowledges drug use as a part of society, and works to minimize the harmful results using evidence-based interventions. Harm reduction advocates for health care providers to meet the drug user “where they are,” and design services along a con-

tinuum, from safer drug use to total abstinence. A non-coercive, non-judgmental approach is critical to the success of harm reduction interventions.

This approach does not minimize the dangers associated with drug use, but recognizes that addiction is a complex disease with stages of change. Individuals have different capacities to change and deal with addiction due to diverse backgrounds of poverty, class, racism, social isolation, trauma and sex-based discriminations. Drug users require support, compassion and non-judgmental attitudes from health care providers to meet their needs. Drug users should have a voice in services designed for them, and peer-to-peer services are often very effective.

Harm Reduction: Naloxone. Drug users may not request naloxone for many reasons, including fear they may be judged or due to prior negative experiences with health care providers. Pharmacists need to create a safe, open environment for drug users to seek services. Fliers, prescription inserts, or marketing services to local providers may be a less confrontational way to advertise naloxone availability to users. When counseling, pharmacists should gauge “where patients are,” and provide resources and information based on their needs. Overdose prevention education and promoting safer drug use is an important component, and should be provided consistently along with naloxone distribution.

Family, friends or other contacts of drug users are often those who approach pharmacists directly for naloxone kits. Pharmacists should not judge the individual’s relationship, approach or coping mechanisms when dealing with their loved one’s drug addiction. Referrals to family counseling or support groups should be offered, but not forced. When pharmacists recommend naloxone to family members or friends who are unaware of naloxone, they should be prepared for misconceptions and myths about naloxone, and be

ready with evidence-based answers.

Harm Reduction: Opioid Epidemic. In addition to expanding access to naloxone, pharmacists should advocate for a continuum of harm reduction strategies to reduce harm from the opioid epidemic. Educational and awareness efforts to prevent opioid misuse and overdose need to be put in place across all age groups. Safer drug use, wound care and high-risk behavior education should be available to all drug users. Syringe exchanges are especially important to reduce skin infections and the transmission of hepatitis and the Human Immunodeficiency Virus (HIV). It is estimated that 3,000 to 5,000 transmissions of HIV and 10,000 transmissions of Hepatitis C occur each year as a result of infected needles. Research shows syringe access programs do not increase drug use, and actually serve as important sources of information related to recovery and treatment.

Patients desperately need affordable options for inpatient and residential treatment. Patients also need access to Medication-Assisted Treatment (MAT), which includes a combination of counseling plus the opioid agonist therapies methadone, buprenorphine, or the antagonist therapy naltrexone. Finally, opioid addiction should be accepted as a disease and not a character flaw. Pharmacists and health care providers should adopt a harm reduction philosophy, which is to provide non-judgmental, evidence-based services to individuals in need, while meeting them “where they are.”

Naloxone Frequently Asked Questions

How do I know if someone is really high or if they have overdosed? The main difference is someone who has overdosed will not respond to the sternal rub (rubbing the breast bone with the knuckles). Stay with the person who is very high and make sure they don’t overdose – remember, most overdoses happen over one to three hours.

How do I tell the difference between opioid overdose and overdose from

other drugs? If a person is unconscious, it can be hard to tell. The best thing to do is call 911, start rescue breathing and give naloxone anyway. Naloxone is safe, so it won't harm the person.

What happens if there are drugs around – can I get in trouble? It is very important to always call 911 when naloxone is given or during an overdose, and it is best to stay with the person who has overdosed until help arrives. Good Samaritan laws creating protection specifically for drug overdoses vary from state to state.

Can I give naloxone to someone who is pregnant? If you are sure a pregnant woman has overdosed – i.e., not responding to painful stimulation and slow or no breathing – it is best to give naloxone. It is very important that the woman goes to the hospital as soon as possible since naloxone can make the fetus go into withdrawal.

Why is naloxone in Suboxone®? Naloxone is only put into Suboxone® to prevent individuals from snorting or injecting the medication. Naloxone does not work if it is swallowed, so if Suboxone® is used correctly, the naloxone will not do anything. The buprenorphine is the component in Suboxone® that helps prevent cravings and withdrawal.

Can a pharmacist dispense a naloxone kit to a person under 18-years-old? Yes, as long as the pharmacist feels in his/her professional judgement that the individual is able to understand an opioid overdose and correctly respond (use the medication and call 911).

Is there a limit to the number of kits a pharmacist can dispense at a time? No, as long as there are no limits in the physician-approved protocol. Pharmacists should use their professional judgement to determine if additional doses are appropriate.

Should a pharmacist treat a refill

naloxone kit differently? A refill can be an important opportunity to provide support and additional resources to the individual(s) involved. However, some people still may not be ready for treatment or additional help, and pharmacists must meet the person “where they are.”

Conclusion

Naloxone is a safe, effective and critical tool to reduce the harm caused by the opioid epidemic. Pharmacists, as accessible health care providers who have an oath to serve our community, have a clear and important role in naloxone distribution and overdose prevention education. Communities should continue to expand strategies to assist in reducing the negative consequences of drug misuse, and naloxone distribution is a major component of a comprehensive strategy to reduce harm from the opioid epidemic.



The authors, the Ohio Pharmacists Foundation and the Ohio Pharmacists Association disclaim any liability to you or your patients resulting from reliance solely upon the information contained herein. Bibliography for additional reading and inquiry is available upon request.

This lesson is a knowledge-based CPE activity and is targeted to pharmacists in all practice settings. **Disclosure.** The OPF trustees and other individuals responsible for planning OPF continuing pharmacy education activities have no relevant financial relationships to disclose.

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Naloxone: Overview and Resources for Pharmacists

1. All of the following have contributed to the opioid epidemic in the U.S. EXCEPT:

- a. belief that prescription drugs are safer than street drugs.
- b. pharmaceutical companies encouraging use of non-opioid alternatives.
- c. the amount of painkillers dispensed.
- d. direct-to-consumer advertising.

2. Drug users transition from prescription opioids to heroin for all of the following reasons EXCEPT:

- a. increased use of prescription drug monitoring programs.
- b. increased availability of affordable heroin.
- c. belief heroin is safer than prescription opiates.
- d. shutting down of "pill mills."

3. Which of the following is 30 to 50 times more potent than heroin and puts users at higher risk of overdose?

- a. Xanax
- b. Tramadol
- c. Marijuana
- d. Fentanyl

4. Naloxone is a:

- a. kappa opioid receptor agonist.
- b. kappa opioid receptor antagonist.
- c. mu opioid receptor agonist.
- d. mu opioid receptor antagonist.

5. Should naloxone ever be given to a pregnant woman who has overdosed?

- a. Yes
- b. No

6. *Addiction* has been defined as a chronic, relapsing disease of the brain.

- a. True
- b. False

.....
Completely fill in the lettered box corresponding to your answer.

- 1. [a] [b] [c] [d]
- 2. [a] [b] [c] [d]
- 3. [a] [b] [c] [d]
- 4. [a] [b] [c] [d]
- 5. [a] [b]
- 6. [a] [b]
- 7. [a] [b] [c] [d]
- 8. [a] [b] [c] [d]
- 9. [a] [b] [c] [d]
- 10. [a] [b] [c] [d]
- 11. [a] [b]
- 12. [a] [b]
- 13. [a] [b] [c]
- 14. [a] [b] [c] [d]
- 15. [a] [b] [c]

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- 1. Rate this lesson: (Excellent) 5 4 3 2 1 (Poor)
- 2. Did it meet each of its objectives? yes no
If no, list any unmet _____
- 3. Was the content balanced and without commercial bias? yes no
If no, why? _____
- 4. Did the program meet your educational/practice needs? yes no
- 5. How long did it take you to read this lesson and complete the quiz? _____
- 6. Comments/future topics welcome.

7. Ideal candidates for naloxone include all of the following patients EXCEPT:

- a. patients on methadone or buprenorphine.
- b. caregivers of an opiate user.
- c. patients on gabapentin.
- d. patients with a history of addiction or mental illness.

8. The most common dosage form of naloxone used by distribution programs is:

- a. intramuscular.
- b. intranasal.
- c. intravenous.
- d. subcutaneous.

9. A naloxone kit should minimally contain all of the following EXCEPT:

- a. two doses of naloxone.
- b. gloves.
- c. quick reference chart.
- d. two nasal adapters.

10. Possible opioid withdrawal symptoms following use of naloxone include all of the following EXCEPT:

- a. agitation.
- b. vomiting.
- c. tachycardia.
- d. coughing.

11. In the state of Ohio, written and verbal counseling are required for dispensing naloxone under protocol.

- a. True
- b. False

12. If unsure whether a person overdosed on opioids, naloxone should not be given.

- a. True
- b. False

13. When counseling patients on naloxone:

- a. discourage questions from family.
- b. do not go to a private counseling area.
- c. use the teach-back method.

14. Medication-Assisted Treatment for opioid addiction includes:

- a. opioid agonist therapy.
- b. opioid antagonist therapy.
- c. counseling.
- d. all of the above.

15. What is the main difference in someone who has overdosed compared to one who is "high?"

- a. Will not respond to sternal rub
- b. Rapid breathing
- c. Enlarged pupils

.....
To receive CPE credit, your quiz must be received no later than May 15, 2019. A passing grade of 80% must be attained. CPE credit for successfully completed quizzes will be uploaded to the CPE Monitor. CPE statements of credit can be printed from the CPE Monitor website. Send inquiries to opa@ohiopharmacists.org.