



Overdose Prevention and Naloxone Rescue Kits for Prescribers and Pharmacists

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Core Topics

- Risk factors for opioid overdose
- How to recognize and respond to an opioid overdose
- How to incorporate naloxone into that overdose response
- Medico-legal issues surrounding the distribution of naloxone, including third party prescribing and Good Samaritan laws

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Obtaining Your CME Credit

To receive CME, CNE, or ACPE credit at the conclusion of this program, you must:

- Register
- Pass a post-test with a score of 70% or greater
- Complete an evaluation

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Program Support

This program is provided by Boston University School of Medicine, and is supported by the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services



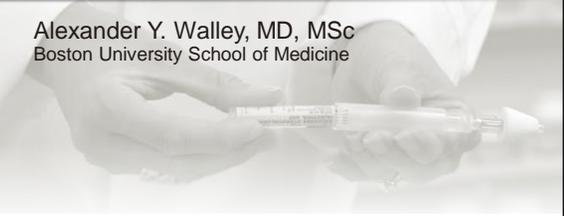

Educational Objectives

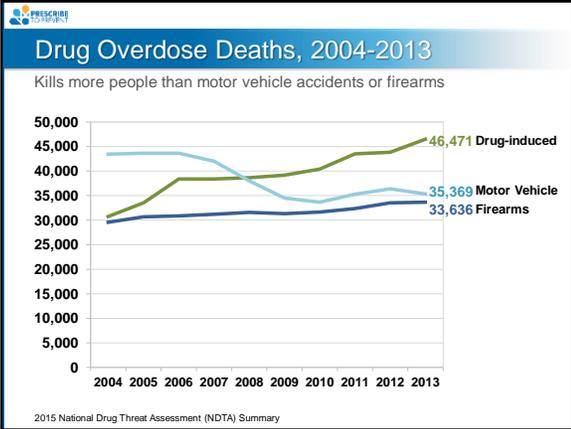
At the conclusion of this activity, participants will be better able to:

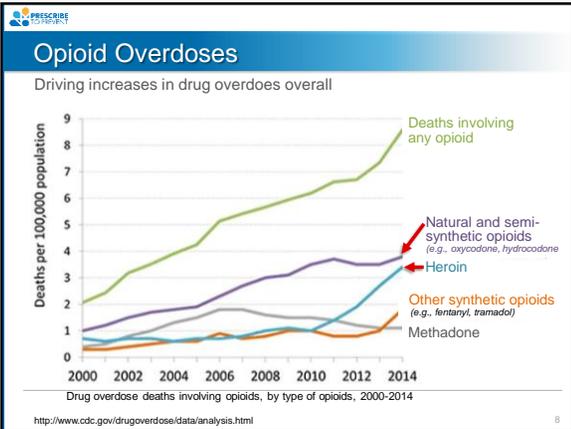
- Explain the epidemiology of overdose
- Explain the rationale for and scope of overdose prevention education and naloxone rescue kit distribution
- Incorporate overdose prevention education and naloxone rescue kits into medical and pharmacy practice by:
 - Educating patients about overdose risk reduction and
 - Furnishing naloxone rescue kits
- Explain the legal issues around furnishing naloxone rescue kits

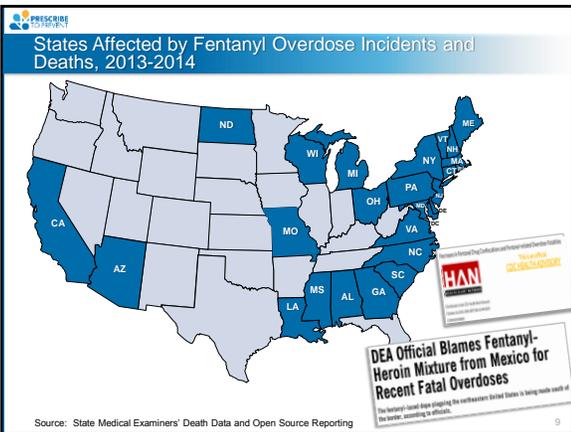
Epidemiology and Overdose Risks

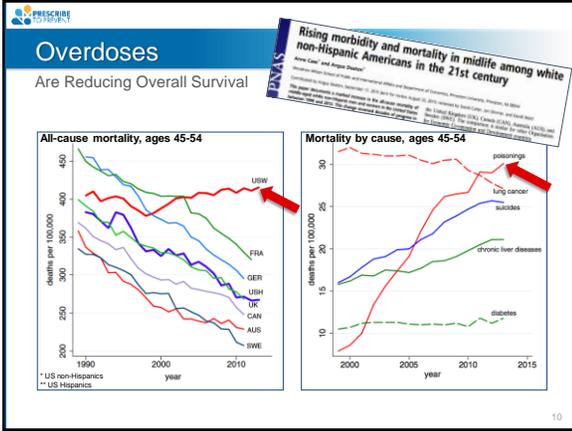
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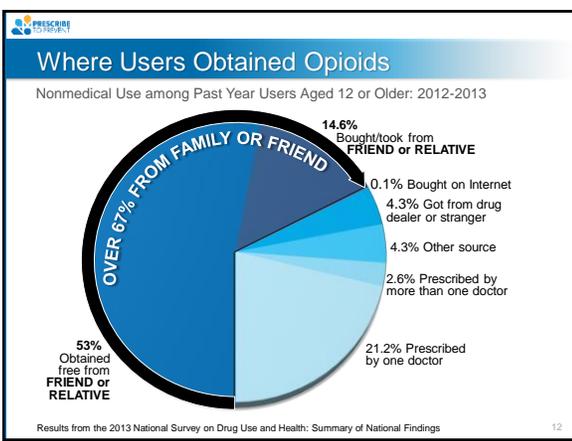



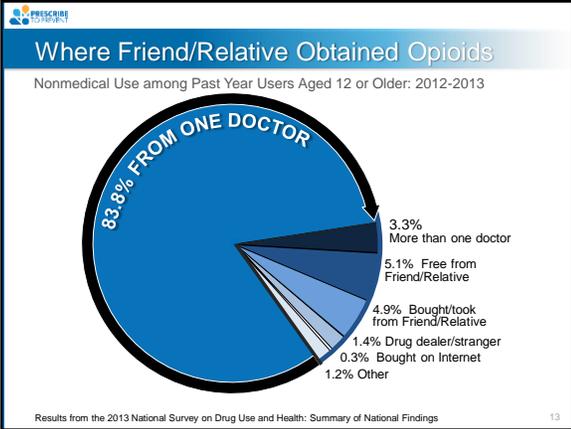












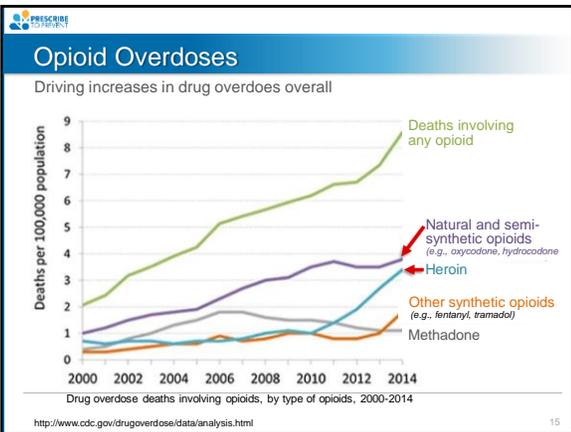
Transition from prescription opioids to heroin

Research paper
 "Every 'Never' I Ever Said Came True": Transitions from opioid pills to heroin injecting
 Sarah C. Mars^{1*}, Philippe Bourgois¹, George Karandinos², Fernando Montero³, Daniel Ciccarone⁴
 2014 Mar;25(2):257-66. doi: 10.1016/j.drugpo.2013.10.004. Epub 2013 Oct 19.

29 year old heroin injector explained how the change had prompted his switch to injecting:

"I was big into OxyContin at first. . . and I still used heroin a little little bit when OxyContin was crushable, but at that point I only sniffed, and I only did it when I had problems finding OxyContin. It wasn't until the OxyContin switched... to... the non-tamper-proof versions [sic], that I really just went straight to heroin and immediately started shooting it, which I guess was a little over a year ago."

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Benzodiazepines and Opioids

Jointly contribute to overdose deaths

- Benzodiazepines are present in 31% of opioid-related overdose deaths
- Opioids are present in 75% of benzodiazepine-related overdose deaths¹
- Among people prescribed opioids, the risk of overdose deaths is 3.8 times higher for people prescribed benzos also²

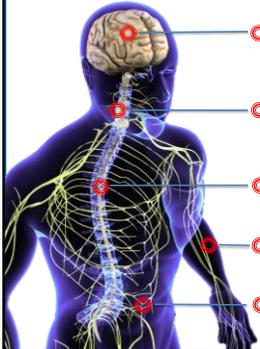


1. Jones CM and McAninch JK. Am J Prev Med. 2015 Oct;49(4):493-501.
2. Park TW, et al. BMJ. 2015 Jun 10;350:h2698.

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How do opioids affect breathing?

Opioid Receptors Throughout the Body



- BRAIN**
Opioid receptors in the cerebellum, nucleus accumbens and hypothalamus control pain perception, emotion, reward and addiction
- BRAINSTEM**
Opioid receptors in the medulla oblongata controls breathing and heart rate. Reduced breathing rate is typically the cause of opioid overdose death
- SPINAL CORD**
Opioids dampen transmission of peripheral pain signals through the dorsal horn of the spinal cord
- PERIPHERAL NEURONS**
Opioids bind pain receptors in the peripheral tissues reducing pain sensation
- INTESTINE**
Opioids inhibit peristalsis which can lead to constipation

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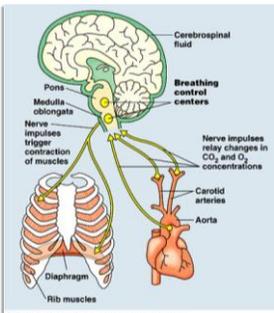
Opioid Overdose

Opioid Overdose Causes

- Reduced sensitivity to changes in O₂ and CO₂ outside of normal ranges
- Decreased tidal volume and respiratory frequency
- Respiratory failure and death due to hypoventilation

Opioid Overdose Toxidrome Develops Over Minutes to Hours

- Decreased respiratory rate, blood pressure, heart rate, body temperature
- Unresponsiveness
- Miosis – pinpoint pupils
- Blue/gray lips and nails



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Common Risks for Opioid Overdose

Mixing Substances/ Polypharmacy
Alcohol, stimulants, marijuana, prescribed and non-prescribed medications

Opioid Dose and Changes in Purity

Previous Overdose

Social Isolation
Using alone

Chronic Medical and Mental Illness
Lung, liver, and kidney compromise
Depression and anxiety

Addiction History

Abstinence

- Release from incarceration
- Completion of detoxification
- Relapse

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For Patients: How to Prevent Overdose

- Only take prescription opioids prescribed to you and as directed
- If you have an opioid problem, I can help you find treatment
- Ensure your prescribers and pharmacists know of all medications you are on
- Don't mix opioids with other drugs or alcohol

For Patients: How to Prevent Overdose

- Be extra careful if you miss or change doses, feel ill, or start new medications
- Store medication in a safe and secure place; dispose unused medication
- Abstinence - not taking opioids for a period; can reduce tolerance and increase overdose risk
- Teach friends/family how to respond to an overdose and the role of naloxone in an overdose

 Taking an Overdose History and Delivering Prevention Education

 **Overdose Education and Naloxone Rescue**
 What your patients need to know:

Prevention risks:

- Mixing substances
- Abstinence - low tolerance
- Using alone
- Unknown source
- Chronic medical disease
- Long acting opioids last longer



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 **For Prescribers: Assess Overdose Risk**
 as part of a Patient's History

- Review medications
- Review medical and social histories
- Take a substance use history
- Check the prescription monitoring program
- Take an overdose history
 - Where is the patient at as far as overdose?



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PRESCRIBER ASSESSMENT

For Prescribers: Assess Overdose History and Plan
as part of a Patient's History

Personal Overdose History

For patients prescribed opioids or benzodiazepines:
"Have you ever taken enough medication that you were drowsy and could not wake up?"

For patients using heroin:
"Have you ever overdosed?"
"What were you taking?"
"How did you survive?"

"What strategies do you use to protect yourself from overdose?"
"How do you keep your medications safe?"
"Are they locked up and secure?"



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PRESCRIBER ASSESSMENT

For Prescribers: Assess Overdose History and Plan
as part of a Patient's History

Overdose Witness History

"How many overdoses have you witnessed?"
"Were any fatal?"
"What did you do?"

"What is your plan if you witness an overdose in the future?"



"How do you:

- recognize an overdose?
- call for help?
- rescue breathe?
- give naloxone?

"Do you have a naloxone rescue kit?"
"Do you feel comfortable using it?"

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PRESCRIBER ASSESSMENT

For Pharmacists: Assessing Risk

Review the list of current prescriptions and optimize medication safety:

- Prescription monitoring program?
- Multiple psychoactive or sedating medications?
- Dispensing buprenorphine or methadone?
- Multiple prescribers and/or multiple pharmacies?
- Patient has a lockbox for medications?



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For Pharmacists: Assessing Risk

Review the list of current prescriptions and optimize medication safety:

- Are prescribers aware of all prescriptions?
- Is patient aware of risks?
- Children or pets at home?
- Patient, friends and family know how to respond?
- Do they have naloxone?



PRESCRIBE TO PREVENT

Overdose Prevention Interventions

PRESCRIBE TO PREVENT

Strategies to Address Overdose

- Prescription monitoring programs¹
- Prescription drug disposal²
- Safe opioid prescribing education³
- Opioid agonist treatment^{4,5}
- Supervised injection facility⁶

1. Paulozzi LJ, et al. Pain Med. 2011 May;12(5):747-54.
 2. Gray NE and Hagemiller JA. Arch Intern Med. 2012;172(15):1186-1187.
 3. Albert S, et al. Pain Med. 2011 Jun;12 Suppl 2:S77-85.
 4. Clausen T, et al. Addiction. 2009 Aug;104(8):1356-62.
 5. Schwartz RP, et al. Am J Public Health. 2013 May;103(5):917-22.6.
 6. Marshall BD, et al. Lancet. 2011 Apr 23;377(9775):1429-37.

Strategies to Address Overdose

Prescription monitoring programs

Paulozzi LJ, et al. Pain Med. 2011 May;12(5):747-54. 31

Strategies to Address Overdose

Prescription drug disposal

Gray NE and Hagemeyer JA. Arch Intern Med. 2012;172(15):1186-1187.

Strategies to Address Overdose

Safe opioid prescribing education

www.scopeofpain.org
www.opioidprescribing.org

Albert S, et al. Pain Med. 2011 Jun;12 Suppl 2:S77-85. 33

Strategies to Address Overdose

Opioid agonist treatment

Methadone Maintenance:
Clausen et al. Addiction 2009

Category	OD deaths per 100 p/ys
Treatment waitlist	~10
During treatment	~2
Off treatment	~10

Methadone Treatment Marks 40 Years

Increased abstinence and decreased opioid use

- Schwartz et al., 2006
- Mattick et al., 2009
- Krupitsky et al., 2011
- Mattick et al., 2014

Less overdose, longer survival

- Langendam et al., 2001
- Clausen et al., 2009
- Schwartz et al., 2013
- Nolan et al., 2016

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Strategies to Address Overdose

Supervised injection facility

Massachusetts needs safe injection sites

A view of the Safe Injection Site in Toronto, Canada, reduced for size. Boston Globe, December 27, 2015

Marshall BD, et al. Lancet. 2011 Apr 23;377(9775):1429-37.

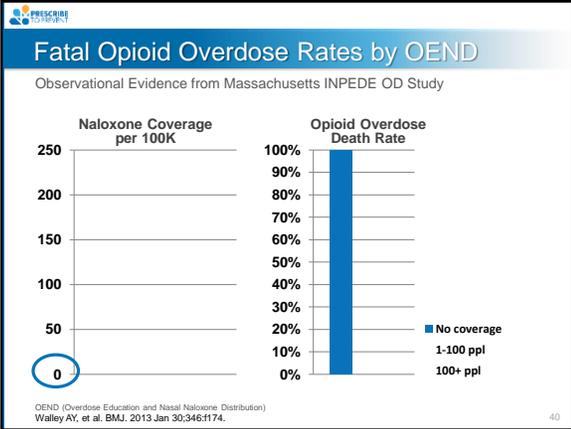
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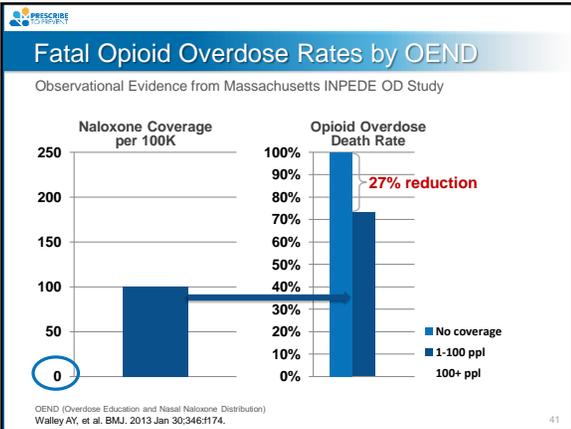
Rationale

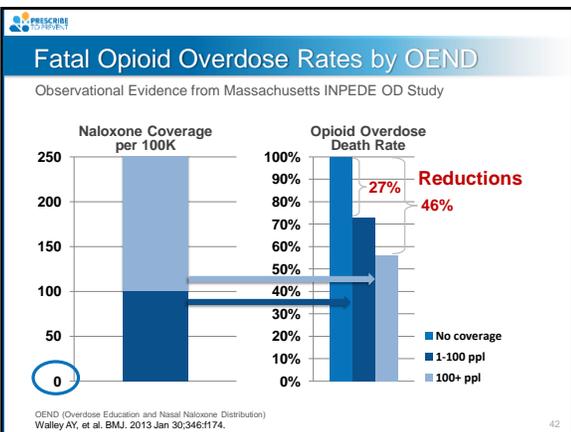
for Overdose Education and Naloxone Rescue Kits

- Most opioid users do not use alone
- Known risk factors:
 - Mixing substances
 - Abstinence
 - Using alone
 - Chronic medical illness
- Opportunity window:
 - Opioid overdose takes minutes to hours
 - Fentanyl overdose takes seconds
 - Reversible with naloxone
- Bystanders are trainable to recognize and respond to overdoses
- Fear of public safety

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Prescribe Naloxone, Save a Life

Overdose Rescue and Response with Naloxone

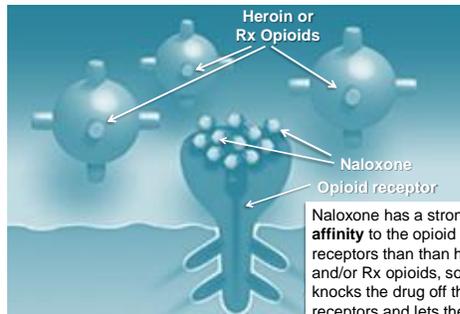
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How Naloxone Reverses Opioid Poisoning



Heroin or Rx Opioids

Naloxone

Opioid receptor

Naloxone has a stronger **affinity** to the opioid receptors than than heroin and/or Rx opioids, so it knocks the drug off the receptors and lets the person breathe again.

http://www.opioidprescribing.com/naloxone_module_1-landing

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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

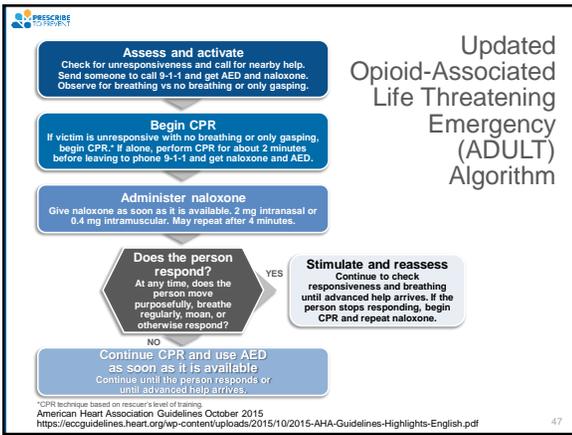
Shelf-life is 12-24 months
Store at room temperature to minimize degradation

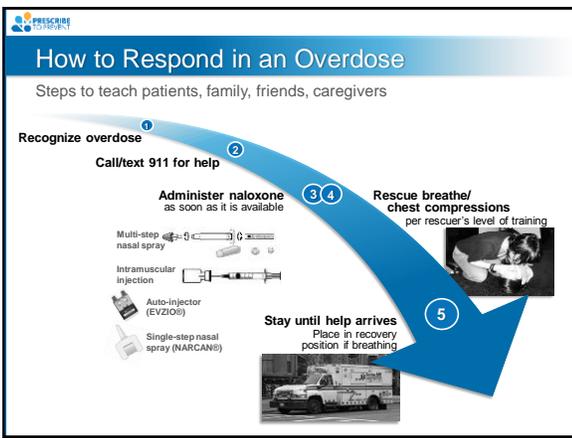


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Comparison of Opioid Overdose Response Order of Actions (2015)

American Heart Association Guidelines	Evzio™ & Narcan® Package Inserts	New York State Department of Health	World Health Organization
Recognize overdose, check for response	Recognize overdose, check for response	Recognize overdose, check for response	Recognize overdose, check for response
Call 911	Give naloxone	Call 911	Place in recovery position
Begin CPR (rescue breathing and chest compressions)	Call 911	Give naloxone OR Begin CPR (<i>if you know it</i>)	Call 911
Give naloxone	Place in recovery position	Give naloxone OR Begin CPR (<i>if you know it</i>)	Perform rescue breathing
If no response, continue CPR for 2-3 minutes; Repeat naloxone	If no response, repeat naloxone after 2-3 minutes	If no response, repeat naloxone after 2-3 minutes	Give naloxone; If no signs of life, perform chest compressions
Place in recovery position; Stay until help arrives	Stay until help arrives	Place in recovery position; Stay until help arrives	If no response, repeat naloxone after 2-3 minutes; Stay until help arrives





1 Recognize Overdose

Steps to teach patients, family, friends, caregivers

- If a person is not breathing or is struggling to breathe
 - Call out name
 - rub knuckles of a closed fist over the sternum
- Look for signs of overdose
 - Slow or absent breathing
 - Gasping for breath or a snoring sound
 - Pinpoint pupils
 - Blue/gray lips and nails

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1 Intoxicated or Overdose?

Steps to teach patients, family, friends, caregivers

Intoxicated	Overdose
<ul style="list-style-type: none"> • Small pupils • Drowsy, but arousable <ul style="list-style-type: none"> – Responds to sternal rub • Speech is slurred • Drowsy, but breathing <ul style="list-style-type: none"> – 8 or more times per minute 	<ul style="list-style-type: none"> • Small pupils • Not arousable <ul style="list-style-type: none"> – No response to sternal rub • Not speaking • Breathing slow or stopped <ul style="list-style-type: none"> – < 8 times per minute – May hear choking sounds or a gurgling/ snoring noise – Blue/gray lips and fingertips

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1 Intoxicated or Overdose?

Steps to teach patients, family, friends, caregivers

Intoxicated	Overdose
<ul style="list-style-type: none"> • Small pupils • Drowsy, but arousable <ul style="list-style-type: none"> – Responds to sternal rub • Speech is slurred • Drowsy, but breathing <ul style="list-style-type: none"> – 8 or more times per minute 	<ul style="list-style-type: none"> • Small pupils • Not arousable <ul style="list-style-type: none"> – No response to sternal rub • Not speaking • Breathing slow or stopped <ul style="list-style-type: none"> – < 8 times per minute – May hear choking sounds or a gurgling/ snoring noise – Blue/gray lips and fingertips

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1 Intoxicated or Overdose?

Steps to teach patients, family, friends, caregivers

Intoxicated	Overdose
<ul style="list-style-type: none"> • Small pupils • Drowsy, but arousable – Responds to sternal rub • Spontaneous breathing • Drowsy, but breathing – 8 or more times per minute 	<ul style="list-style-type: none"> • Small pupils • Not arousable • No breathing • Stopped breathing – 0 times per minute – May hear choking sounds or a gurgling/ snoring noise – Blue/gray lips and fingertips

Stimulate and observe (pointing to Intoxicated column)

Give naloxone Rescue breaths/ Chest compressions (pointing to Overdose column)

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1 Overdose Education and Naloxone Rescue

What your patients need to know:

Prevention - the Risks:	Recognition	Response - What to do:
<ul style="list-style-type: none"> • Mixing substances • Abstinence- low tolerance • Using alone • Unknown source • Chronic medical disease • Long acting opioids last longer 	<ul style="list-style-type: none"> • Unresponsive to sternal rub with slowed breathing • Blue lips, pinpoint pupils 	<ul style="list-style-type: none"> • Call/text for help - 911 • Administer naloxone • Rescue breathe/chest compressions (per rescuer's level of training) • Rescue position • Stay until help arrives

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2 Call/Text 9-1-1 for Help

Steps to teach patients, family, friends, caregivers

- After identifying an overdose, call or text 9-1-1 immediately
- Quicker response improves survival
- When calling or texting 9-1-1 report:
 - Someone is unresponsive and not breathing or struggling to breathe
 - Give a clear address and location



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3 4 Administer Naloxone

Steps to teach patients, family, friends, caregivers



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3 4 Rescue Breathing

Steps to teach patients, family, friends, caregivers

- Make sure airway is clear
- Place one hand on chin
- Tilt head back to open airway
- Pinch nose closed
- Give two slow rescue breaths into mouth
- Make sure chest rises with each breath
- Give 1 breath every 5 seconds until person can breathe on own
- If still unresponsive and you have naloxone available, get it at this time



*Provide CPR/chest compressions based on rescuer's level of training.

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5 Stay Until Help Arrives

Steps to teach patients, family, friends, caregivers

After administering naloxone:

- Continue rescue breathing with one breath every five seconds until emergency responders arrive
- After two-three minutes, if the person is still unresponsive with slow or no breathing, administer another dose of naloxone



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5 Stay Until Help Arrives
 Steps to teach patients, family, friends, caregivers

- **Do not leave the person alone** after giving naloxone
- If the person took a long acting opioid (e.g. methadone, OxyContin), he or she could go back into overdose after naloxone wears off
- Make sure the person does not take any more opioids

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5 Stay Until Help Arrives: Rescue Position
 Steps to teach patients, family, friends, caregivers

- If the responder has to leave at anytime – to call 911 or get naloxone – use the rescue position



Put the person on their side with their top leg and arm crossed over their body

- This position makes it difficult for them to roll over and lessens the chance of choking or vomiting caused by precipitated withdrawal

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Naloxone Rescue Kits

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Naloxone Prescribing Summary

- Prescribe naloxone rescue kits to people at risk for overdose
- Remember the risks we reviewed:
 - Opioid combinations (alcohol and/or benzodiazepines)
 - Opioid dose and purity changes
 - Previous overdose
 - Social isolation
 - Substance use disorder
 - Abstinence
 - Chronic medical and/or mental illness
- If you are in a state that permits 3rd party prescribing, also prescribe to friends or family of people who are at risk of an overdose

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Naloxone Conversation Starters

“Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can’t handle the opioids you take that day, or if you take opioids with alcohol or other drugs. Naloxone is a lifesaver, just like a seatbelt or a fire extinguisher.”

“These medications can be helpful but have a range of side effects, like slowing down or even stopping breathing completely. Naloxone can help if this happens by restoring breathing.”

“Opioid medications increase the risk of breathing emergency for the person who takes the opioid and anyone in their household. Naloxone is needed in case of emergency.”

“Let’s keep you and your family as healthy as possible with these medications in your house. Just in case, get naloxone.”

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	Injectable (and intranasal) generic	Intranasal branded	Injectable generic	Auto-injector branded
Brand name		Narcan Nasal Spray		Evzio Auto-Injector
Product comparison				
FDA approved	X (for IV, IM, SC)	X	X	X
Labeling includes instructions for layperson use		X		X
Layperson experience	X		X	X
Assembly required	X		X	
Fragile	X			
Can titrate dose	X		X	
Strength	1 mg/mL	4 mg/0.1 mL	0.4 mg/mL OR 4 mg/10 mL	0.4 mg/0.4mL
Total volume of kit/package	4 mg/4 mL	8 mg/ 0.2 mL	0.8 mg/2 mL OR 4 mg/10 mL	0.8 mg/0.8 mL
Storage requirements (All protect from light)	Store at 59-86 °F Fragile: Glass.	Store at 59-77 °F Excursions from 39-104 °F	Store at 68-77 °F Fragile: Glass.	Store at 59-77 °F Excursions from 39-104 °F
Cost/kit	\$\$	\$\$	\$	\$\$\$

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 PRESCRIBE TO PREVENT
Prescribe Naloxone, Save a Life

Legal Environment

Corey Davis, JD, MSPH
The Network for Public Health Law




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What are the basic legal issues around prescribing and dispensing Naloxone?



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Naloxone Legal Overview

- Prescribing to own patient is fully consistent with state and federal laws regulating prescription drugs
- Risk of liability is no higher than with other medications, and may be lower than some
- Most states have passed laws further limiting liability for naloxone prescription
- Most states permit naloxone prescription to third parties (friends, family members, etc.)
- Most states permit naloxone to be obtained from a pharmacy without the patient first seeing a prescriber



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EVIDENCE

General Prescribing Considerations

for Naloxone

Prescribers must ensure that any medication is prescribed:

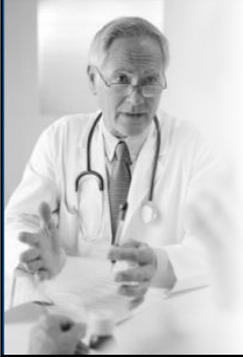
- In good faith
- In the usual course of professional practice
- For a legitimate medical purpose

A naloxone prescription issued for a patient in the course of the prescriber/patient relationship meets all three criteria.

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EVIDENCE

Prescribing Best Practices



Prescribers should ensure that patients understand:

- How to identify possible opioid overdose
- How to administer naloxone
- Risk of side effects including withdrawal
- Importance of calling 911
- Other ways (such as drug treatment) of reducing opioid overdose risk

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EVIDENCE

Review of Legal Environment

- Every clinician action entails some risk. However, risk of prescribing/dispensing naloxone not higher than any other medication
- In most states, naloxone prescribing carries lower risk than almost any other medication
- Outpatient naloxone prescription is a mainstream intervention formally supported by AMA, ASAM, APhA, CDC, etc.
- A recent review found no cases of suits filed against prescribers or dispensers of outpatient naloxone
- As with any medication, important to educate patient and answer any questions



 PRESCRIBE
ESSENTIALS

What is third-party prescribing, and how does it work with naloxone?



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 PRESCRIBE
ESSENTIALS

Third Party Prescribing

Third party prescribing is the prescription of a medication for use on a person with whom the prescriber doesn't have a provider/patient relationship – the “third party.”

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 PRESCRIBE
ESSENTIALS

Third Party Prescribing

In general, medication may only be prescribed in the normal course of professional practice:



```

graph LR
    A[1. Clinician examines patient] --> B[2. Clinician diagnoses patient]
    B --> C[3. Clinician prescribes appropriate medication]
  
```

Third party prescribing permits the prescriber to skip directly to step 3, the prescribing of the appropriate medication.

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Third Party Prescribing

Many patients at risk of overdose are not seen by a clinician due to:

- Wait time for appointment
- Expense, particularly for uninsured/underinsured
- Stigma, shame
- Lack of knowledge or motivation



Often, a third party (family member, friend) will seek assistance from a trusted practitioner

Third Party Prescribing

To increase access to naloxone



42 states have modified their laws to permit third party prescription

- In states where permitted, legal risk of third party prescribing is no different than first party prescribing
- Typically, prescription is in name of person who will be called on to help (friend, family member)

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Third Party Prescribing: Example Language

(A) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to:

- (i) a person at risk of experiencing an opiate-related overdose or
- (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.

(B) Such practitioner shall not, as a result of the professional's acts or omissions, be subject to any civil or criminal liability, or any professional disciplinary action.

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 PRESCRIBE
 IS POSSIBLE

Is it possible for pharmacists to dispense naloxone to patients who haven't first seen a prescriber?



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 PRESCRIBE
 IS POSSIBLE

Pharmacist Practice

Yes, in most states pharmacists may dispense naloxone w/o patient first obtaining a prescription via one or more mechanisms:

- Pharmacist prescribing
 - Permitted in at least 4 states (CT, ID, ND, NM)
- Collaborative practice agreements
 - Permitted in at least 11 states
- Standing orders for naloxone dispensing
 - Permitted in at least 34 states

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 PRESCRIBE
 IS POSSIBLE

Collaborative Practice

- Rules and requirements are very state-specific; some only permit “management,” not “initiation”
- All states require written agreement between prescriber and pharmacist that sets out terms of the agreement
- Successful naloxone implementations in several states
- As with all such arrangements, both prescriber and pharmacist must ensure patient meets criteria, understands uses and limitations of medication

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PRESCRIBER EDUCATION

Standing orders for naloxone dispensing

- Can also be thought of as “non patient-specific medication order”
- Authorizes naloxone to be dispensed to any person who meets specified criteria, as opposed to named patient
- Order must specify which actions to take, when they are to be taken, and who is to take them
- 34 states explicitly permit prescription and dispensing of naloxone via standing order
- 17 states permit naloxone to be dispensed by person not otherwise authorized to dispense medications

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PRESCRIBER EDUCATION

How does community distribution work?



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PRESCRIBER EDUCATION

Community-Based Distribution

Use of standing order to delegate dispensing, including to non-traditional dispensers

Seventeen states permit naloxone to be dispensed by individuals or orgs not otherwise authorized to dispense

As with all naloxone laws, there are important variations between states

Where permitted, liability protections generally apply to community distribution just as traditional dispensing

As with all standing orders, a physician or other prescriber must set the terms of dispensing, and is ultimately responsible

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 Do these laws address concerns related to legal liability?



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 **Addressing Naloxone Liability Concerns**

Yes, nearly every state has provided civil and/or criminal immunity to naloxone prescribers, dispensers, and administrators

- Prescriber civil immunity: 37 states
- Dispenser civil immunity: 37 states
- Lay administrator civil immunity: 41 states



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 **Overdose Good Samaritan Laws**

- Overdose bystanders often do not call 911
 - Fear arrest for drug possession, outstanding warrants or other reasons
- Overdose bystanders may fear that they could get in trouble if they administer naloxone to save someone
 - This is unlikely to happen, but has been a barrier, particularly at the organizational level



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