Overdose Prevention and Naloxone Rescue Kits for Prescribers and Pharmacists

Prescribe Naloxone, Save a Life

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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

2

Program Support

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

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Educational Objectives

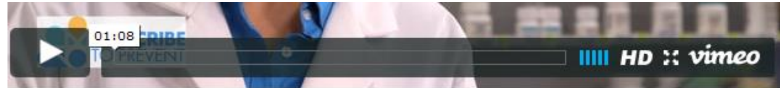
At the conclusion of this activity, participants will be better able to:

- 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

4

Video Vignettes

Embedded within this presentation are illustrative video vignettes showing interactions among a pharmacist, patient and prescriber, that demonstrate the core concepts of overdose prevention education, including naloxone rescue kits.



Videos will pop up automatically, and will have a play button as seen above. To view the video, please click on the play button.

You can also find a library of brief videos that demonstrate model conversations between prescribers, pharmacists, and patients, the link for which can be found in the right navigation bar on this page.

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Faculty

Alexander Y. Walley, MD, MSc
Boston University School of Medicine

Jeffrey Bratberg, PharmD, FAPhA
University of Rhode Island College of Pharmacy

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

Faculty have no relevant relationships to disclose. Faculty do not plan on discussing off-label/investigational uses of a commercial product.

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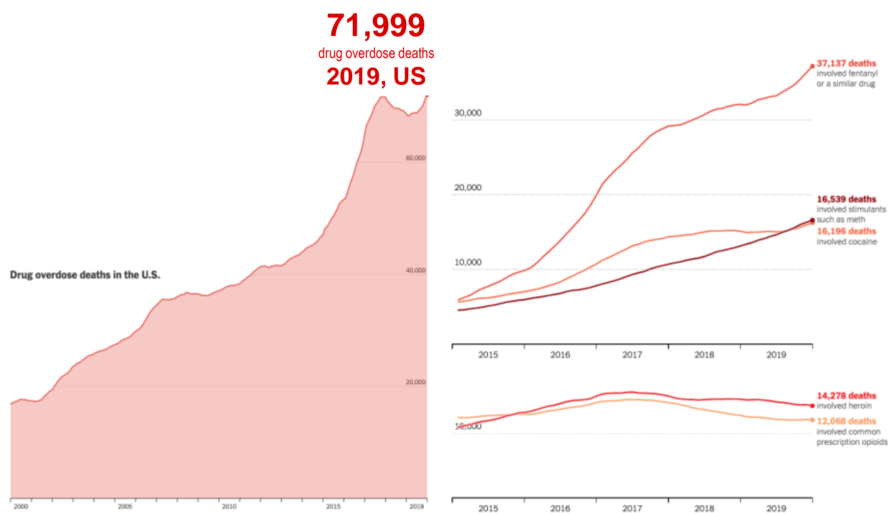
Epidemiology and Overdose Risks

Alexander Y. Walley, MD, MSc
Boston University School of Medicine

Fentanyl is driving increases in overall drug overdoses



Centers for Disease Control and Prevention

Opioid Overdoses

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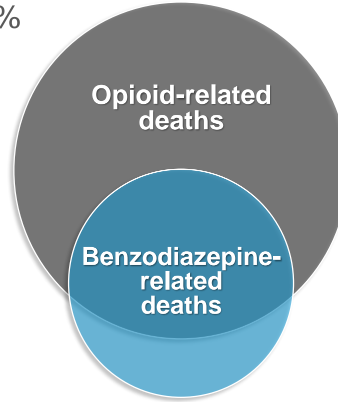
Benzodiazepines and Opioids

Jointly contribute to overdose deaths

- Benzodiazepines are present in 31% of opioid-related overdose deaths
- Opioids are present in 75% of benzodiazepine-related overdose deaths[1]
- Among people prescribed opioids, the risk of overdose deaths is 3.8 times higher for people prescribed benzos also[2]



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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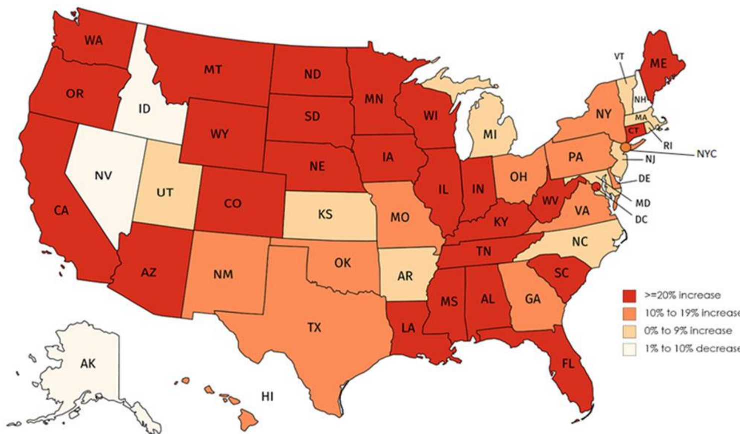
States Affected by Fentanyl Overdose Incidents and Deaths

June 2019 to May 2020



Percentage change in 12-months ending provisional data on all fatal drug overdoses, 50 states, the District of Columbia, and New York City: 12-months ending in June 2019 to 12-months ending in May 2020

Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic

HAN
HEALTH ALERT NETWORK
This is an official CDC HEALTH ADVISORY

CDC Health Alert Network CDCHAN-00438

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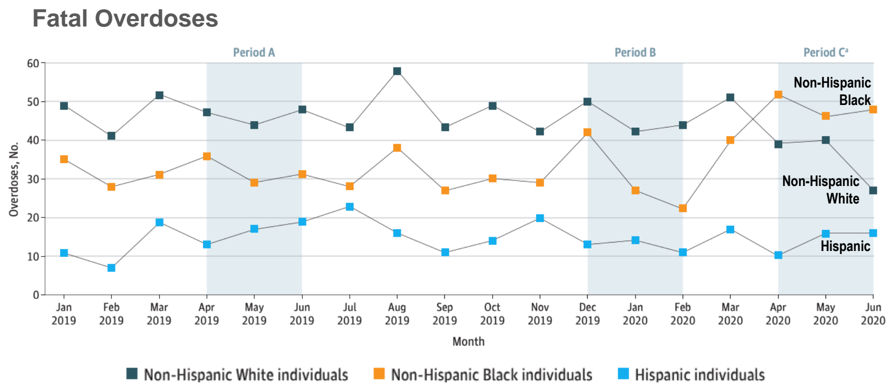
Changes in Overdose Rates Vary by Race and Ethnicity

Magnitude of increase in drug overdose deaths involving synthetic opioids other than methadone per 100,000 population, by ethnicity, 2013-2017

Centers for disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System – Mortality, 2013-2017

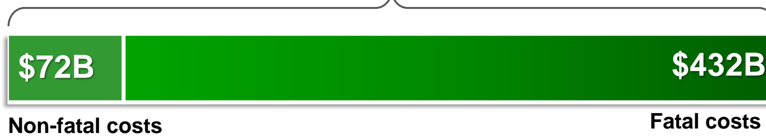
Philadelphia During the Pandemic

Fatal opioid overdoses surged among Blacks



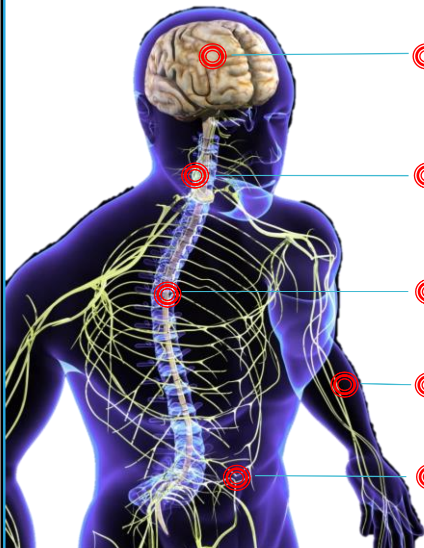
Khatri UG, Pizzicato LN, Viner K, et al. Racial/Ethnic Disparities in Unintentional Fatal and Nonfatal Emergency Medical Services–Attended Opioid Overdoses During the COVID-19 Pandemic in Philadelphia. *JAMA Netw Open.* 2021;4(1):e2034878.

Estimated Cost of the Opioid Crisis, 2015



White House Council of Economic Advisors, 2017.

How do opioids affect breathing?



Opioid Receptors Throughout the Body

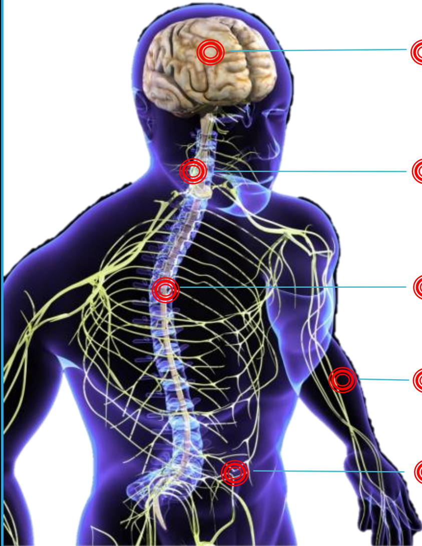
BRAIN
Opioid receptors in the cerebellum, nucleus accumbens and hypothalamus control pain perception, emotion, reward and addiction

BRAINSTEM
Opioid receptors in the medulla oblongata control 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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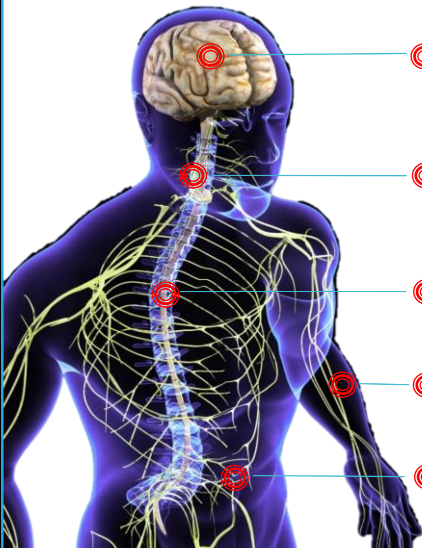

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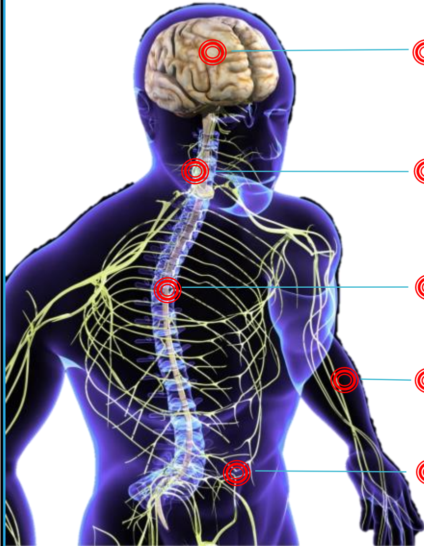

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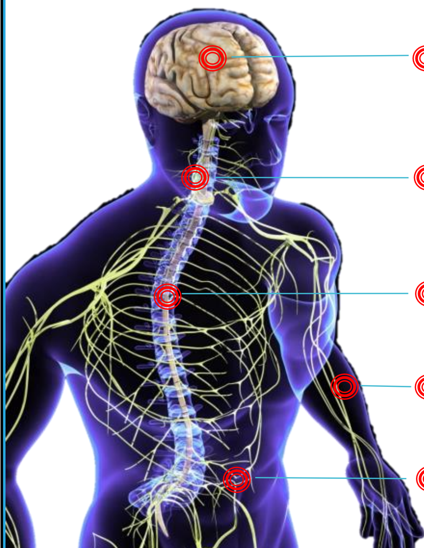

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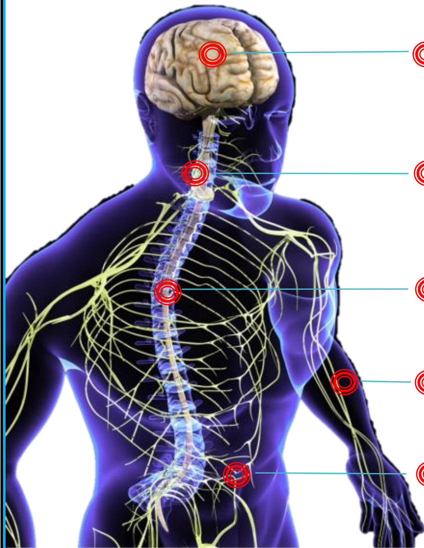

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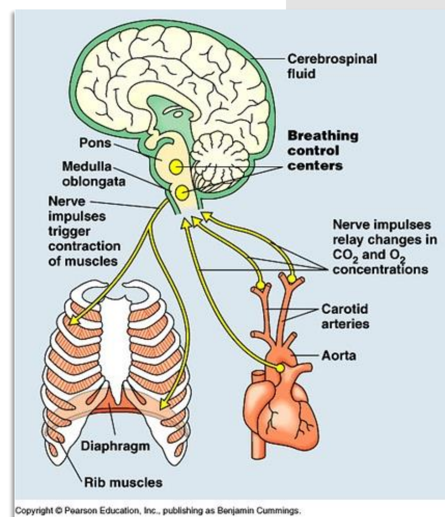
Opioid Overdose

Opioid Overdose Causes

- Reduced sensitivity to changes in O_2 and CO_2 outside of normal ranges
- Decreased tidal volume and respiratory frequency
- Respiratory failure and death due to hypoventilation

Opioid Overdose Toxidrome Develops Over Seconds 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

Opioid Dose and Changes in Purity

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

Previous Overdose

Social Isolation
Using alone

Addiction History

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

Abstinence
- Release from incarceration
- Completion of detoxification
- Relapse

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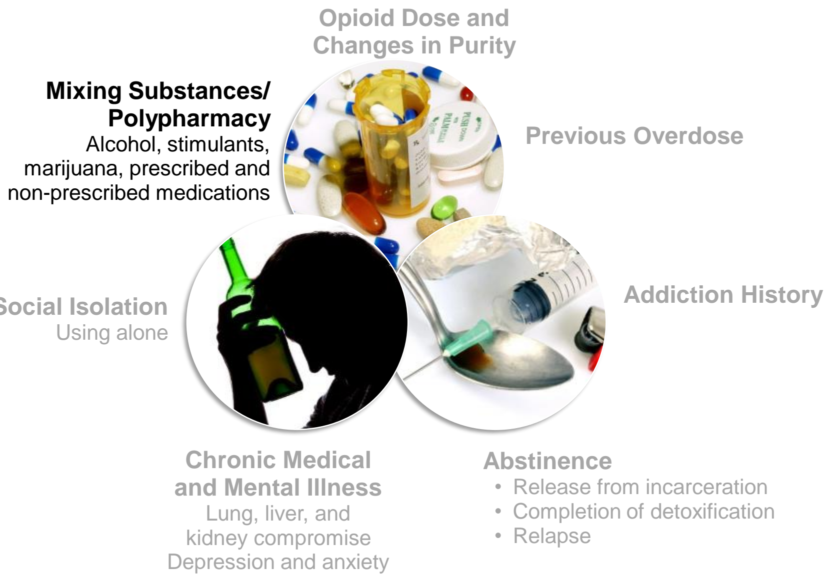

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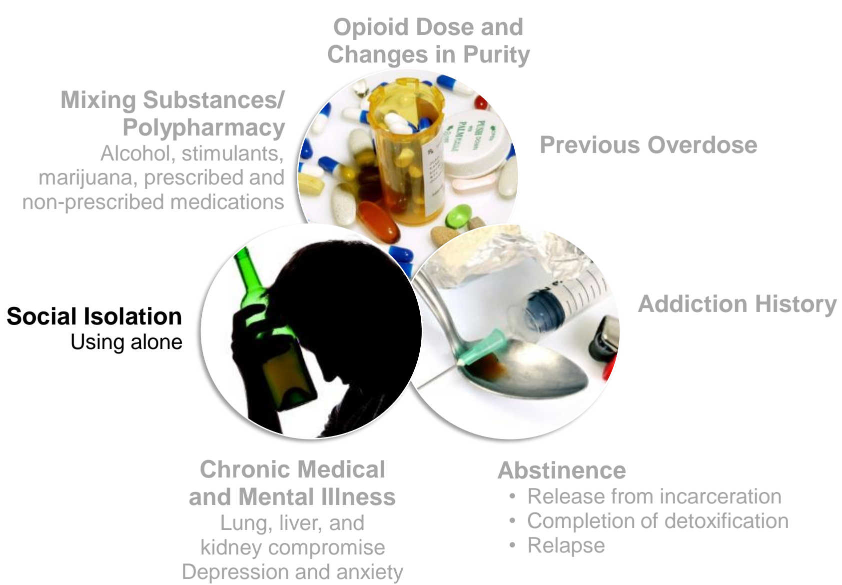

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For Patients: How to Prevent Overdose

- Only take prescription opioids prescribed to you and as directed
- If you have a problem with opioids, I can help you be safer and find treatment
- Ensure your prescribers and pharmacists know of all medications you are on
- It's best not to mix opioids with other drugs or alcohol

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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

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Taking an Overdose History and Delivering Prevention Education

For Prescribers: Assess Overdose Risk

as part of a Patient's History

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

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Making a Risk Reduction Plan with Your Patients

Ask your patients:

- How do you protect yourself against overdose?
- How do you keep your medications safe at home?

And their loved ones:

- What is your plan if you witness an overdose in the future?
- Have you received training to prevent, recognize, or respond to an overdose?

ASAM American Society *of* Addiction Medicine

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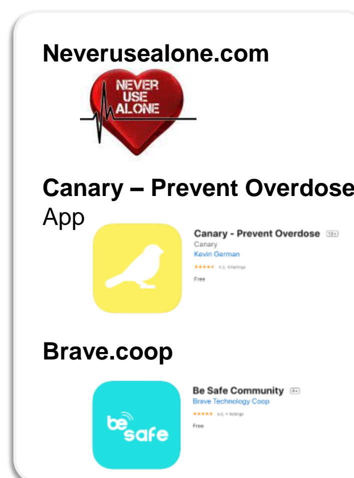
Making a Risk Reduction Plan with Your Patients

- **Start low and go slow**
  - Use a small amount and give slowly to gauge potency
- **Before COVID pandemic:**
  - Use with other people present
  - Take turns to prevent simultaneous overdose
  - Have naloxone ready and an immediate way to call for help
- **Since COVID pandemic**
  - When using alone, connect with someone by phone or video to monitor while and immediately after using



Especially important for people using fentanyl… now more complicated with COVID-19 pandemic

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Naloxone Rescue Kits as Overdose Prevention

Rationale
for Overdose Education and Naloxone Rescue Kits

- Most people who use opioids 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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Endorsements for Naloxone Rescue Kits

American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

"**APhA** supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose"
www.pharmacist.com/policy/controlled-substances-and-other-medications-potential-abuse-and-use-opioid-reversal-agents-2

AMA
AMERICAN MEDICAL ASSOCIATION

"The **AMA** has been a longtime supporter of increasing the availability of Naloxone for patients, first responders and bystanders who can help save lives and has provided resources to bolster legislative efforts to increase access to this medication in several states."
www.ama-assn.org/ama/pub/news/news/2014/2014-04-07-naxolene-product-approval.page

ASAM
American Society of Addiction Medicine

Public Policy Statement on the Use of Naloxone for the Prevention of Drug Overdose Deaths

ASAM Board of Directors April 2010

"Naloxone has been proven to be an effective, fast-acting, inexpensive and non-addictive opioid antagonist with minimal side effects... Naloxone can be administered quickly and effectively by trained professional and lay individuals who observe the initial signs of an opioid overdose reaction."
www.asam.org/docs/publicy-policy-statements/1naloxone-1-10.pdf

"I, **Surgeon General of the United States Public Health Service**, VADM Jerome Adams, am emphasizing the importance of the overdose-reversing drug naloxone… knowing how to use naloxone and keeping it within reach can save a life."
https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html

World Health Organization
substance use
Community management of opioid overdose

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

"It is clear from the data that there is still much needed education around the important role naloxone plays in reducing overdose deaths. The time is now to ensure all individuals who are prescribed high-dose opioids also receive naloxone as a potential life-saving intervention."
~ CDC Director Robert R. Redfield, M.D.
https://www.cdc.gov/media/releases/2019/p0806-naloxone.html

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Strategies and Guidelines

SAMHSA
Opioid Overdose Prevention TOOLKIT

Opioid Use Disorder Facts
Five Essential Steps for First Responders
Information for Prescribers
Safety Advice for Patients & Family Members
Recovering From Opioid Overdose

SAMHSA

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

HHS.gov — U.S. Department of Health & Human Services

FOR IMMEDIATE RELEASE
December 19, 2018

Contact: ASH Press Office
202-205-0143
ashmedia@hhs.gov

HHS recommends prescribing or co-prescribing naloxone to patients at high risk for an opioid overdose

Adm. Brett P. Giroir, MD, assistant secretary for health and senior advisor for opioid policy, today released guidance - PDF for healthcare providers and patients detailing how naloxone – the opioid overdose reversal drug – can help save lives and should be prescribed to all patients at risk for opioid complications, including overdose.

"Given the scope of the opioid crisis, it's critically important that healthcare providers and patients discuss the risks of opioids and how naloxone should be used in the event of an overdose," said Adm. Giroir. "We have begun to see some encouraging signs in our response to the opioid crisis, but we know that more work is required to fully reverse the decades-long epidemic. Co-prescribing naloxone when a patient is considered to be at high risk of an overdose, is an essential element of our national effort to reduce overdose deaths and should be practiced widely."

To reduce the risk of overdose deaths, the guidance released today reinforces and expands upon prior CDC guidelines. It recommends that clinicians prescribe or co-prescribe (prescribed in conjunction with additional medication) naloxone to individuals at risk for opioid overdose, including, but not limited to: individuals who are on relatively high doses of opioids, take other medications which enhance opioid complications or have underlying health conditions. By co-prescribing, or prescribing naloxone to at risk individuals, patients and their loved ones could be better equipped for a possible complications of overdose, including slowed or stopped breathing. Clinicians should also educate patients and those who are likely to respond to an overdose, including family members and friends, on when and how to use naloxone in its variety of forms.

2018 Opioid Overdose Prevention Toolkit: https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742
CDC Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/drugoverdose/prescribing/guideline.html

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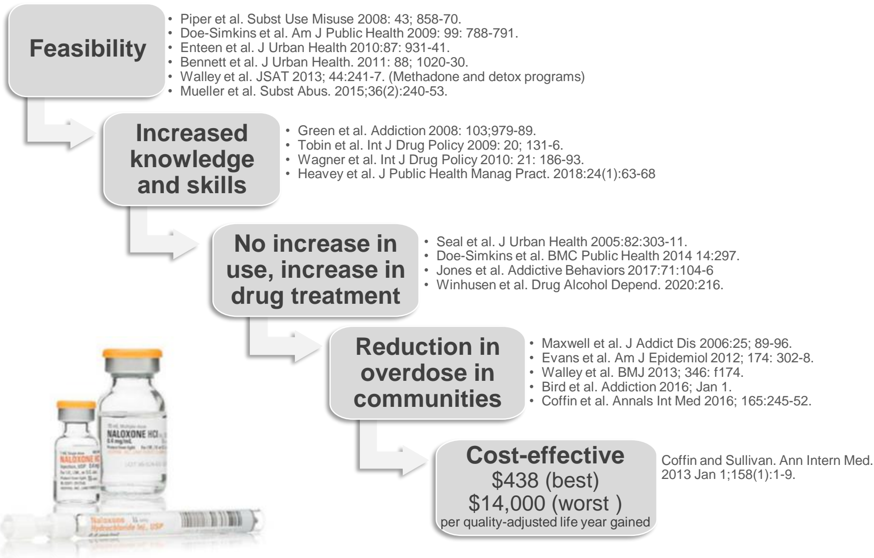
Evaluations

of Overdose Education and Naloxone Distribution Programs



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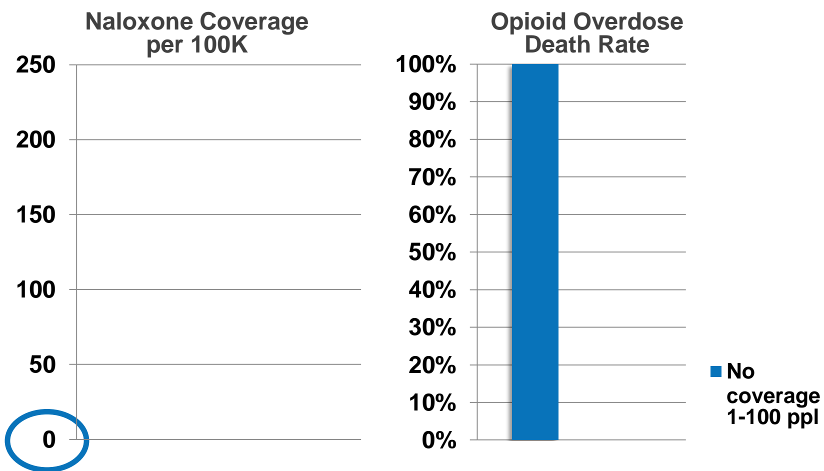
Fatal Opioid Overdose Rates by OEND

Observational Evidence from Massachusetts INPEDE OD Study



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OEND (Overdose Education and Nasal Naloxone Distribution)
Walley AY, et al. BMJ. 2013 Jan 30;346:f174.

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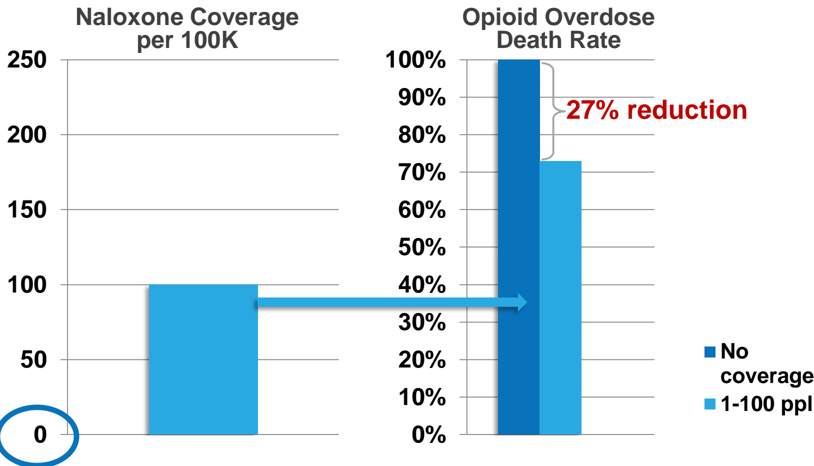

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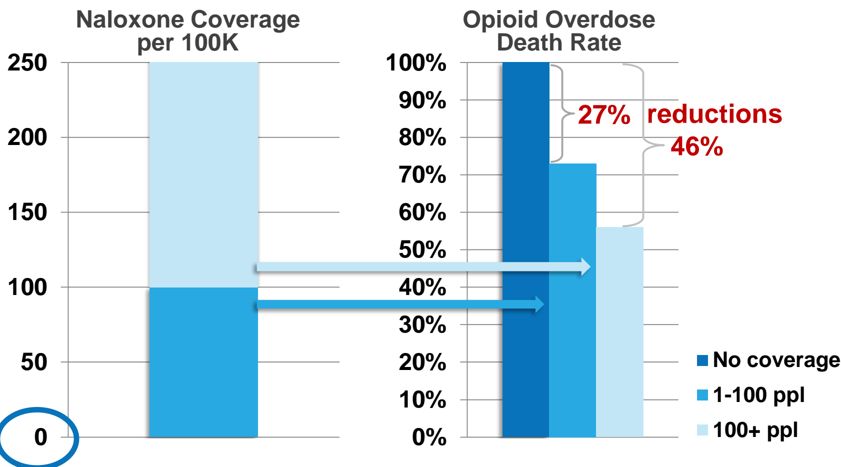

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Co-prescribing Naloxone and ED Visits

Annals of Internal Medicine — ORIGINAL RESEARCH

Nonrandomized Intervention Study of Naloxone Coprescription for Primary Care Patients Receiving Long-Term Opioid Therapy for Pain

Phillip O. Coffin, MD, MIA; Emily Behar, MA; Christopher Rowe, MPH; Glenn-Milo Santos, PhD, MPH; Diana Coffa, MD; Matthew Bald, MD; and Eric Vittinghoff, PhD

Objective: To evaluate the feasibility and effect of implementing naloxone prescription to patients prescribed opioids for chronic pain at 6 safety-net primary care clinics

Results

- 38% of 1985 patients receiving long term opioids co-prescribed naloxone rescue kits
  - Patients with higher opioid doses and previous opioid-related ED visits were more likely to be prescribed naloxone kits
- Opioid-related ED visits were reduced by 47% at 6 months and 63% at 12 months among those who were co-prescribed naloxone, compared with those who were not
- No change was detected in the net prescribed opioid doses for patients who were co-prescribed naloxone

Coffin PO, et al. Ann Intern Med. 2016 Aug 16;165(4):245-52.

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Risk Compensation and Moral Hazard

Does naloxone distribution increase drug use?

Naloxone

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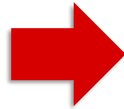
Risk Compensation and Moral Hazard

Naloxone distribution does not increase drug use

Naloxone



Maxwell, et al. Journal of Addictive Diseases, 2006.
Seal, et al. Journal of Urban Health, 2005.
Wagner et al., 2010 International Journal of Drug Policy.
Doe-Simkins, et al. BMC Public Health, 2014.
Jones, et al. Addictive Behaviors 2017:71:104-6.

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Overdose Rescue and Response with Naloxone

Jeffrey Bratberg, PharmD, FAPhA
Clinical Professor
University of Rhode Island
College of Pharmacy

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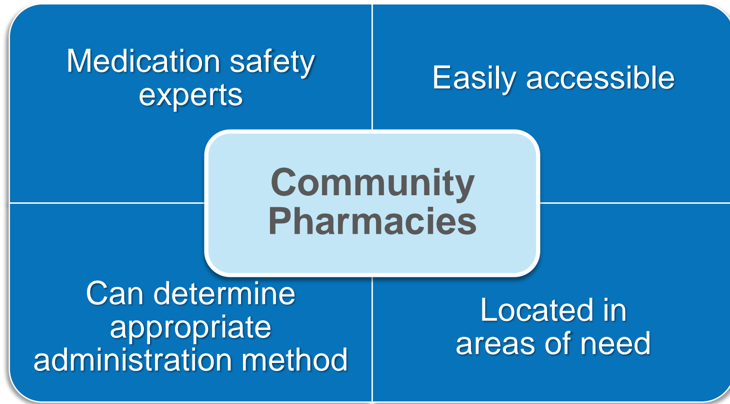
Why distribute through community pharmacies?



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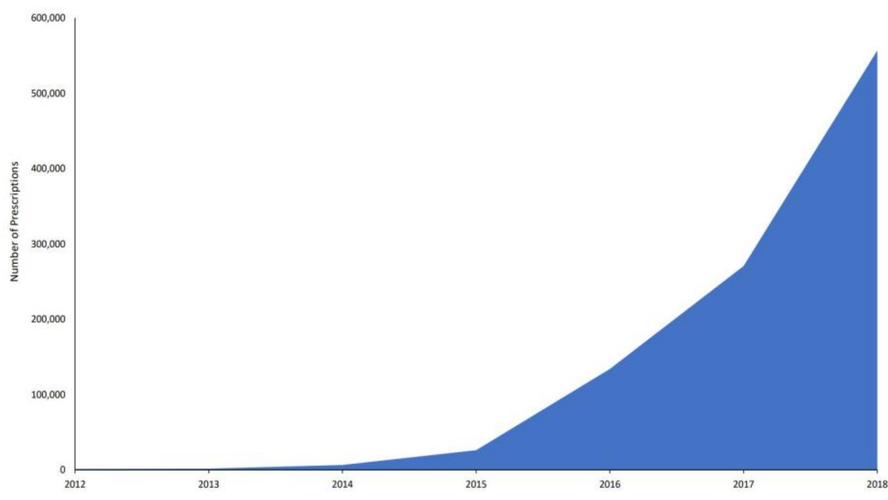
Naloxone Dispensing from U.S. Retail Pharmacies, 2012-2018



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Guy GP, et al. MMWR Morb Mortal Wkly Rep. 2019 Aug 9; 68(31): 679–686.
https://emergency.cdc.gov/coca/ppt/2019/Naloxone-Prescribing-COCA-Call-Slides-Final-09.17.19.pdf

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#vitalsigns
AUG. 2019

Life-Saving Naloxone from Pharmacies

More dispensing needed despite progress

CDC Vitalsigns™

2x
The number of prescriptions for naloxone doubled from 2017 to 2018.

1 in 70
Only 1 naloxone prescription is dispensed for every 70 high-dose opioid prescriptions.

3x
Rural counties are nearly 3 times more likely to be ranked low dispensing than metropolitan counties.

https://www.cdc.gov/vitalsigns/naloxone/index.html

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Many factors contribute to the problem.

- Most (71%) of Medicare prescriptions for naloxone required a copay compared to 42% for commercial insurance
- Primary care providers only prescribed about 2 naloxone prescriptions for every 100 high-dose opioid prescriptions
- Naloxone dispensing is 25 times greater in the highest-dispensing counties than the lowest

CDC Opioid Prescribing Guideline: https://bit.ly/2howXqN
HHS Opioid Guideline: https://bit.ly/2EEh8YO
https://www.cdc.gov/vitalsigns/naloxone/index.html

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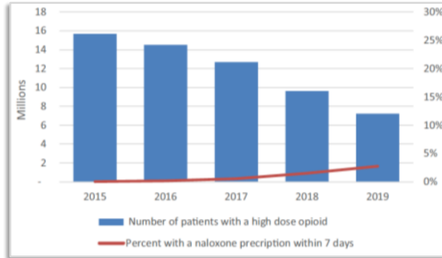
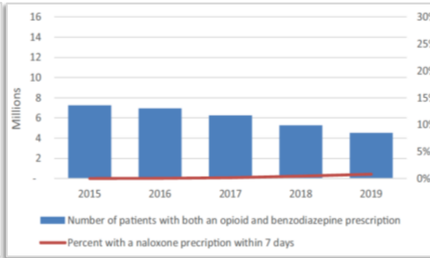
Percent of Patients at Increased Risk of Overdose Receiving a Concurrently Dispensed Naloxone Prescription within 7 days, 2015-19



High-dose Opioid
(≥ 50 morphine milligram equivalents/day)



Opioid + Benzodiazepine Prescription
(dispensed both an opioid and benzodiazepine prescription within 7 days)

Guy GP Jr, et al. J Gen Intern Med. 2021 Mar 9. doi: 10.1007/s11606-021-06662-3.

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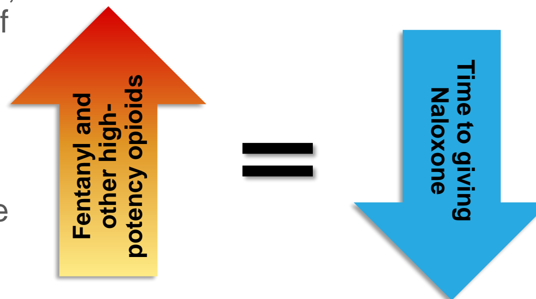
Fentanyl and Naloxone

- Carry naloxone
- Tell others where it is
- Keep it handy

- Fentanyl acts in seconds to minutes, so administration of naloxone needs to be faster
- When respiratory depression due to fentanyl occurs, the faster naloxone is administered, the greater the chance of benefit and lives saved



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PRESCRIBE TO PREVENT

Naloxone Fast Facts

- Although serious adverse events have been reported from naloxone, most events are related to opioid withdrawal, and even then, are rarely seen
- Naloxone has **no effect**, and therefore **no adverse effects**, in people who have **no opioids** in their body
- Naloxone users can be effectively trained in minutes
- A randomized controlled trial that compared the intramuscular and intranasal routes found comparative efficacy for reversal of respiratory depression
- No changes in naloxone drug concentration followed exposure to heat or freeze-thaw cycles for up to 28 days compared to room temperature maintenance

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More Naloxone Fast Facts

- Family members of people at risk of overdose are highly motivated to obtain and use naloxone; Good Samaritans, people who live, work with, and care about people who use opioids all may ask for naloxone at the pharmacy counter
- A majority of people who died from opioid overdose in one state had visited a pharmacy for opioid prescriptions in the month prior to death
- Heroin users who had access to naloxone decreased their drug use and accessed treatment more frequently

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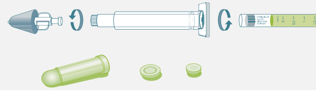
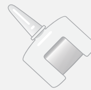
A MULTI-STEP NASAL SPRAY
2 mg/2 mL



B INTRAMUSCULAR VIAL & PRE-FILLED SYRINGE
0.4 mg/1 mL & 5 mg/0.5 mL

C SINGLE-STEP NASAL SPRAY
4 mg & 8 mg formulations



D INTRAMUSCULAR AUTO-INJECTOR
2 mg/0.4 mL DISCONTINUED 10.30.20

Types of Naloxone

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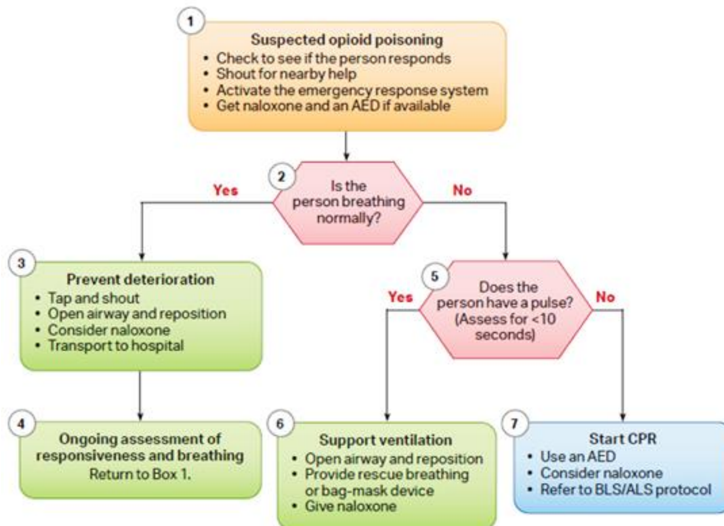

American Heart Association Opioid-Assisted Emergency for Healthcare Providers Algorithm

Dezfulian C, Orkin AM, Maron BA, et al. Circulation. 2021;143(16):e836-e870. Reproduced with permission.

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Pharmacists: Primary Care and Public Health Professionals

Public Health
- Immunizations
- Medication therapy management
- Linkage to specialist care
- Patient and community education
- Emergency preparedness, mitigation, and response

Community Harm Reduction
- Naloxone
- Non-prescription syringes access
- Treatment as Prevention (HIV, HCV)
- Point-of care testing (HIV, COVID-19)
- Medications for opioid use disorder (MOUD)

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Strand MA, et al. Prev Chronic Dis 2020;17:8.
Strand MA, et al. Prev Chronic Dis. 2020 Jul 23;17:E69.
Bratberg JP, et al. JACCP 2020;3(2):400–3.
Thomson K, et al. Prev Med 2019;124:98–109.
Mospan CM. J Am Pharm Assoc (2003) 2019;59(5):613–4.
Bishop C, et al. Res Social Admin Pharm 2019;15(6):627–31.
Thakur T, et al. Pharmacy 2019;7(2):60.
Freeland C, et al. Prev Chronic Dis 2020;17:200062.
Coon SA, et al. JACCP: [cited 2020 Sep 29].
Kulczycki A, et al. J Am Pharm Assoc (2003). 2020 Sep-Oct;60(5):686-693.
Strand MA, Res Social Adm Pharm. 2016 Mar-Apr;12(2):247-56.

Pharmacist Responsibility for Overdose Prevention

"I've learned that even if I have personal beliefs, it's the patients safety that matters the most so I need to put my personal beliefs aside and promote and dispense naloxone for the safety of others. I will do my duty as a pharmacist to promote the health and well-being of the community as a whole and that means doing my part in spreading awareness about naloxone."

– *UNM Student Pharmacist*

"I believe we have to, as pharmacists, expand what we're doing instead of just pill pushers, per se. We have to really help, pretty much help the healthcare system out and perform these services [counsel on overdose prevention] which we could easily perform and pretty much it would be a lot more convenient for people, too … I mean, that's what we were trained to do. And it would be nice to actually use some of those skills."

– *Pharmacist, PRI231, p17*

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Bachyrycz A, et al. Curr Pharm Teach Learn. 2019 Feb;11(2):166-171.
Zaller ND, et al. Subst Use Misuse. 2013 Jun;48(8):590-9.

Offering a naloxone prescription can increase communication, trust and openness between patients and providers

"By being able to offer something concrete to protect patients from the danger of overdose, I am given an opening to discuss the potential harms of opioids in a non-judgmental way."

– *San Francisco primary care provider*

Naloxone can increase:

- Communication
- Trust
- Openness

San Francisco Department of Public Health. Opioid Stewardship and Chronic Pain: A Guide for Primary Care Providers. San Francisco, CA. October 2017. https://www.chcf.org/wp-content/uploads/2017/12/PDF-OpioidStewardshipChronicPain.pdf Accessed on 15 June 2021.

Communicating with Patients About Naloxone

- The word "overdose" may have negative connotations and prescription opioid users may not relate to it

Some patients have overdosed and don't realize it

- Out of 60 patients on opioid therapy for pain, 22 (37%) had stopped breathing or required help to be woken up due to opioids

45% of these patients denied overdosing calling it a bad reaction

San Francisco Department of Public Health. Opioid Stewardship and Chronic Pain: A Guide for Primary Care Providers. San Francisco, CA. October 2017. https://www.chcf.org/wp-content/uploads/2017/12/PDF-OpioidStewardshipChronicPain.pdf Accessed on 15 June 2021.

Key Skills of Motivational Interviewing (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."

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Use of Motivational Interviewing (MI) for Opioid Use Disorder

Key Steps

1. 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 __________."

Refer to overdose as a "breathing emergency" when someone is resistant to messages of their personal risk of overdose

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Key Steps of MI

2. **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 ________________?"

3. Ask for patient/caregiver thoughts on the new information

4. **Address concerns** and reframe when needed:
   - "So you're wondering…" "That's a great question..."
   - Conditional commitment: "It sounds like if X could be managed/avoided/provided you would consider Y..."

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Common Mistakes to Avoid

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"

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

"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

Combination benzodiazepine + opioid is not "a little risky…"

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2021 APhA House of Delegates Action

The American Pharmacists Association (APhA) has affirmed

People First Language

APhA encourages the use of "people first" language in all written and oral forms of communication.

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Non-Judgmental Language "Words Matter"

Words to Avoid	Words to use
Addict	Person with substance use disorder
Alcoholic	Person with alcohol use disorder
Drug problem, drug habit	Substance use disorder
Drug abuse	Drug misuse, harmful use
Drug abuser/junkie	Person with substance use disorder
Drug user	Person who uses drugs/injects drugs
Clean	Abstinent, not actively using
Dirty	Actively using
A clean drug screen	Testing negative for substance use
A dirty drug screen	Testing positive for substance use
Former/reformed addict/alcoholic	Person in recovery/person in long-term recovery
Opioid replacement/methadone maintenance	Medication-assisted treatment

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https://cpnp.org/ed/presentation/2018/pharmacist-guide-harm-reduction-strategies-people-who-inject-drugs-0?view=link-1-1530212066&.pdf

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Barriers

Education / Awareness
- Standing order rules
- integration into pre- and post-licensure training

Pharmacy Stocking
- Recalls / Shortages
- Refusal to stock / Limited formulations stocked

Cost

Stigma
- Public / Caregivers
- Pharmacists / Prescribers

Access by High-Risk Populations
- Criminalization of drug use
- Corrections OEND limitations
- Lack of harm reduction and syringe service programs

Health Records Integration
- Electronic health record (EHR) / prescription record integration
- Prescription drug monitoring program (EHR & naloxone integration)

Forms of Stigma

https://harmreduction.org/issue-area/issue-drugs-drug-users/understanding-drug-related-stigma/

Perpetuating stigma or reducing risk?

Perspectives on Pharmacy-based Naloxone

"If it was up to me, every single opiate prescription that was being filled would also be dispensed with Narcan.

Even if the patients aren't using them or the families aren't using it, it would help, I think, over time, to kind of reduce the stigma and that Narcan is only for heroin."

– RI Pharmacist 2016

"[W]e can say, you know, 'I have to hand this out to you on any prescription refill, and this is just to let you know there is a little section here on Narcan and if you have any questions, please feel free to ask.'

And leave it at that and move on."

– MA Pharmacist 2016

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Green TC, Case P, Fiske H, et al. J Am Pharm Assoc (2003). 2017;57(2S):S19-S27.e4.

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2021 APhA House of Delegates Action

- The American Pharmacists Association (APhA) supports policies and practices that increase the availability and affordability of naloxone
- APhA supports the availability of naloxone as both a prescription and non-prescription medication
- APhA encourages pharmacists and payers to ensure equitable access to and affordability of at least one naloxone formulation regardless of prescription status
- APhA encourages payers to provide fair reimbursement to dispensers of naloxone

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Pharmacist Offers Universal Screening

"We offer naloxone to everyone who takes these medications.

I can answer your questions and tell you how to use them."

Patient and Caregiver Requests

"Where can I get naloxone?"

Do your part!

Actively offer naloxone and honor requests

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Prescriptions

- Any opioid prescription > 50 MME
- Has prescription for IR and ER opioid
- Any risky opioid/benzodiazepine combination
- Any buprenorphine

Patients

- Previous naloxone use
- Opioid Use Disorder diagnosis
- Opioid Overdose
- Substance Use Disorder (SUD)
- Alcohol Use Disorder (AUD)
- Mental health conditions
- Respiratory or neurologic conditions that affect breathing

Populations

- Friends and family of those at risk
- OTC syringe buyers
- People entering/leaving:
  - Opioid treatment
  - SUD treatment
  - Correctional institutions
  - Behavioral health

Offer Naloxone for Higher Risk Scenarios

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» Safety Policies

As service providers and public health professionals who work with people who use drugs, we know that sometimes people use drugs in our facilities. Particularly in the case of injection drug use, a bathroom or other private area at a trusted services agency may be the safest and most secure location when the alternative is using outdoors, in business bathrooms, or similarly problematic places.

Many programs, and even businesses, have taken steps to improve safety and hygiene in places where people might use drugs. The first goal is to protect clients and staff. When done thoughtfully, such strategies can also foster therapeutic relationships by promoting open and frank dialog with drug using clients.

Examples of steps that can be taken include:

- Training staff on overdose response including the use of naloxone, equipping spaces or individuals with overdose rescue kits, and adopting policies and procedures for overdose management.

This is a sample policy developed for on-site overdoses – it was created for pharmacies, but can easily be adapted to different venues.

- In an annual survey, 17% of pharmacists in Rhode Island and Massachusetts reported having responded to an overdose at their practice site
- 34% had a protocol in place for responding and knew where to find it
- Having a protocol and knowing where to find it is associated with greater comfort in providing naloxone education to patients

Green TC, Soipe A, Baloy B, et al. Subst Abus. 2020 Mar 18:1-5.

On-site Overdose Response Protocol

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Legal Environment

Corey Davis, JD, MSPH

The Network for Public Health Law

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What is the basic legal landscape regarding 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 likely lower than many
- All states have passed laws further limiting naloxone-related liability
- Most states permit naloxone prescription to third parties and via standing orders and similar mechanisms
- Most states permit naloxone to be distributed by individuals not otherwise permitted to distribute medications

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*Davis CS, Carr D, Southwell J, Beletsky L. *Engaging Law Enforcement in Overdose Reversal Initiatives: Authorization and Liability for Naloxone Administration.* American Journal of Public Health 2015; 105(8):1530-7.

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Prescribers should ensure that patients understand:

- How to identify possible opioid overdose
- How to administer naloxone
- Importance of calling 911
- Other ways of reducing opioid overdose risk (including evidence-based treatment, if appropriate)

Prescribing Best Practices

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

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Third Party Prescribing

Third party prescribing is the prescription of a medication to someone other than the person to whom it's likely to be administered

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Third Party Prescribing

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

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:
  - Expense, particularly for uninsured/underinsured individuals
  - Stigma, shame
  - Lack of knowledge
- Often, a family member or friend will seek assistance from a trusted practitioner. Third party prescribing permits those practitioners to prescribe naloxone to that individual, even though they aren't the person at risk.

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Third Party Prescribing

- Legal risk of third party prescribing is no different than traditional 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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Naloxone Prescription Mandates

- As of late 2020, ten states mandate that naloxone be prescribed or offered in certain situations
- In two states (CA and OH) prescribers are only required to offer a prescription, while in eight (AZ, FL, NJ, NM, RI, VA, VT, WA) they are required to provide a prescription for the medication
- Circumstances that trigger these requirements vary from state to state, but most are related to co-prescribing of opioids or where the patient is at increased risk of overdose

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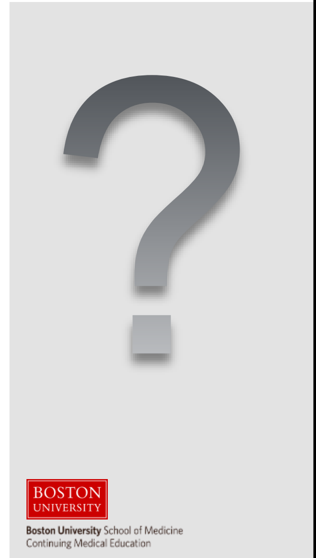
Is it possible for pharmacists to dispense naloxone to patients who haven't first seen a prescriber?



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Pharmacist Practice

Yes, in every state pharmacists may dispense naloxone w/o patient first seeing another prescriber via one or more mechanisms:

- Pharmacist prescribing
  - Permitted in at least 8 states (CT, ID, ME, ND, NM, OK, OR, WY)
- Statewide protocols
  - Permitted in at least 17 states
- Standing orders for naloxone dispensing
  - Permitted in at least 44 states

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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 a named patient
- 44 states explicitly permit prescription and dispensing of naloxone via standing order
  - In at least 23 states standing orders for naloxone distribution have been issued by a state official, and many pharmacy chains have issued them for their pharmacies

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How does community distribution work?

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Community-Based Distribution

- Thirty-eight states permit naloxone to be distributed by laypeople
- Liability protections generally apply to community distribution just as traditional dispensing
- In most states, naloxone can be distributed outside of medical settings via standing orders
- As with all naloxone distribution, a physician or other prescriber must set the terms of dispensing

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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: 44 states
- Dispenser civil immunity: 43 states
- Lay administrator civil immunity: 45 states

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Overdose Good Samaritan Laws

Overdose bystanders often do not call 911

- Sometimes people are afraid of getting arrested for drugs that they may have, or because they may be on probation or parole
- Many times they don't want to get the person who overdose in trouble, even if they themselves have nothing to fear

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Overdose Good Samaritan Laws

- Every state except TX, KS, and WY has a law that provides limited criminal immunity to Good Samaritans who summon help in an overdose
- This immunity is typically limited to minor crimes, but recent laws are more protective
  - For example, 25 states now provide protection from probation or parole violations
- Education and buy-in is sometimes lacking

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Review of Legal Environment

- Legal risk of prescribing/dispensing naloxone is no higher than any other medication
- In most states, naloxone prescribing carries lower risk than almost any other medication
- Naloxone prescription is a mainstream intervention supported by AMA, APhA, ASAM, and many other organizations
- 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

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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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