Disclosure

- Thomas Franko is a consultant for WebMD

Objectives

- Examine statistics and relevant public health trends related to substance use disorder
- Discuss recent regulatory changes related to substance use disorder
- Discuss the risk/benefit of newer strategies in using medications for opioid use disorder
- Discover strategies for opioid-related harm reduction and the impact related

Assessment Question 1

Which of the following is true regarding drug use in the United States in 2023?

A. Those meeting diagnostic standards for substance use disorder were primarily between 18-25 years old

B. Less than half of patients who felt they met DSM-V criteria entered recovery

C. Heroin was the top reported unregulated substance misused

D. Fear of employer retribution was the primary reason people did not seek treatment

Assessment Question 2

Which of the following statements about regulations about substance use disorder is true?

A. The 2016 CDC Opioid Guidelines provided a holistic and patient-centered approach to pain management

B. Buprenorphine prescribing dramatically increased following the passage of the MAT Act

C. SAMHSA rule changes now permit take-home methadone

D. The "X" waiver was upheld through the passage of the MATE Act

Assessment Question 3

Which of the following regarding naloxone utility is true?

A. Higher doses of naloxone are needed to reverse the effects of fentanyl

B. Intranasal naloxone is the preferred delivery device for the public

C. Nalmefene is more effective than naloxone

D. Low-dose naloxone has comparable incidence of opioid withdrawal symptoms to that of high-dose

Assessment Question 4

Which of the following statements about harm reduction strategies is true?

A. Naloxone-focused vending machines are not effective in increasing access for patients

B. Academic detailing is a viable method of improving pharmacist confidence in naloxone communication

C. Funding for research on harm reduction vending machines is unavailable

D. The presence of naloxone vending machines resulted in increased drug-related death

Epidemiology

- National Survey on Drug Use and Health
  - In people 12 and older in 2023
    - 47 million people used an illicit substance
      - Most common substance was cannabis
      - Slightly over 9 million people misused opioids (Rx, heroin, fentanyl)
    - 48.5 million people met diagnostic standards for substance use disorder
      - 29 million with an alcohol use disorder
      - 27 million with a drug use disorder
      - Highest proportion was in people 18-25 vs. > 26 years old

Epidemiology

- Most people (> 90%) with a substance use disorder did not receive any treatment
  - Almost all did not get treatment as they thought they could handle it alone, were not ready to start, or were not ready to stop/cut back on drugs and/or alcohol
  - Other reasons include:
    - Worried what others may think
    - Excessive costs
    - No time
    - Not knowing where to get treatment
    - Privacy concerns
    - Fear of losing employment/housing/family
- Of 64 million people who believed they had a substance use disorder, 66% (42 million) consider themselves in recovery

National Data

Over 87,000 people died from a drug-related issue from Oct '23 – Sept '24

- Down from 114,000 (about 24% drop) from same time the previous year
- Fewest deaths since June 2020

Many continue to be opioid-related

- Fentanyl and its derivatives is a major drug of concern

Ongoing concern over stimulants

- Include both cocaine and methamphetamine

Xylazine still present in some cases

- Known as "tranq"
- Alpha adrenergic receptor agonist
- Can lead to significant skin ulceration

Movement from an opioid epidemic to a holistic substance use epidemic

Centers for Disease Control and Prevention. CDC Reports Nearly 24% Decline in U.S. Drug Overdose Deaths. Published Feb 25, 2025. Accessed Feb 28, 2025. Available at: https://www.cdc.gov/media/releases/2025/2025-cdc-reports-decline-in-us-drug-overdose-deaths.html
The White House. Dr. Rahul Gupta Releases Statement on CDC's New Overdose Death Data. Published January 11, 2023. Accessed October 16, 2023. Available at: https://www.whitehouse.gov/ondcp/briefing-room/2023/01/11/dr-rahul-gupta-releases-statement-on-cdcs-new-overdose-death-data-2/

Ohio Data

Drug-Related Deaths

- Projected that over 3,500 people died through September 2024
- 4,063 people in 2022
- 4,313 people in 2021

Naloxone Distribution via Project DAWN

- Over 250,000 units distributed in 2023
- Over 171,000 in 2022 and 72,000 in 2021

Buprenorphine Use > 6 Months

- Over 44,000 people in 2023
- Slightly up from 2022 and similar to 2021

Centers for Disease Control and Prevention. Provisional Drug Overdose Death Counts. Reviewed Feb 12, 2025. Accessed March 9, 2025. Available at: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

State of Ohio. State of Ohio Integrated Behavioral Health Dashboard. Refreshed April 12, 2024. Accessed March 9, 2025. Available at: https://data.ohio.gov/wps/portal/gov/data/view/ohio-ibhd

Naloxone Dispensing and Utility

National data from 2019-2023 demonstrate a small increase in naloxone dispensing

- 0.6 naloxone devices dispensed per 100 people
- ~2.1 million prescriptions for naloxone
- Increase from same time last year (~1.6 million prescriptions)
- Ohio = 0.8/100 people

2023 data detailing opioid dispensing

- Decrease from 2019 from 46.8/100 people to 37.5/100 people in 2023
- Maintained decline seen in 2022 (39.5/100 people)
- Ohio = 40.7/100 people in 2023

Centers for Disease Control and Prevention. Naloxone Dispensing Rate Maps. Reviewed November 7, 2024. Accessed March 9, 2025. Available at: https://www.cdc.gov/overdose-prevention/data-research/facts-stats/naloxone-dispensing-rate-maps.html

Centers for Disease Control and Prevention. Opioid Dispensing Rate Maps. Reviewed November 7, 2024. Accessed March 9, 2025. Available at: https://www.cdc.gov/overdose-prevention/data-research/facts-stats/opioid-dispensing-rate-maps.html

Community Pharmacy Naloxone Distribution

Naloxone dispensing from community pharmacies remains low

- Some states require individual pharmacists to be certified to dispense naloxone, not all pharmacists have obtained this certification
- The cost of naloxone can be excessive for some patients
- The reimbursement to the pharmacy can be below acquisition price
- Stigma amongst some pharmacists remains a barrier

Possible that OTC naloxone makes for wider access

- Many have concerns over the price (~$45)
- Purchasing in a pharmacy still requires a person to socially interact which can perpetuate stigma
- Possible that not all pharmacies stock naloxone or store it behind the counter

Spector AL, et al. BMC Public Health. 2022 Jul 19;22(1):1387. doi: 10.1186/s12889-022-13741-5. Franko TS II, Yencha B, Sayre J. J Am Coll Clin Pharm. 2023;1-7. doi:10.1002/jac5.1894

Guideline and Regulatory Changes

2016 CDC Opioid Prescribing Guidelines

- Many feel it went too far too quickly
- Resulted in several patients having their opioids removed abruptly
- Spurred the development of several pieces of state legislation aimed to “protect” the public from overprescribing of opioids

The guidelines certainly worked to reduce the number of prescribed opioids

- 81/100 people in 2012 to 43/100 people in 2020 and 39/100 in 2022
- At least 40 states have enacted some form of legislation around opioids be that on duration of use or limitations on total daily dose

...ss. *Stateline*, an initiative of The Pew Charitable Trusts. Updated March 1, 2022. Accessed March 16, 2025. Available at: https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/03/01/states-likely-to-resist-cdc-proposal-easing-opioid-access

CDC 2016 Guideline Fallout

In 2019 the CDC collaborated with FDA in a warning to prescribers to not quickly stop opioids in patients or even to taper too quickly

- CDC even noted that the policies generated from the 2016 guidelines have contributed to harm, negative outcomes, emotional issues and suicidal ideation

CDC did release an updated guideline in 2022 which provided more flexibility to prescribers to better tailor regimens to patient needs

Vestal C. States Likely to Resist CDC Proposal Easing Opioid Access. *Stateline*, an initiative of The Pew Charitable Trusts. Updated March 1, 2022. Accessed March 16, 2025. Available at: https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/03/01/states-likely-to-resist-cdc-proposal-easing-opioid-access

MAT and MATE Acts of 2022

Mainstreaming Addiction Treatment (MAT) Act

- Removes the "X" waiver required to prescribe buprenorphine for substance use disorder
  - Effective immediately
  - Anyone who can prescribe a schedule 3 product can now prescribe this
  - Substance Abuse and Mental Health Services Administration (SAMHSA) strongly encourages providers to get involved with buprenorphine prescribing

Medication Access and Training Expansion (MATE) Act

- Prescribers must complete an 8-hour training on substance use disorders when renewing or initially receiving their DEA license
  - Effective June 27, 2023
  - Appears to be a one-off training
  - Training must include opioids or substance use disorder and management of dental pain
  - The old DATA-2000 training does count for this
  - Training does not need to occur in one sitting, it can be done cumulatively over time

University of Maryland. School of Medicine. MAT and MATE Acts. Accessed April 12, 2024. Available at: https://www.medschool.umaryland.edu/dacs/MAT--MATE-Acts/

Buprenorphine Prescribing

Prescriptions for buprenorphine remained stable at a national level, but did vary widely from state to state

- However, rates slightly dropped from 2021-2022 (~100,000 drop)

Several states still have regulations which are more strict than federal with unknown willingness to change in light of the MAT Act

Many providers (and pharmacies) are fearful of intense regulatory oversight and/or law enforcement involvement

Centers for Disease Control and Prevention. United States Dispensing Rate Maps. Reviewed November 7, 2024. Accessed March 9, 2025. Available at: https://www.cdc.gov/overdose-prevention/data-research/facts-stats/buprenorphine-dispensing-maps.html

Silwal A, Talbert J, Bohler RM, Kelsch J, Cook C, Blevins D, Gallivan M, Hunt T, Hatcher SM, Thomas CP, Williams S, Fanucchi L, Lofwall MR. State alignment with federal regulations in 2022 to relax buprenorphine 30-patient waiver requirements. Drug Alcohol Depend Rep. 2023 May 2;7:100164. doi: 10.1016/j.dadr.2023.100164. PMID: 37234704; PMCID: PMC10206439.

Proposed Federal Laws in 2024

Proposed Law	Intent	Last Movement
Substance Use Disorder Workforce Act (HR 7050)	Aimed to increase residency positions for hospitals with pain or SUD programs via Medicare	Dec 2024 – referred to committee
Closing the Substance Use Care Gap Act of 2024 (HR 10047)	Expanded access to treatment services	Oct 2024 – referred to committee
Substance Use Disorder Treatment and Recovery Loan Repayment Program Reauthorization Act of 2023 (HR 3355)	Reauthorized through FY28 that federal student loans would be forgiven for people that provide treatment/recovery services in recognized facilities	Dec 2024 – referred to committee
Comprehensive Addiction Resources Emergency Act of 2024 (S 4286)	HHS must purchase and distribute opioid reversal agents to states. It also increases HHS grant funding for treatment services and research as well as mandate reporting of diversion controls for dispensers, distributors and manufacturers of CII's	May 2024 – referred to committee

Congress.gov. Legislation. 118th Congress. Accessed March 9, 2025. Available at: https://www.congress.gov/bill/118th-congress/senate-bill/4286/all-actions

Updated Rules and Regulations in 2024

2024 Substance Abuse and Mental Health Services Administration (SAMHSA) Final Rule Change

- Updated to person-first terminology across the administration
- Provided more opportunities for patients to be admitted to treatment programs
- Incorporates patient-provide shared decision making and harm reduction into its recommendations
- Permits nurse practitioners and physician assistants to prescribe medications for opioid use disorder (MOUD) in outpatient treatment programs where allowed by state law

Substance Abuse and Mental Health Services Administration. The 42 CFR Part 8 Final Rule Table of Changes. Updated Jan 31, 2024. Accessed March 9, 2025. Available at: https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

2024 SAMHSA Rule Changes

Telehealth services

- Prescribers can initiate buprenorphine via audio-only interactions
- Audio-visual interactions can result in initiating both buprenorphine and methadone
- SAMHSA notes that telehealth services are evidence-based, safe and effective

Take-home doses of methadone

- Incrementally increases days' supply that patients can take at home
- Removes the need to report to a treatment center daily for methadone
- Patients can now take home
  - 7 days' worth during first two weeks of treatment
  - 14 days' worth during second two weeks of treatment
  - 28 days' worth thereafter

Substance Abuse and Mental Health Services Administration. The 42 CFR Part 8 Final Rule Table of Changes. Updated Jan 31, 2024. Accessed March 9, 2025. Available at: https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

Substance Abuse and Mental Health Services Administration. Methadone Take-Home Guidance Extension Guidance. Updated Nov 6, 2024. Accessed March 9, 2025. Available at: https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/methadone-guidance

Suzetrigine (Journavx)

Newly approved in Jan 2025

Selective blocker of Na 1.8 voltage-gated channels

- Channels located on peripheral sensory neurons
- Responsible for generating action potentials to transmit pain signals
- Blocking these channels prevents the transmission of pain to the central nervous system

Dosing

- 100 mg as the initial dose at least 1 hour before or 2 hours after food
- 12 hours later (and all subsequent dosing) is 50 mg regardless of food
- High caloric meals at the initial dose were shown to reduce absorption

Journavx Package Insert. Vertex Pharmaceuticals Inc. Revised Jan 2025. Accessed March 16, 2025. Available at: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209s000lbl.pdf

Suzetrigine (Journavx)

Warnings/Precautions/Contraindications

- Contraindicated with 3A4 inhibitors
- Caution in patients with severe hepatic disease

Adverse effects

- Itching/rash, muscle spasm

Indication

- Moderate to severe acute pain
- Evidence is based on placebo studies for post-surgical pain

Opportunities

- Not known to cause respiratory depression or promote substance use
- Need more evidence for chronic pain, different pain etiologies, and comparisons against traditional pain medicine

Journavx Package Insert. Vertex Pharmaceuticals Inc. Revised Jan 2025. Accessed March 16, 2025. Available at: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209s000lbl.pdf

Low-Dose Buprenorphine Concept

Low-level evidence suggests that combined use of BUP and full mu opioid agonist results in no withdrawal and reduced euphoria

Similar data demonstrates that 0.2 mg BUP IV did not precipitate withdrawal in patients taking methadone

Bernese Method: titration/wean of BUP with any full mu opioid agonist aimed to reduce withdrawal symptoms

Hämmig R, et al. Subst Abuse Rehabil. 2016;7:99-105. doi: 10.2147/SAR.S109919

Why Low-Dose Initiation?

Difficult for patients to tolerate the withdrawal necessary to start BUP via traditional initiation

Chronic fentanyl use persisting in system

Unpredictable duration, much longer waiting period

Increased rates of precipitated withdrawal

Facilitates transition from methadone or other opioids prescribed for chronic pain where stopping full opioid agonist is unrealistic

Cohen S, et al. J Addict Med. 2022. 16(4):399-406. doi: 10.1097/ADM.0000000000000945.

Bernese Method

Initiate buprenorphine/naloxone at low doses

- 0.5/0.125 mg sublingual (SL) daily in many studies
- Gradually increase to a traditional therapeutic range (e.g., > 8 mg daily)
- Traditionally completed between 7-10 days but times vary

Continue full mu opioid agonists during titration

- Some studies weaned during this time
- Others maintained until buprenorphine/naloxone was optimized

Evidence suggests this limits withdrawal symptoms

- Data is limited and of low quality

Randhawa PA, Brar R, Nolan S. CMAJ. 2020 Jan 20;192(3):E73. doi: 10.1503/cmaj.74018. Hämmig R, et al. Subst Abuse Rehabil. 2016 Jul 20;7:99-105. doi: 10.2147/SAR.S109919.

Low-Dose Buprenorphine Efficacy

- 63 patients over 18 studies
- Prescription and/or illicit opioids
- Initial buprenorphine dosing ranged from 0.2-0.5 mg SL
- Time periods ranged from 3-112 days and averaged 4-8 days
- COWS demonstrated, at most, mild withdrawal

Ahmed S, Bhivandkar S, Lonergan BB, Suzuki J. Am J Addiction. 2021;30(4):305-315. doi: 10.1111/ajad.13135.

Is it Worth the Effort?

No standardized approach established

- Potential for withdrawal symptoms still exist

Unknown dosing associated with illicit opioid use

- Concern with prescribing controlled substances to someone actively using

Pharmacies unwilling to fill prescriptions for low-dose cross-tapers

- Concerns over patient safety
- Regulatory oversight
- Adulteration (cutting to specified doses) of end product

Robbins JL, Englander H, Gregg J. J Am Board Fam Med. 2021;34(Suppl):S141-S146. doi: 10.3122/jabfm.2021.S1.200236
Ahmed S, Bhivandkar S, Lonergan BB, Suzuki J. Am J Addiction. 2021;30(4):305-315. doi: 10.1111/ajad.13135

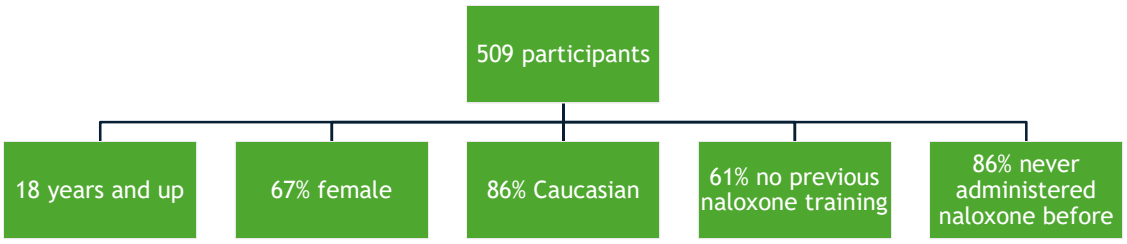
Bystander Naloxone Administration

Naloxone administration from bystanders rose over 40% from 2020-2022

- Only accounts for 4% of naloxone administered during that time
- Majority delivered by first responders

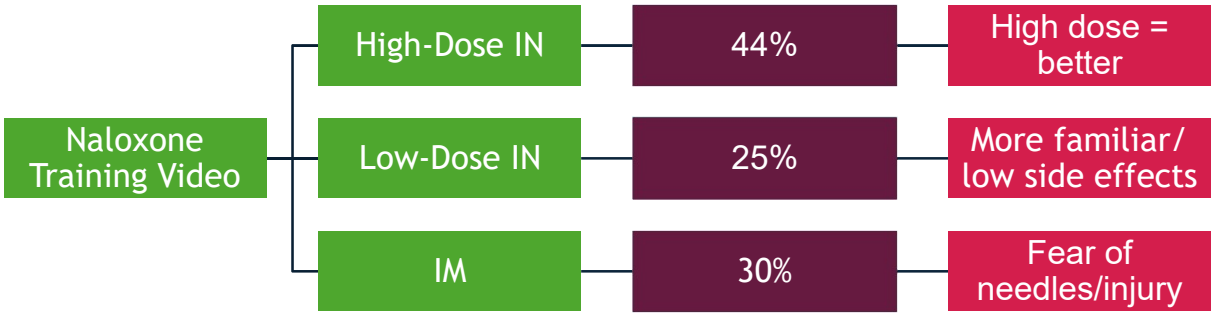
Gage CB, et al. JAMA Netw Open. 2024;7(10):e2439427. doi: 10.1001/jamanetworkopen.2024.39427

Public Perceptions on Naloxone Use



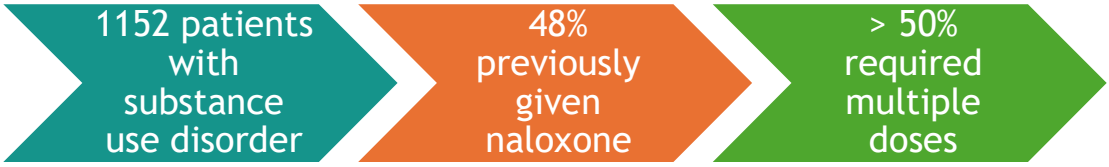
Marks KR et al. Bystander preference for naloxone products: a field experiment. Harm Reduction Journal. 2023: 20;171.

Public Perceptions on Naloxone Use



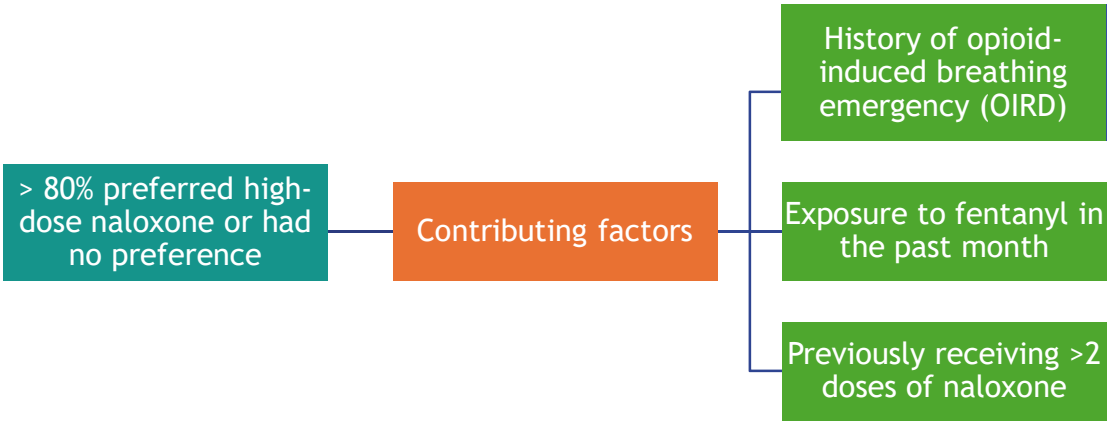
Marks KR et al. Bystander preference for naloxone products: a field experiment. Harm Reduction Journal. 2023: 20;171.

Patient Perceptions on Naloxone Use



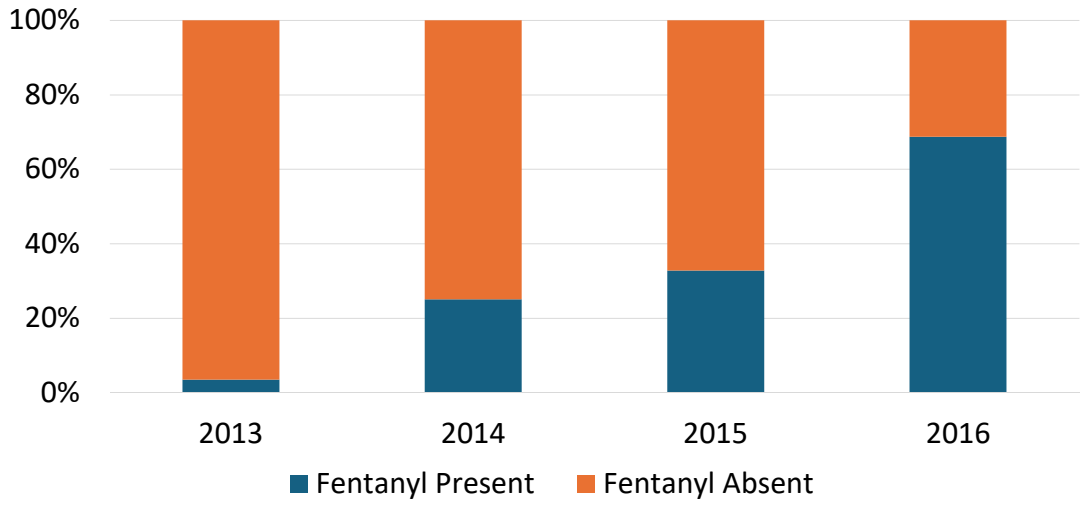
Strickland JC, et al. Int J Drug Policy. 2022;106:103751. doi: 10.1016/j.drugpo.2022.103751

Patient Perceptions on Naloxone Use



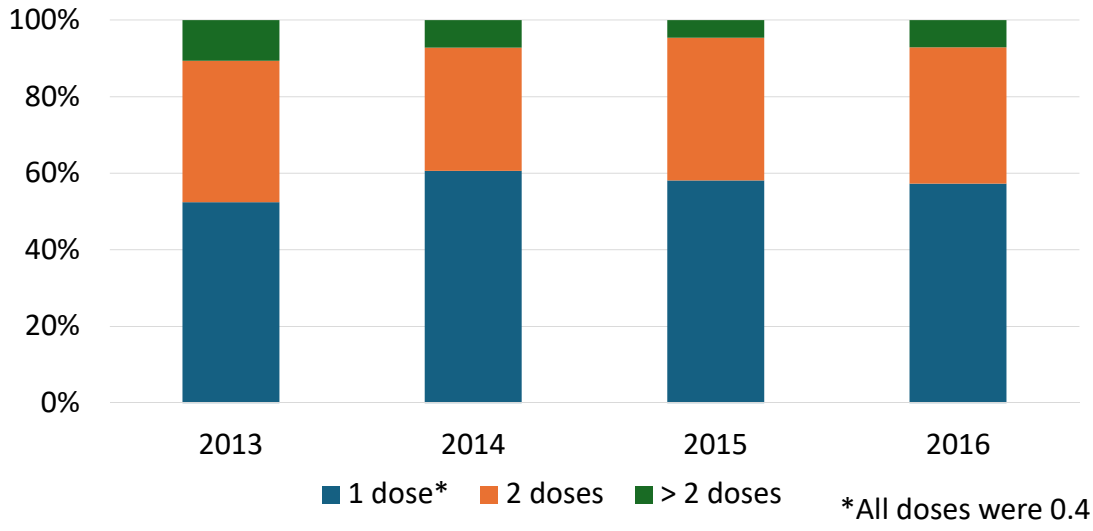
Strickland JC, et al. Int J Drug Policy. 2022;106:103751. doi: 10.1016/j.drugpo.2022.103751

Allegheny Opioid Overdose Deaths



A Bell et al. Amount of naloxone used to reverse opioid overdoses outside of medical practice in a city with increasing illicitly manufactured fentanyl in illicit drug supply. Subst Abus. 2019; 40(1):52-5.

Allegheny Naloxone Reversals



*All doses were 0.4 mg IM

A Bell et al. Amount of naloxone used to reverse opioid overdoses outside of medical practice in a city with increasing illicitly manufactured fentanyl in illicit drug supply. Subst Abus. 2019; 40(1):52-5.

Impact of Fentanyl

Kentucky EMS Naloxone Utilization 2018-2021				
	2018	**2019**	**2020**	**2021**
OIRD Encounters	6853	7304	9801	9888
Average naloxone dose	4.5 mg	4.5 mg	4.7 mg	4.7 mg
OIRD survival	99.6%	99.4%	99.3%	99.1%
Fentanyl seizures	3375	3859	4174	XXX
Fentanyl-related deaths	55	59	67	73

Rock P, Slavova S, Westgate PM, Nakamura A, Walsh SL. Drug Alcohol Depend. 2024 Feb 1;255:111062. doi: 10.1016/j.drugalcdep.2023.111062

Naloxone Dosing Differences

- 354 naloxone doses given by New York state police from March 2022 - August 2023

	4 mg Intranasal	**8 mg Intranasal**
Survival	99%	99%
Average Dose	1.67 (6.7 mg)	1.58 (12.6 mg)
Symptoms of Withdrawal	19%	37%
Declined Advanced Care	27%	19%

Payne ER, Stancliff S, Rowe K, Christie JA, Dailey MW. MMWR Morb Mortal Wkly Rep 2024;73:110–113. doi: http://dx.doi.org/10.15585/mmwr.mm7305a4

Impact of Opioid Withdrawal

Bergstein and colleagues completed interviews with patients and first responders regarding post-revival care

- Patients noted three main reasons for not seeking advanced care
  - Intolerable withdrawal symptoms
  - Fear of inadequate care in the hospital
  - Stigmatizing treatment by medical personnel
- First responders supported solutions
  - Titration of naloxone dosing to ease withdrawal symptoms
  - More community response
  - Address burnout within the first responder community

Bergstein RS, King K, Melendez-Torres GJ, Latimore AD. Refusal to accept emergency medical transport following opioid overdose, and conditions that may promote connections to care. Int J Drug Policy. 2021 Nov;97:103296. doi: 10.1016/j.drugpo.2021.103296. Epub 2021 May 30. PMID: 34062289.

Naloxone vs. Nalmefene

	Naloxone 4 mg Intranasal	Nalmefene 2.7mg Intranasal
Tmax	30 minutes	15 minutes
Time to effect	<2 minutes	2.5-5 minutes
Half-life	2.1 hours	11.4 hours
Affinity (K_i)	3.70 nM	0.91 nM

Narcan® (naloxone) nasal spray package insert. Revised Aug 2020. Accessed Jan 2, 2025. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208411Orig1s004lbl.pdf
OPVEE® (nalmefene) nasal spray package insert. Revised June 2023. Accessed Jan 2, 2025. Available from: https://opvee.com/wp-content/uploads/2023/07/Combined-USPI_Patient-Info_IFU_Clean_05July2023.pdf
Infante AF, Elmes AT, Gimbar RP, Messmer SE, Neeb C, Jarrett JB. Int J of Drug Policy. 2024;124:104323. doi: 10.1016/j.drugpo.2024.104323. Bourdonnec B, et al. Bioorganic & Med Chem Letters. 2008;18(6):2006-2012. doi: 10.1016/j.bmcl.2008.01.106. Ghirmai S, et al. J Med Chem. 2008;51(6):1913-24. doi: 10.1021/jm701060e

Naloxone vs. Nalmefene

Suspected OIRD in the Hospital Setting			
	Naloxone 2 mg IV	Nalmefene 1 mg IV	Nalmefene 2 mg IV
Change in respiratory rate (breaths/min) over 5 minutes	10 → 20.3	8.2 → 19.9	11.3 → 17.8
Adverse effects	15.5%	15.9%	30.9%

Kaplan JL, et al. Ann Emerg Med. 1999 Jul;34(1):42-50. doi: 10.1016/s0196-0644(99)70270-2

Bottom Line – Against Higher Doses

- Despite increases in fentanyl-related deaths, real-world data does not demonstrate a medical need for higher naloxone doses.
- Compared to standard IN doses, higher-doses are associated with similar survival rates and rates of accepted of hospital transfer.
- Higher doses are associated with an increased risk for withdrawal symptoms. This risk would likely be greater and prolonged with nalmefene administration.

Naloxone Misconceptions

Misconception	Evidence
Naloxone enables drug use	• Evidence shows no relationship between naloxone availability and increased drug use. • Access has led to a 63% decrease in ER visits in patients on chronic opioid therapy. • The only thing naloxone enables is your ability to breathe.
Naloxone is only for those with a substance use disorder	• 97% of people believe those on chronic opioid therapy should have naloxone. • Child/pet exposure, and dosing confusion in seniors also possible. • In 2017, the U.S. Surgeon General stated that everyone should have, and know how to use naloxone.
Naloxone is a waste of taxpayer money	• While the price has risen over the last few years, data shows naloxone is a cost saving tool, especially focusing on dollars per quality adjusted life year saved.
Naloxone access results in "Narcan Parties"	• No empiric evidence exists to demonstrate this is true.

Franko T. Removing the stigma of medications for opioid use disorder. Pharmacy Today. 2020 Oct; 26(10): S2-63

Naloxone Misconceptions

What if the patient does not respond to naloxone?

- Doubtful the respiratory depression is solely due to opioids
- Naloxone will not work against non-opioid causes of respiratory depression such as alcohol
- Could be a non-opioid related medical issue (e.g., heart attack).

What about fentanyl exposure?

- Exposure is over-inflated by the media and acts more as a scare tactic
  - Fentanyl is lipophilic so incidental skin exposure is unlikely to cause harm, simply wash with soap and water
  - Fentanyl is not easily aerosolized so unlikely to become airborne
  - Rainbow fentanyl is real, but is not intended to target children or be mixed with candy

Davis C, Carr D, Samuels E. Paraphernalia Laws, Criminalizing Possession and Distribution of Items Used to Consume Illicit Drugs, and Injection-Related Harm. Am J Public Health. 2019 Nov;109(11):1564-1567. doi: 10.2105/AJPH.2019.305268. Epub 2019 Sep 19. PMID: 31536408; PMCID: PMC6775926
Anne Arundel County Department of Health. Naloxone: Frequently Asked Questions. 2025. Accessed March 16, 2025 Available at: https://www.aahealth.org/naloxone-frequently-asked-questions/
Moss M, Warrick B, Nelson L, et al. ACMT and AACT Position Statement: Preventing Occupational Fentanyl and Fentanyl Analogue Exposure to Emergency Responders. J Med Toxicol. 2017 Dec; 13(4): 347-351
Carpenter J, Murray B, Atti S, Moran T, Yancey A, Morgan B. Naloxone Dosing After Opioid Overdose in the Era of Illicitly Manufactured Fentanyl. J Med Toxicol. 2020 Jan; 16(1): 41-48

Innovative Harm Reduction Strategies

Naloxone/Harm Reduction Vending Machines

- Increase availability of naloxone and other harm reduction materials
- Can be located at a variety of areas
- Eliminates the need for human interaction to obtain harm reduction supplies
- Strong evidence exists demonstrating their impact

Reid M, Whaley S, Allen S. Harm Reduction Vending Machines: What are they and do they work? Johns Hopkins Bloomberg School of Public Health. Accessed January 12, 2024. Available at: https://opioidprinciples.jhsph.edu/harm-reduction-vending-machines-what-are-they-and-do-they-work/

Naloxone Vending Machine Data

Victor and colleagues distributed six naloxone vending machines to Michigan jails

- Naloxone made available to those re-entering society as well as visitors
- Historically, naloxone distributed upon request only and/or to those with suspected opioid use disorder
- Naloxone distribution increased by over 65% with one site demonstrating a 1000% increase in naloxone distribution within six months

Victor G, Hedden-Clayton B, Lenz D, Attaway PR, Ray B. Naloxone vending machines in county jail. J Subst Use Addict Treat. 2024 Dec;167:209521. doi: 10.1016/j.josat.2024.209521. Epub 2024 Sep 10. PMID: 39260806.

Naloxone Vending Machine Data

Syringe Service Program in Clark County, NV placed 17 machines over a four-year period

- Noted a 15% decrease in forecasted opioid-related deaths after the first year of the program
- Noted increase in deaths following March 2020 above predicted values

Allen ST, O'Rourke A, Johnson JA, Cheatom C, Zhang Y, Delise B, Watkins K, Reich K, Reich R, Lockett C. Evaluating the impact of naloxone dispensation at public health vending machines in Clark County, Nevada. Ann Med. 2022 Dec;54(1):2692-2700. doi: 10.1080/07853890.2022.2121418. PMID: 36168975; PMCID: PMC9542801.

Naloxone Vending Machine Data

The University of Cincinnati and a local harm reduction group studied the utility of a vending machine dispensing harm reduction supplies

- Within the first year over 3,300 naloxone doses were dispensed and over 10,000 fentanyl testing strips
- Deaths related to opioids decreased by 10% within the first year

Arendt D. Expanding the accessibility of harm reduction services in the United States: Measuring the impact of an automated harm reduction dispensing machine. J Am Pharm Assoc (2003). 2023 Jan-Feb;63(1):309-316. doi: 10.1016/j.japh.2022.10.027. Epub 2022 Nov 12. PMID: 36549931; PMCID: PMC9870941.

Naloxone Dispensing in the Emergency Department

Hardin and colleagues looked at naloxone distribution in the emergency department (ED) within a California health system

- Naloxone distribution was examined in phases governed by existing regulation at the time
  - Phase 1 – physicians presceibed naloxone to be filled, for no cost, at a pharmacy
  - Phase 2 – physicians could provide naloxone to patients at the point of discharge
  - Phase 3 – ED staff (including pharmacists) could provide naloxone to patients at the point of discharge
- Results
  - Phase 1 – 348 prescriptions provided with 133 filled
  - Phase 2 – 327 naloxone products given to patients only by physicians
  - Phase 3 – 3, 677 naloxone products given to patients by ED staff

Hardin J, Seltzer J, Galust H, Deguzman A, Campbell I, Friedman N, Wardi G, Clark R, Lasoff D. Emergency Department Take-Home Naloxone Improves Access Compared to Pharmacy Dispensed Naloxone. *J Emerg Med*. Published online December 3, 2023. DOI: https://doi.org/10.1016/j.jemermed.2023.11.020

Pharmacy-Based Naloxone Distribution

Initial, pilot study exploring use of student-pharmacists to provide field education (academic detailing) to community pharmacists on naloxone use and communication

39 community pharmacies randomized into the intervention and control arms

Naloxone orders from a single wholesaler for three months before and after the training period were reviewed

Franko TS II, Yencha B, Sayre J. Assessment of student pharmacist-led academic detailing on independent community pharmacy naloxone orders. *J Am Coll Clin Pharm*. 2024; 7(1): 39-45. doi:10.1002/jac5.1894

Pharmacy-Based Naloxone Distribution

	Intervention Arm (N = 15)	Control Arm (N = 19)	
Naloxone shipped during pre-intervention period	21	26	P = 0.59
Naloxone shipped during post-intervention period	31	29	P = 0.25

Franko TS II, Yencha B, Sayre J. Assessment of student pharmacist-led academic detailing on independent community pharmacy naloxone orders. *J Am Coll Clin Pharm*. 2024; 7(1): 39-45. do 10.1002/jac5.1894

Pharmacy-Based Naloxone Distribution

While numbers increased, they were not significant

- Likely due to a low sample size
- Opportunity for further growth of this program exists

Potential impact of negative reimbursement rates for naloxone products

- Over-the-counter version currently priced ~$45
- Reimbursement rates for prescription products vary

Franko TS II, Yencha B, Sayre J. Assessment of student pharmacist-led academic detailing on independent community pharmacy naloxone orders. *J Am Coll Clin Pharm.* 2024; 7(1): 39-45. doi:10.1002/jac5.1894

Opportunities for Pharmacy Moving Forward

Continue to use Prescription Drug Monitoring Programs (PDMP) appropriately

- Can be a tool to build or a weapon to destroy
- Engage in conversations with patients (e.g., Screening, Brief Intervention, and Referral to Treatment or SBIRT)
- Opportunity for increased revenue to your pharmacy through SBIRT billing codes
  - Some states recognize pharmacists as providers via Medicaid which provides further revenue-generating opportunities

Kosobuski L, O'Donnell C, Koh-Knox Sharp CP, Chen N, Palombi L. The Role of the Pharmacist in Combating the Opioid Crisis: An Update. Subst Abuse Rehabil. 2022 Dec 28;13:127-138. doi: 10.2147/SAR.S351096. PMID: 36597518; PMCID: PMC9805704.

Substance Abuse and Mental Health Services Administration. Coding for Screening and Brief Intervention Reimbursement. Updated April 17, 2024. Accessed March 16, 2025. Available at: https://www.samhsa.gov/sbirt/coding-reimbursement

Pennsylvania Pharmacists Association. PA Medicaid to Allow Pharmacists to Enroll as Providers and Bill for Pharmacy Services. Published February 12, 2024. Accessed April 16, 2025. Available at: https://www.papharmacists.com/news/news.asp?id=664824

Opportunities for Pharmacy Moving Forward

Engagement with buprenorphine management following passage of the MAT Act

- Advocate at a state-level for ability

Explore more opportunity to provide intramuscular naltrexone

- Does not require DEA approval

Embrace academic detailing of fellow pharmacists on critical substance use disorder issues

- Stigma reduction
- Confidence in communication skills

Kosobuski L, O'Donnell C, Koh-Knox Sharp CP, Chen N, Palombi L. The Role of the Pharmacist in Combating the Opioid Crisis: An Update. Subst Abuse Rehabil. 2022 Dec 28;13:127-138. doi: 10.2147/SAR.

To Learn More…

American Pharmacists Association (APhA) Opioid Resource Page	• https://www.pharmacist.com/Practice/Patient-Care-Services/Opioid-Use-Misuse
APhA Institute on Substance Use Disorders	• https://aphainstitute.pharmacist.com/
Pennsylvania Pain and Addiction Summit	• https://www.wilkes.edu/signature-events/pain-and-addiction-summit/index.aspx

Conclusion

The opioid crisis has improved but there is still a long road ahead

Advocacy efforts work (e.g., MAT Act passed) so we must continue to advocate at all levels for more resources and opportunities

Changes in SAMHSA rules and new data on best practices for opioid reversal may improve access and quality of care for patients

Harm reduction efforts work, we must continue to explore methods to bring help to where people are

Assessment Question 1

Which of the following is true regarding drug use in the United States in 2023?

A. Those meeting diagnostic standards for substance use disorder were primarily between 18-25 years old

B. Less than half of patients who felt they met DSM-V criteria entered recovery

C. Heroin was the top reported unregulated substance misused

D. Fear of employer retribution was the primary reason people did not seek treatment

Assessment Question 2

Which of the following statements about regulations about substance use disorder is true?

A. The 2016 CDC Opioid Guidelines provided a holistic and patient-centered approach to pain management

B. Buprenorphine prescribing dramatically increased following the passage of the MAT Act

C. SAMHSA rule changes now permit take-home methadone

D. The “X” waiver was upheld through the passage of the MATE Act

Assessment Question 3

Which of the following regarding naloxone utility is true?

A. Higher doses of naloxone are needed to reverse the effects of fentanyl
B. Intranasal naloxone is the preferred delivery device for the public
C. Nalmefene is more effective than naloxone
D. Low-dose naloxone has comparable incidence of opioid withdrawal symptoms to that of high-dose

Assessment Question 4

Which of the following statements about harm reduction strategies is true?

A. Naloxone-focused vending machines are not effective in increasing access for patients
B. Academic detailing is a viable method of improving pharmacist confidence in naloxone communication
C. Funding for research on harm reduction vending machines is unavailable
D. The presence of naloxone vending machines resulted in increased drug-related death