Medications for Opioid Use Disorder: The Pharmacist's Role

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Disclosure

- The course and speaker have no relevant financial interest or relationships to disclose

Learning Objectives

- Outline the role of medications for the treatment of opioid use disorder (OUD)
- Describe methods to expand access to OUD and the importance of stigma reduction
- Review regulatory changes and challenges for OUD treatment
- Discuss pain management misconceptions for people with OUD

ICHP Spring Meeting 2024

Opioid Epidemic

America's Opioid Epidemic

To combat ongoing opioid crisis, Gov. J.B. Pritzker announces Overdose Action Plan

ICHP Spring Meeting 2024

Ongoing-Growing Opioid Epidemic

In 2021 there were an estimated 107,622 deaths in the United States from drug overdoses, representing a 15% increase from the year prior and a 30% increase from 2019

In 2021, there were 3,717 drug overdose fatalities in Illinois, which is a loss of more than 10 Illinois residents each day and the leading cause of accidental death for Illinois residents aged 18-49

Provisional 2022 data (Q1 – Q2) in the United States show a 3.3% increase in the number of opioid overdose fatalities when compared to the same time frame in 2021

Drug Overdose Death Rates | National Institute on Drug Abuse (NIDA) (nih.gov)
FastStats - Drug Overdoses (cdc.gov)
Data and Reporting (illinois.gov)

Epidemiology

12 Month-ending Provisional Number and Percent Change of Drug Overdose Deaths

Based on data available for analysis on: January 7, 2024

Figure 1a. 12 Month-ending Provisional Counts of Drug Overdose Deaths: United States

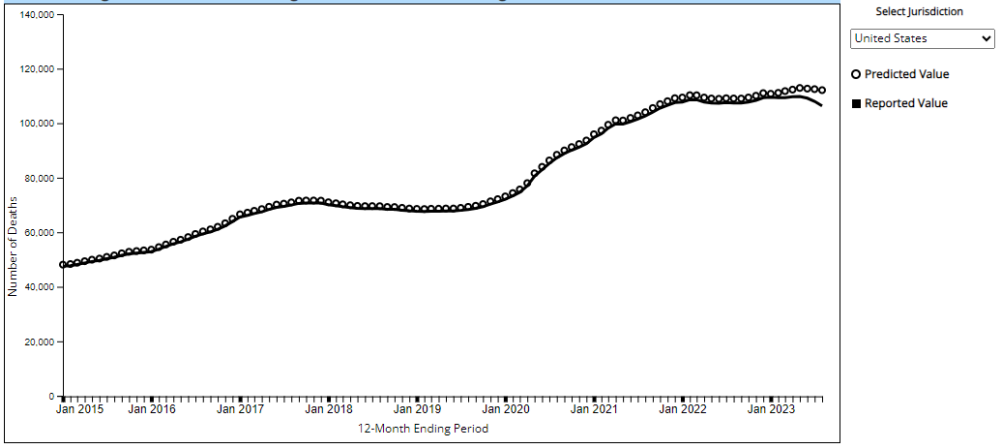
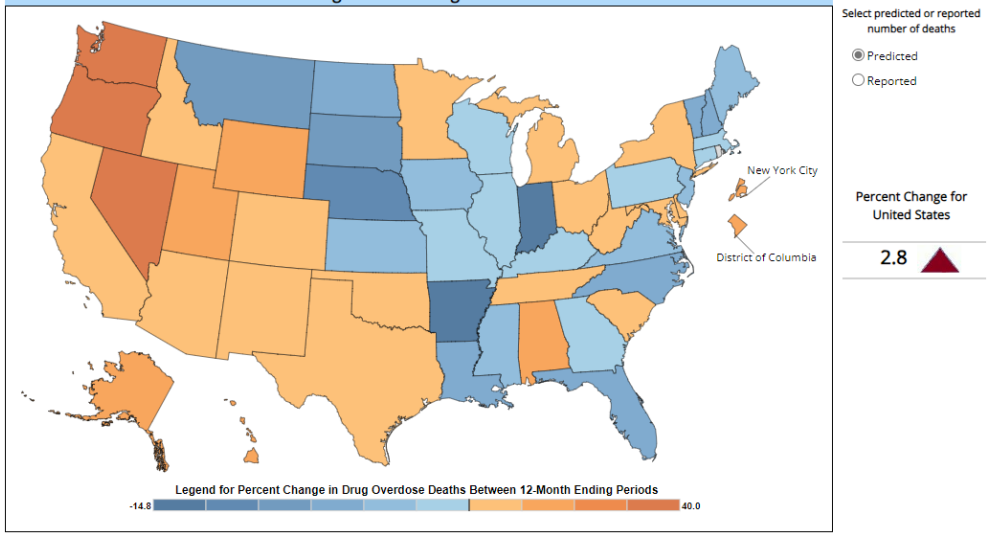


Figure 1b. Percent Change in Predicted 12 Month-ending Count of Drug Overdose Deaths, by Jurisdiction: August 2022 to August 2023

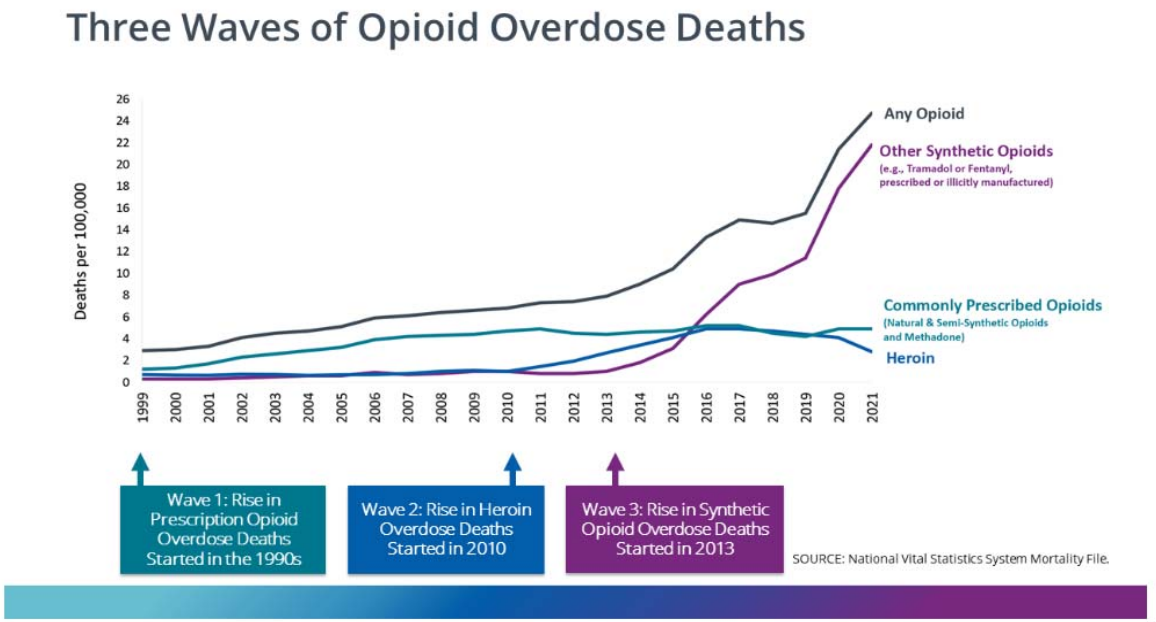


[Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov)]

Three Waves – Opioid Overdose Epidemic

Classes of opioids:

- Natural
- Semi-synthetic
- Fully synthetic



From 1999-2021, nearly 645,000 people died from an overdose involving any opioid, including prescription and illicit opioids[1].

Understanding the Opioid Overdose Epidemic | Opioids | CDC

Rise of Illicit Fentanyl, Poly-drug Use

- Illicitly manufactured fentanyl market continues to change - found in combination with heroin, counterfeit pills, and cocaine.
- Rise of synthetic opioids is attributed to continued increase in fatalities in Illinois.
- Poly-drug use accidental/intentional is evolving.

Data and Reporting (illinois.gov)
Understanding the Opioid Overdose Epidemic | Opioids | CDC

Fourth Wave – Opioid Overdose Crisis

Stimulants

Current use entwined with the ongoing opioid epidemic

High mortality involving cocaine and methamphetamine

The Rise of Illicit Fentanyls, Stimulants and the Fourth Wave of the Opioid Overdose Crisis - PMC (nih.gov)

Definitions

Addiction

- Treatable, chronic medical disease complex interactions among brain circuits, genetics, the environment, and individuals' life experiences

Physical Dependence

- State of adaptation manifested by a syndrome that can be produced by abrupt cessation, rapid dose reduction, decreased blood level, or administration of antagonist
- Urge to take drug to function, leads to compulsivity and cravings

Tolerance

- State of adaptation same exposure to a drug induces changes that markedly diminish effect with continued use
- Body needs more drug, cellular adaptations upon repeated activation of receptors

American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.).
Mehta V, et al. Rev Pain. 2009;3(2):10-14.

DSM-V diagnostic criteria for OUD

In order to confirm a diagnosis of OUD, at least two of the following should be observed within a 12-month period

- Larger amounts or longer period than intended
- Persistent desire
- Excessive time
- Cravings
- Failure to fulfill obligations
- Social Problems
- Lack of occupational activities
- Physically hazardous
- Psychological problems
- Tolerance
- Withdrawal

American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.).

DSM-V Criteria Opioid Withdrawal Syndrome

Occurrence one of the following:

- Cessation of (or reduction in) opioid use that has been heavy and prolonged (weeks or longer)
- Administration of an opioid antagonist after a period of use

Three (or more) minutes to several days after above criteria:

- Dysphoria
- Nausea or vomiting
- Myalgias
- Lacrimation or rhinorrhea
- Mydriasis, piloerection, or sweating
- Fever
- Insomnia

American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.).

Withdrawal assessment tools

OUD assessment tools

- Objective opioid withdrawal scale (OOWS), subjective opioid withdrawal scale (SOWS), clinical objective opioid withdrawal scale (COWS)

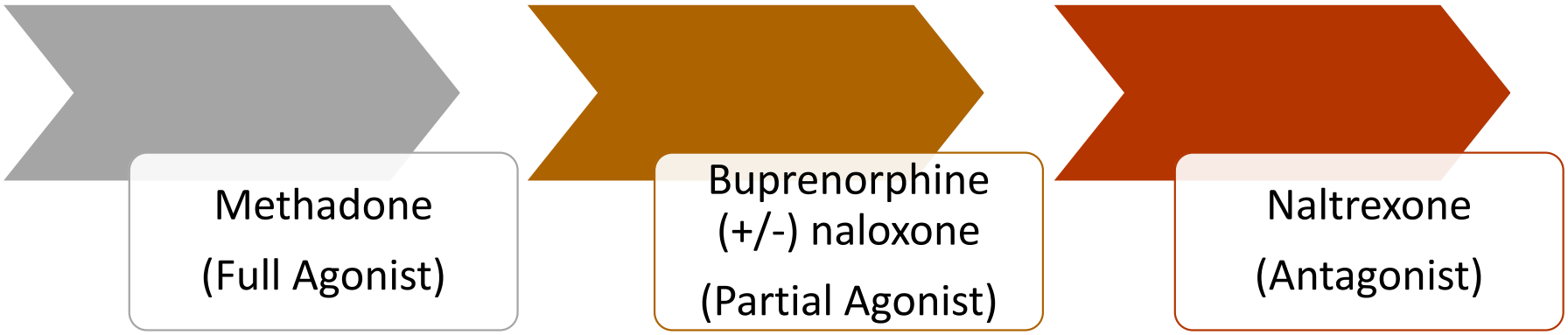
SOWS and COWS criteria

- Scale of 0-4 on each question
- Pulse rate, GI upset, sweating, restlessness, tremor, yawning, pupil size, runny nose, gooseflesh skin, bone and joint aches, anxiety

Nuamah JK, et al. BMC Medical Informatics and Decision Making. 2019; 19: 113

Medications for Opioid Use Disorder (MOUD)

- Medication-assisted treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders
- MOUD reduce illicit opioid use, retain patients in treatment, reduce risk of overdose (goal is remission and sustained recovery)
- Opioid agonist therapy (OAT) associated profound mortality benefit
- MOUD in conjunction with MAT



Medications for Substance Use Disorders | SAMHSA

Methadone

Synthetic, full mu opioid receptor agonist

Recommended for patients who are physiologically dependent on opioids

Initial dose range

- 30 mg
- Reassess in 3-4 hours, a second dose a 10mg on day 1
- Not to exceed 40 mg, unless documentation that 40 mg did not suppress opioid abstinence symptoms.

Usual Dose

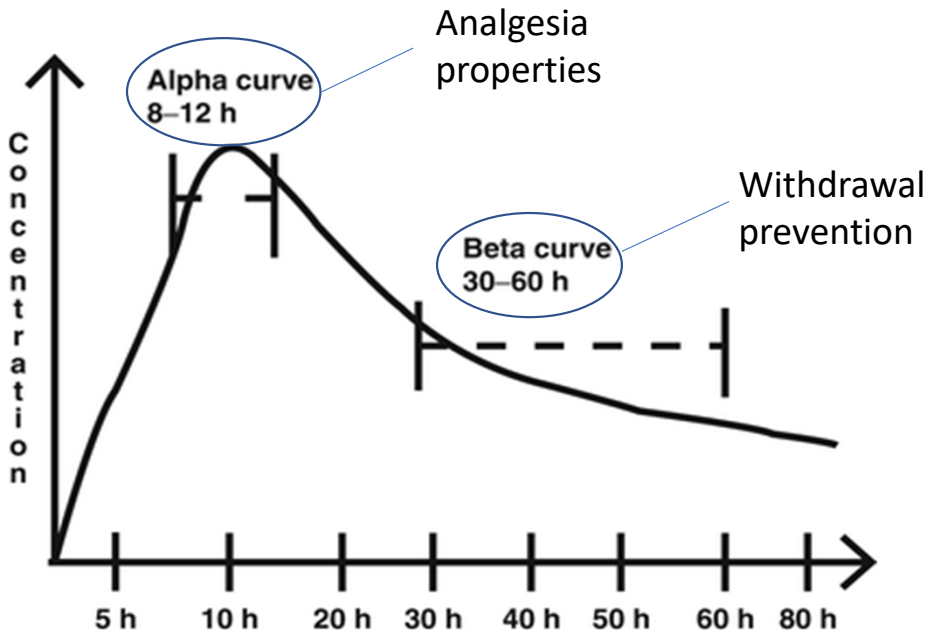
- 60 to 120mg
- Patients may require higher or lower doses, but doses <60mg have been shown to have decrease response in reducing cravings

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Dolophine. Package insert. Roxane laboratories, Inc. 2014
Kohan L, et al. Reg Anesth Pain Med. 2021;46:840–859

Methadone

PK/PD

- Substrate 3A4 (major), 2B6 (major)
- Highly protein bound
- Bioavailability: 36-100%
- T½: 8-59 hours
  - Alpha-curve: 8-12 hours
  - Beta-curve: 30-60 hours
- Tpeak: 1-7.5 hours



ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Dolophine. Package insert. Roxane laboratories, Inc. 2014.
Kohan L, et al. *Reg Anesth Pain Med.* 2021;46:840–859.

Methadone

Cautions

- Liver disease, concomitant use with other respiratory depressive agents, psychiatric diagnosis which may impair daily visits, history of seizure, risk of serotonin syndrome

Adverse effects

- Hypotension, dizziness, QTc prolongation, significant respiratory depression, hypoglycemia, constipation, nausea

Contraindications

- Known respiratory depression, bronchial asthma, paralytic ileus

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Dolophine. Package insert. Roxane laboratories, Inc. 2014.
Kohan L, et al. *Reg Anesth Pain Med.* 2021;46:840–859.

Methadone

Duration of therapy

- Optimal treatment duration not established
- Long-term treatment is recommended (increase rate of relapse patients drop out of programs)
- If relapse occurs, reinstitute therapy immediately

Advantages

- Slows brain uptake and reduces euphoria in oral dosing
- Beneficial to patients finding no response to other MOUD

Disadvantages

- Drug-drug interactions (QTc prolongation)
- Requires outpatient treatment programs and frequent visits

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Dolophine. Package insert. Roxane laboratories, Inc. 2014
Kohan L, et al. Reg Anesth Pain Med. 2021;46:840–859

Buprenorphine (+/-) naloxone

Works on the mu-, kappa-, delta-, & Opioid Like-1 receptor

- Partial mu opioid receptor agonist that reduces drug cravings and withdrawal symptoms
- Historically recommended for patients who are currently experiencing mild to moderate withdrawal symptoms

Initiation

- Standard
- Macro dosing
- Micro dosing

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Subutex. Package insert. Indivior Inc. 2018.
Kohan L, et al. *Reg Anesth Pain Med.* 2021;46:840–859.

Buprenorphine (+/-) naloxone

PK/PD

- Substrate 3A4 (major)
- Norbuprenorphine is active metabolite
- Highly protein bound
- Bioavailability= films 46-65%, SubQ injection 70%, SL tab 29%
- T½ = film 27.6 hrs, SubQ injection 43-60 days, SL tab 37 hrs
- Tpeak = film 2.5-3 hrs, SubQ injection 24 hrs and steady state in 4-6 months, sublingual 30-60 mins

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Subutex. Package insert. Indivior Inc. 2018.
Kohan L, et al. *Reg Anesth Pain Med.* 2021;46:840–859.

Buprenorphine (+/-) naloxone

Adverse effects

- Headache, insomnia, nausea, withdrawal symptoms, hypotension, diaphoresis

Warnings

- Risk of CV and respiratory depression, pre-existing hepatic impairment, abuse/dependence, adrenal insufficiency

Duration

- No recommended time limit for therapy (tapering is a slow process that should occur over several months)

Advantages

- Reduce drug cravings without producing euphoria or dangerous side effects
- Well tolerated
- Low overdose risk

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Subutex. Package insert. Indivior Inc. 2018.
Kohan L, et al. *Reg Anesth Pain Med.* 2021;46:840–859.

Buprenorphine (+/-) naloxone

- Standard dosing: for patients who are currently experiencing mild to moderate withdrawal symptoms

Induction: 4 to 8 mg dose

- Reassess after 1 hour and give additional dose if symptoms improve

Target dose of at least 8 to 16 mg/day

- Doses of 16 mg/day have been associated with greater efficacy

Max dose of 24 mg/day

- Little evidence of efficacy at higher doses

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Subutex. Package insert. Indivior Inc. 2018.
Kohan L, et al. *Reg Anesth Pain Med.* 2021;46:840–859.

Buprenorphine (+/-) naloxone

- Macro dosing: alternative for patients who would benefit from achieving a full therapeutic dose rapidly

Initial: 16mg dose

- Post reversal of opioid overdose with naloxone
- Precipitated withdrawal at lower initial doses

Subsequent dose 8-16mg

- Dose of 16mg is generally inadequate to provide relief of withdrawal symptoms (particularly illicit fentanyl)

Total dose of up to 32 mg on day 1

- Little evidence of efficacy at higher doses

MacrodosingPrimer.pdf (metaphi.ca)
Buprenorphine Emergency Department Quick Start - Bridge to Treatment

Buprenorphine (+/-) naloxone

- Micro dosing: for patients not experiencing withdrawal or high concern for precipitating withdrawal
  - Current dosing protocols were based on the Bernes method
  - Sublingual (tablets/films cut to dosing) and IV to Sublingual
  - Inpatient and Outpatient Inductions

	Total daily buprenorphine dosage (mg)	Day 1	Day 2	Day 3	Day 4	Day 5
Bernes method		0.2 SL	0.2 SL	2.8 SL	4.5 SL	5 SL
Hammig (2016)		0.2 SL	0.8 SL	1.2 SL	1.8 SL	2.0 SL
Terasaki (2019)		0.5 SL	1.0 SL	2.0 SL	4.0 SL	8.0 SL
Crane (2020)		0.1 IV	1.1 IV	1.2 IV	1.6 IV	1.5 IV
Teck (2021)		0.4 SL	0.4 SL	0.8 SL	1.2 SL	1.6 SL
Jablonski (2022)		1.0 IV	1.8 IV	4.0 SL	–	–

Jablonski LA, et al. Drug Alcohol Depend. 2022 Aug 1;237:109541.
Murray et al. Addiction Science & Clinical Practice (2023) 18:38

Buprenorphine injection (Sublocade)

For patients who have moderate to severe disorder who have been on oral buprenorphine for at least 7 days

Dose

- 300 mg subcutaneously for two months then 100 mg subcutaneously once a month
- If stable on 100 mg monthly, may start 300 mg every 2 months

Missed doses

- Give maintenance dose immediately if within 26 days after scheduled dose

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Sublocade. Package insert. Indivior, inc. 2021.
Kohan L, et al. *Reg Anesth Pain Med.* 2021;46:840–859.

Buprenorphine injection (Brixadi)

For patients on heroin or short-acting opioids. Initiate when signs of opioid withdrawal occur (no sooner 12 hours after last use)

Dose

- Test dose (trans mucosal buprenorphine)
- 16 mg subcutaneously, an additional 8 mg (weekly) within 3 days, an additional 8 mg (weekly) after at least 24 hours after the previous dose
- Maintenance dose 16-32 mg weekly

Missed doses

- Administer a missed dose as soon as possible, then resume every 7-day interval from the last administered dose (weekly) or every 28-day interval from last administered dose (monthly).

Brixadi. Package insert. Braeburn Inc. 2023.

Naltrexone (ReVia, Vivitrol)

Pure, full competitive opioid receptor antagonist. Highest affinity for mu-receptors

Recommended as treatment for preventing relapse in OUD

Dosing

- Oral treatment: patients who you can supervise and enforce adherence
  - Dose: 50 mg daily, or three times weekly in two 100 mg doses followed by 150 mg
- Long-acting injection (Vivitrol)
  - 380 mg IM into the gluteal muscle every 4 weeks

There is no recommended duration for either oral or extended-release

Initiation requires abstinence for 7 days before starting

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Revia. Package insert. Duramed Pharmaceuticals, inc. 2013.
Vivitrol. Package insert. Alkermes, Inc. 2010.
Kohan L, et al. *Reg Anesth Pain Med*. 2021;46:840–859.

Naltrexone (ReVia, Vivitrol)

PK/PD

- Metabolism: noncytochrome-mediated dehydrogenase
- Bioavailability: 5-40%
- Half-life= oral 4 hours, IM 5-10 days
- Excretion: urine

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Revia. Package insert. Duramed Pharmaceuticals, inc. 2013.
Vivitrol. Package insert. Alkermes, Inc. 2010.
Kohan L, et al. *Reg Anesth Pain Med*. 2021;46:840–859.

Naltrexone (ReVia, Vivitrol)

Adverse Effects

- Syncope, gastrointestinal upset, elevated LFTs, headache, pharyngitis, dizziness, insomnia

Warnings and precautions

- Hepatotoxicity, accidental opioid overdose, acute opioid withdrawal, depression

Contraindications

- Current physiological opioid dependence or current opioid use, acute opioid withdrawal, failure to pass naloxone challenge, acute hepatitis, hepatic failure

ASAM. National practice guideline for the treatment of opioid use disorder 2020 focused update.
Revia. Package insert. Duramed Pharmaceuticals, inc. 2013.
Vivitrol. Package insert. Alkermes, Inc. 2010.
Kohan L, et al. *Reg Anesth Pain Med*. 2021;46:840–859.

Naltrexone injection (Vivitrol)

Injection may be present for over 1 month after each dose

Patient must be educated about use of opioids for acute pain

REMS program: risk of overdose, hepatotoxicity, review pain medications

Vivitrol. Package insert. Alkermes, Inc. 2010.

Stigma and Bias

- Stigma
  - "stigma" comes from the Greek verb "στίζω" (stizo) which means "to mark with a scar"
  - Almost timelessly and universally, a negative meaning
  - Complex and far reaching effects
- Bias
  - Natural inclination for or against
  - Disproportionate weight in favor or against
  - Usually in a way considered to be unfair

Werder et al. Journal of the American Psychiatric Nurses Association 2022 28:1, 9-22.

Stigma and Bias - OUD

Can cause fundamental health inequities

- Potential to be an independent social determinant of health

Stigma in health care setting toward patients with OUD has been well documented

- Prevent patient from receiving evidence-based treatment

Werder et al. Journal of the American Psychiatric Nurses Association 2022 28:1, 9-22.
Madden et al. Subst Use Misuse. 2021;56(14):2181e2201.

Combating Stigma

Language Matters

- Abuse
- Habit
- Addict
- Junkie
- Dirty
- Drug treatment
- Manipulative
- Denial
- Tracks

Change

- Substance Use Disorder
- Symptoms withdrawal without
- Person with OUD
- Person in active use
- Currently using opioids not prescribed
- Opioid Agonist treatment
- Attempting to meet needs
- Disagrees with diagnosis
- Visible injection marks

Werder et al. Journal of the American Psychiatric Nurses Association 2022 28:1, 9-22.
Madden et al. Subst Use Misuse. 2021;56(14):2181e2201.
Words Matter - Terms to Use and Avoid When Talking About Addiction | National Institute on Drug Abuse (NIDA) (nih.gov)

Factors Cause Stigma in OUD

Provider Based	General Public
Self or Internalized	Structural (Policy)

Werder et al. Journal of the American Psychiatric Nurses Association 2022 28:1, 9-22
Madden et al. Subst Use Misuse. 2021;56(14):2181e2201

Individual Factors Stigma

Provider Based

- Stigmatizing language in medical record/literature
- Misconception or lack of knowledge treatment OUD

General Public

- Lack of awareness disease process
- Misinformation or lack of education on role of treatment (programs)

Self or Internalized

- Low self-worth
- Shame

Structural/Policy

- Restrictive regulations
- Barriers to treatment

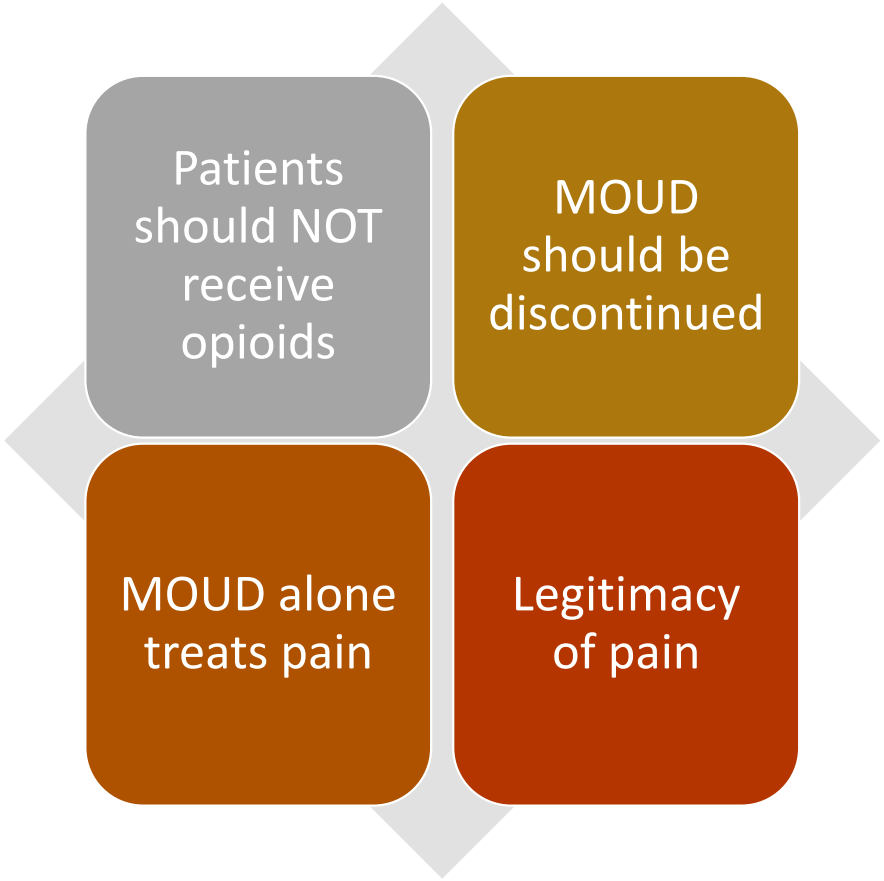
Werder et al. Journal of the American Psychiatric Nurses Association 2022 28:1, 9-22
Madden et al. Subst Use Misuse. 2021;56(14):2181e2201

Stigma and Patient Care

- Missed treatment opportunities
- Inadequate withdrawal management
- Patient directed discharge
- Placement restrictions
- Inconsistent or inadequate pain management

McNeil et al. Soc Sci Med. 2014;105:59e66.
Chan Carusone et al. Harm Reduct J. 2019;16(1):16.
Ti L et al. Am J Public Health. 2015;105(12):e53ee59.
Madden et al. Subst Use Misuse. 2021;56(14):2181e2201
Werder et al. Journal of the American Psychiatric Nurses Association 2022 28:1, 9-22.

Misconceptions – Pain and OUD



Pain Management in OUD

Shared decision-making with patients

- Reduces anxiety

Balance MOUD with other medical concerns

- Prevent patient directed discharge

Multi-modal pain management

- Inadequate treatment lead to illicit drug use

SAMHSA. Medications for Opioid Use Disorder. TIP Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.
Acute Pain Management in the Individual with Opioid Use Disorder - Providers Clinical Support System-Medications for Opioid Use Disorders (pcssnow.org)
Veazie et al. Washington (DC): Department of Veterans Affairs (US); 2019 Aug

Pain Management in OUD

MOUD

- Initiation/Continuation
- Specific PK/PD medications
- Split dosing
- Avoid opioids previously abused

Multi-Modal

- Higher doses opioids due to tolerance and/or effect MOUD
- Scheduled or continuous dosing
- Oral opioids preferred (transition as clinically appropriate)

SAMHSA. Medications for Opioid Use Disorder. TIP Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.
Acute Pain Management in the Individual with Opioid Use Disorder - Providers Clinical Support System-Medications for Opioid Use Disorders (pcssnow.org)
Veazie et al. Washington (DC): Department of Veterans Affairs (US); 2019 Aug

Buprenorphine in acute pain

Reminder

- Buprenorphine high-affinity mu-opioid receptor (acts as a partial agonist)
- Affinity is 5.4 times stronger than fentanyl and 20 times greater than morphine

Mild to moderate pain

- Administered at maintenance dose, or
- Divide total daily dose to be administered either three or four times daily

Injectable

- Maximize non-opioid therapy
- Add opioids at high-dose if non-opioids ineffective
- Require high-dose opioids if long acting received within past 6 months

SAMHSA. Medications for Opioid Use Disorder. TIP Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

Methadone in acute pain

Legally ordered and administered to patients admitted to hospital or long term care facility, primarily for other reasons (21&42 CFR)

Confirmation with outpatient treatment program

Patients in pain should receive their full daily dose of methadone (barring contraindications), baseline dose should not be considered for pain management

Split total daily dose to every 6 to 8 hours

Continue daily home dose and add an opioid agonist

SAMHSA. Medications for Opioid Use Disorder. TIP Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

Naltrexone in acute pain

Oral naltrexone provides blockade of receptor for up to 72 hours

ER injectable provides measurable naltrexone levels for up to 1 month or longer after last injection

Stop/suspend use of oral naltrexone

Situations where cessation of naltrexone is not possible

Note: A 7-10 day opioid free period is recommended before resuming naltrexone

SAMHSA. Medications for Opioid Use Disorder. TIP Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

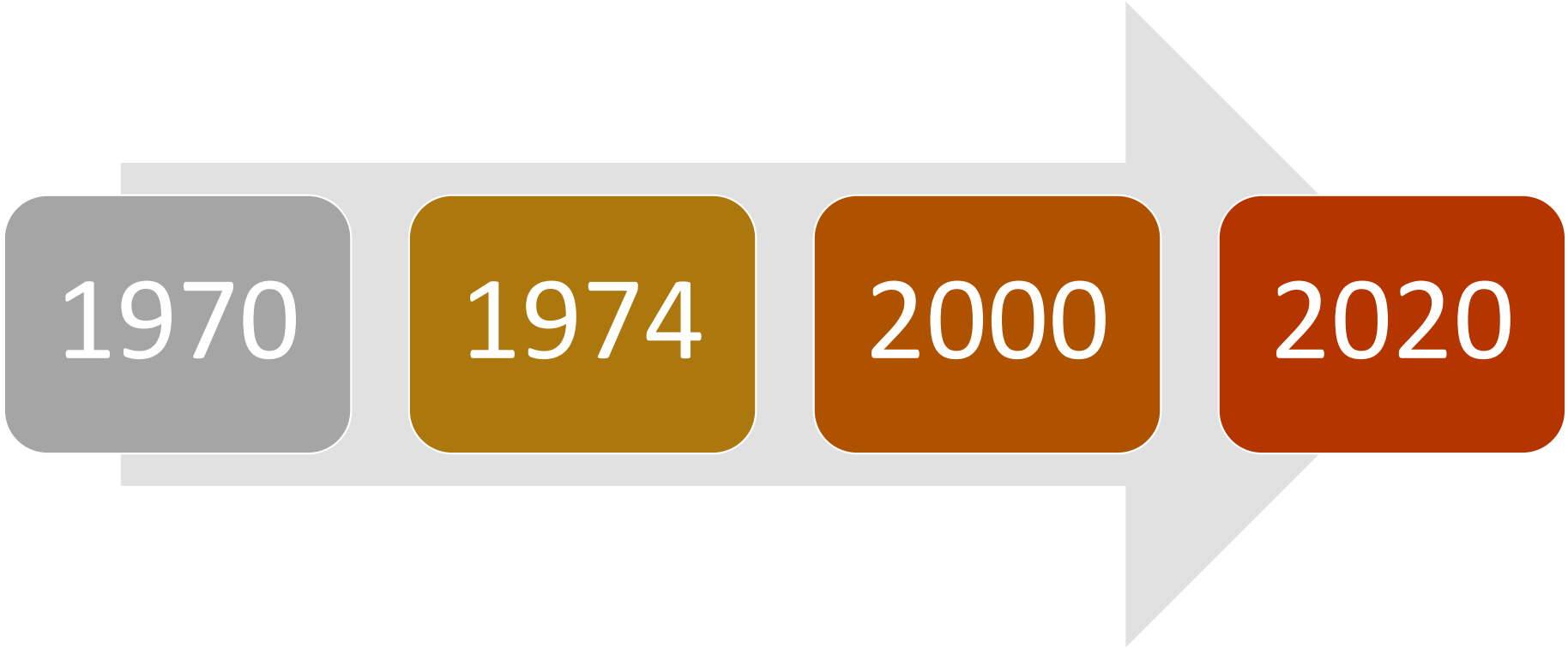
History, Rules, and Regulations

- 1970 DEA implements and enforces
    - Comprehensive Drug Abuse Prevention and Control Act
- 1974 DEA published regulations
    - Narcotic Addict Treatment Act (NATA)
        - Administer and dispense certain narcotic medications at a federally approved narcotic treatment program
        - Requires separate registration
- 2000 Drug Addiction Treatment Act (DATA 2000)
    - Waives requirement separate registration (X Waiver)
        - “Qualifying physician”
        - Submit a notification of intent
        - Limitations number of patients

SAMHSA. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. TIP Series 40. Publication No. (SMA) 04-3939.

Congress.gov | Library of Congress

History, Rules, and Regulations



Updates, Rules, and Regulations

12/11/20 Easy Medication Access and Treatment of Opioid Addiction (the Act)

- Goal - significantly expand immediate and emergency access medications for individuals suffering from acute withdrawal symptoms while the individual awaits further, long term treatment

42 CFR Part 8 Final Rule

- First substantial update to the OTP treatment standards 20 years
- Expand access and improve experiences in the treatment SUD
- Flexibilities during COVID-19 public health emergency permanent

Statutes, Regulations, and Guidelines for Medicated-Assisted Treatment | SAMHSA
42 CFR Part 8 Final Rule | SAMHSA
Congress.gov | Library of Congress

Updates, Rules, and Regulations

2023 Consolidation Appropriations Act

- X waiver removal (buprenorphine)
  - Removing restrictions on providers and increasing access for patients to MOUD
  - Any provider with DEA license can prescribe
  - Requiring provider to complete a one-time eight hour training

Statutes, Regulations, and Guidelines for Medicated-Assisted Treatment | SAMHSA
Congress.gov | Library of Congress

Updates, Rules, and Regulations

DEA Update published 08/08/23

- "so that practitioners … are allowed to dispense not more than a three-day supply of narcotics drugs to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both)."
  - Intended methadone linkage to care
  - Dispense only (NOT prescribe)
    - Challenging to operationalize
    - Inpatient dispense on discharge

21CFR Part 1306 revision 8/08/23
2023-16892.pdf (govinfo.gov)

Barriers to Access

- Methadone
  - Outpatient treatment program only
- Buprenorphine
  - Pharmacy dispense availability
- Long acting (most states-clinic visits) – buprenorphine and naltrexone
- Inpatient formulary restrictions

SAMHSA. Outpatient Treatment Program Guidance. 3/16/2020 (Updated 3/19/2020)
Qato et al. JAMA Health Forum. 2022;3(8):e222839.
Weiner et al. JAMA Network Open. 2023;6(5):e2316089

Methadone

Outpatient Treatment Program

- Comply federal and state regulations/guidelines

Consequences

- Limited Location/Hours
- Enrollment Restrictions
- Frequent Visits
- Complicated transitions of care

Progress

- For all states – request blanket exception for all stable patients to receive 28 days; less stable (OTP believes can safely handle) 14 days Take-Home dose
- IL PMP includes methadone (patient consent required to report)
- Tele-Health

SAMHSA. Outpatient Treatment Program Guidance. 3/16/2020 (Updated 3/19/2020)
Methadone Take-Home Flexibilities Extension Guidance | SAMHSA

Buprenorphine

Required retail/outpatient compliance

- Controlled Substance Act
- Responsibility and duty to ensure validity of controlled substances
- Drug Enforcement Agency (DEA)-pharmacist deliberately ignores questionable prescription may be prosecuted
- DEA requires all suppliers to monitor pharmacy orders of controlled substances via Suspicious Orders Report System

Consequences

- Delayed shipments
- Not stocked in pharmacy inventories
- Declined or not filled prescriptions

Progress

- DEA - X waiver removal

Qato et al. JAMA Health Forum. 2022;3(8):e222839.
Weiner et al. JAMA Network Open. 2023;6(5):e2316089

Pharmacist's Role – Outpatient

Pharmacists are the most accessible medical provider

- Expanding MOUD access
  - Provider <–> Pharmacist <–> Patient Relationships
    - Identify providers – develop collaborative practice
    - Remove bias/stigma – develop patient relationships
  - Supplier restrictions
    - Identify restrictions – develop workflows ensure maintain adequate stock
  - Educate others
    - Colleagues (pharmacists, providers, pharmacy technicians, public)
  - Advocate
    - Less restrictions on stocking/dispensing
    - Increased access to long acting injections in retail setting

SAMHSA/DEA Virtual Town Hall: Expanding Buprenorphine Access in Pharmacies to Treat Opioid Use Disorder

Pharmacist's Role - Inpatient

Pharmacists already treat patients with co-occurring SUD

- Expanding MOUD access
  - Clinical services to include a pharmacist
  - Medication Use Process Development
  - Medication supply
    - Formulary addition and/or changes
    - Stocking
    - Inventory
    - Proper Storage
  - Staff education and medication review
  - Medication access and handoff
  - Naloxone co-prescribing decision support

Tran et al. Am J Health Syst Pharm. 2021 Feb 8;78(4):345-353.
Kerins et al. J Am Pharm Assoc (2003). 2023 Jan-Feb;63(1):204-211.e2

Pharmacist's Role – Inpatient/Outpatient

- Harm reduction Resource
  - Substance test kits
    - Fentanyl and xylazine test strips
  - Naloxone availability
    - Over the counter access, at hospital discharge, insurance authorizations
    - Overdose reversal education and training
  - Medical
    - Screening substance use disorder and infectious disease, linkage vaccination and prevention
    - Wound care supplies
  - Supplies
    - Promote sterile injection and reduce infections
    - Sharp disposal and medication disposal kits

Harm Reduction | SAMHSA

Education and Resources

- Continuing Education
  - Providers Clinical Support System (PCSS)
    - Training Courses Archive - Providers Clinical Support System-Medications for Opioid Use Disorders (pcssnow.org)
  - American Pharmacist Association
    - Opioid Use & Misuse (pharmacist.com)
  - California Bridge
    - CA Bridge - Bridge to Treatment
- Additional resources
  - Substance Abuse and Mental Health Services Administration (SAMSHA)
    - Programs | SAMHSA
  - American Society of Addiction Medicine (ASAM)
    - ASAM - American Society of Addiction Medicine
  - Center Disease Control
    - Understanding the Opioid Overdose Epidemic | Opioids | CDC
  - National Institute on Drug Abuse (National Institute of Health)
    - NIDA.NIH.GOV | National Institute on Drug Abuse (NIDA)
  - Erowid's anonymous drug data analysis program
    - DrugsData.org: Test Results

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