PHARMACY VISION 2020

CSHP SEMINAR 20 • OCTOBER 21-25

Disneyland RESORT

Back to Life: A review of opioid use disorder and therapeutic strategies

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DISCLOSURE

Krystal Riccio has taken part in the following transactions that may be considered a potential conflict of interest:

- Speakers Bureau for AbbVie
- Grant Reviewer for SAMHSA

Learning Objectives

Pharmacist:

1. Review neurological changes surrounding opioid use disorder.
2. Describe harm reduction strategies for patients living with opioid use disorder.
3. Identify various approaches for the treatment of opioid use disorder.
4. Evaluate the evidence and recommendations surrounding the use of medication-assisted treatment in the management of opioid use disorder.

LEARNING OBJECTIVES

Pharmacy Technician:

1. Review neurological changes associated with opioid use disorder.
2. Describe public health initiatives that reduce infection and death rates among people living with opioid use disorder.
3. List current opioid use disorder treatment options: non-medication and medication-assisted treatment.

PHARMACIST QUESTION #1

Which of the following patients should you discuss naloxone with?

A. TF is a 54 yr-old who is prescribed Norco 5/325- 1 tablet orally twice daily as needed for chronic back pain. TF comes in every other month to pick up fills of 30 tablets.

B. MA fills a prescription for Oxycontin 10 mg orally every 12 hours and Percocet 5/325mg 1 every 6 hours as needed for pain.

C. RM is prescribed a 10-day supply of oxycodone/apap 5/325mg- 1 tablets orally every 8 hours as needed for pain following a cesarean section.

D. CJ fills a prescription for fentanyl 25mcg transdermal patches each month to treat cancer associated pain. This patient has a 4 month history of fills.

PHARMACIST QUESTION #2

What is the pharmacology of methadone?

A. Methadone is a partial agonist and has a low affinity at the mu-receptor.

B. Methadone is a partial agonist and has a high affinity at the mu-receptor.

C. Methadone is a full agonist and has a high affinity at the mu-receptor.

D. Methadone is a full agonist and has a low affinity at the mu-receptor.

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PHARMACIST QUESTION #3

What is the recommended strategy to avoid precipitating withdrawal during induction?

A. Buprenorphine should be initiated within 4 hours of the last dose of heroin.

B. Buprenorphine should be started only after the patient is experiencing significant opioid withdrawal symptoms.

C. Patients should abstain from opioid use for at least 7 days before initiating buprenorphine.

D. Buprenorphine is a low-risk medication for precipitating withdrawal.

PHARMACIST QUESTION #4

What is TRUE regarding evidence surrounding OUD treatment?

A. Maintenance treatment leads to superior outcomes compared to detoxification.

B. Maintenance therapy with methadone 80mg is superior to buprenorphine 16mg.

C. Naltrexone XR is non-inferior to methadone or buprenorphine in mortality outcomes.

D. Treatment retention is superior with buprenorphine compared to methadone.

PHARMACY TECHNICIAN QUESTION #1

Which of the following strategies can reduce the risk of harm in a person living with OUD?

A. Vaccination history review
B. Naloxone distribution
C. Safe-sex education
D. Needle distribution
E. All of the above

PHARMACY TECHNICIAN QUESTION #2

Which of the following medications can be dispensed by the pharmacy for OUD treatment?

A. Methadone
B. Buprenorphine/naloxone
C. Naltrexone XR
D. All of the above

PHARMACY TECHNICIAN QUESTION #3

What is the most effective form of treatment for OUD?

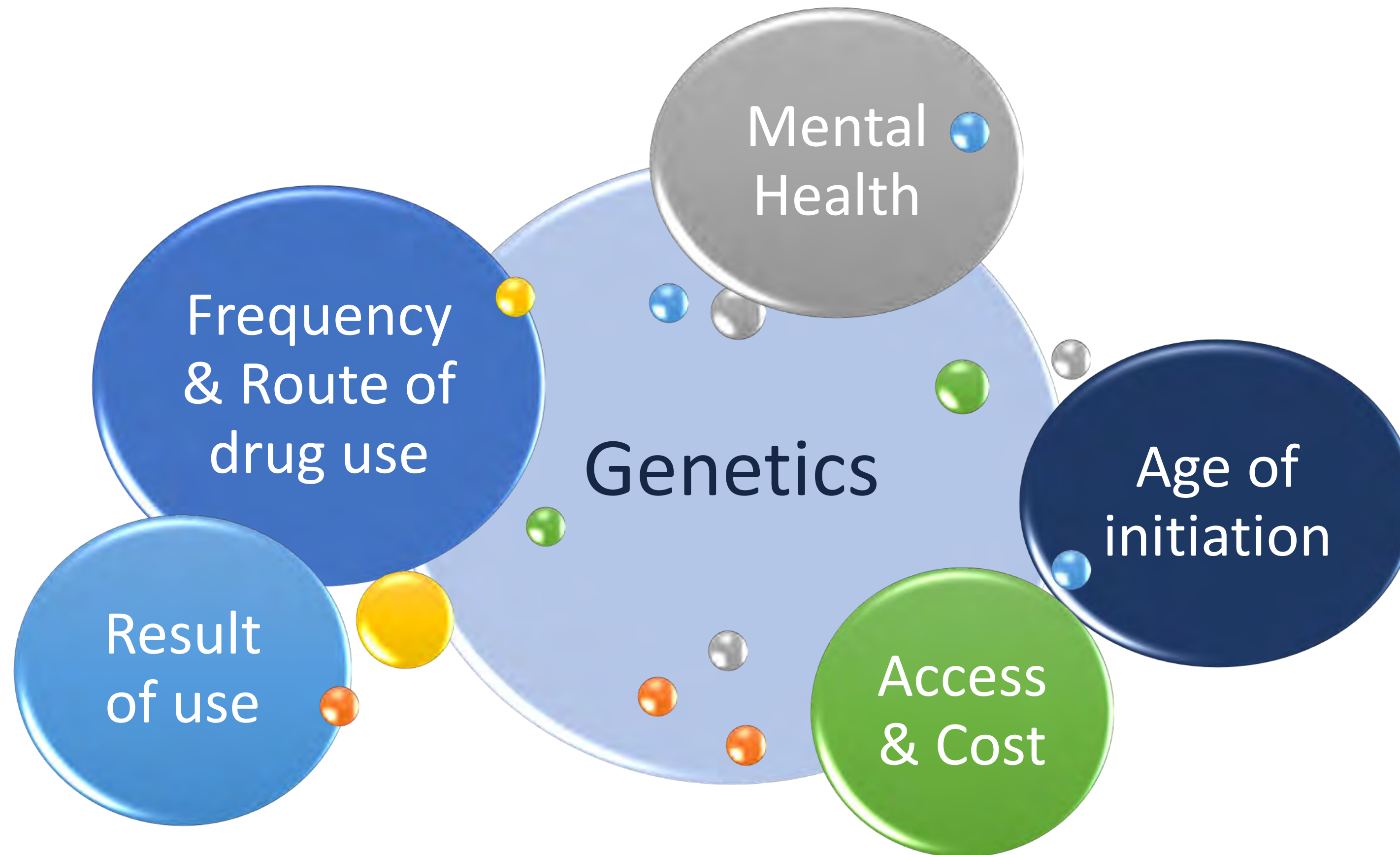
A. 12-step abstinence programs
B. Medically supervised detoxification
C. Opioid-agonist therapy within an opioid treatment program
D. Naloxone therapy

Approximately 1.7 million Americans have a prescription painkiller OUD

526 thousand have heroin related OUD[1]

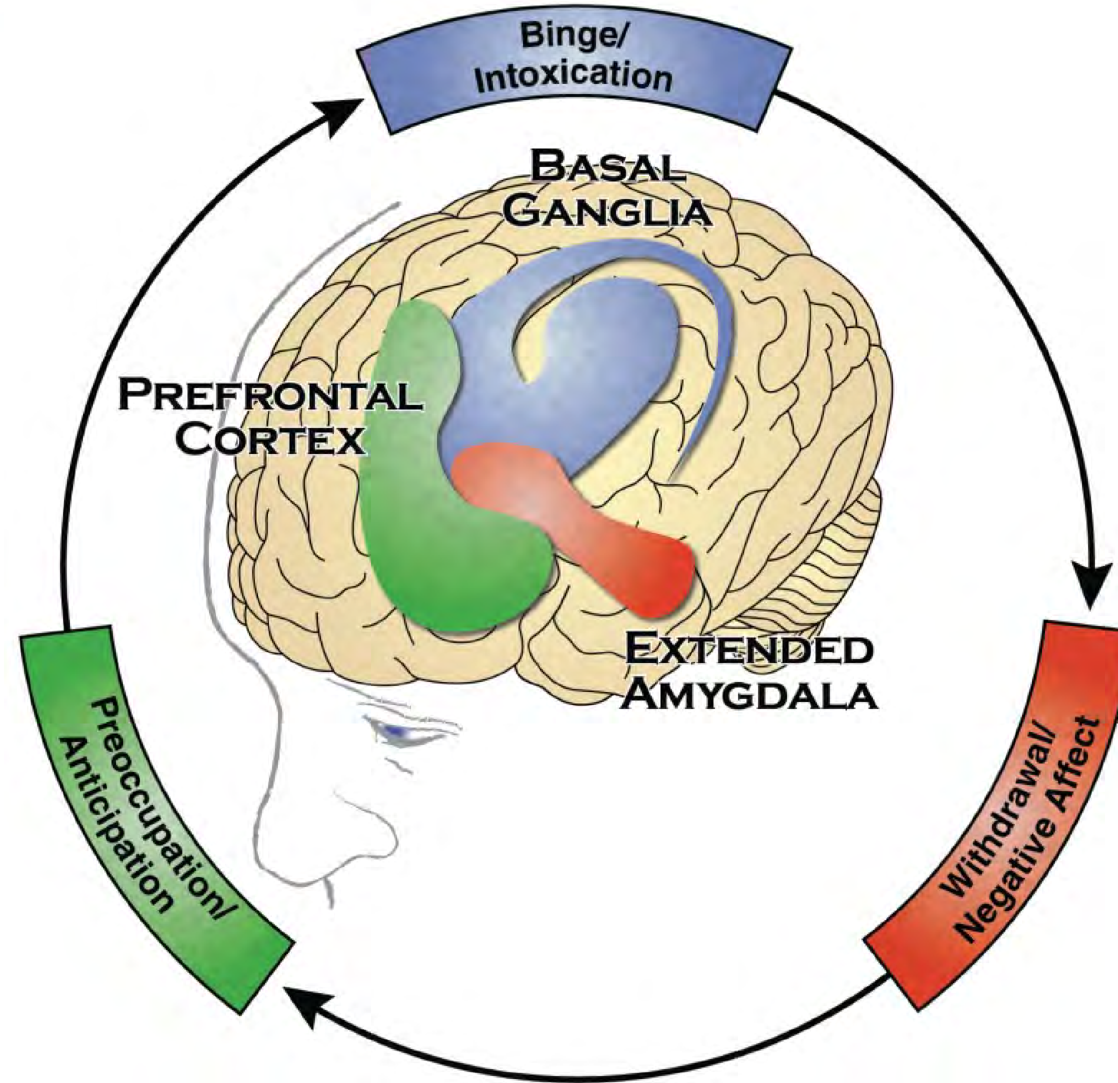
NEUROBIOLOGY OF OPIOID USE DISORDER (OUD)

PREDISPOSING FACTORS FOR OUD



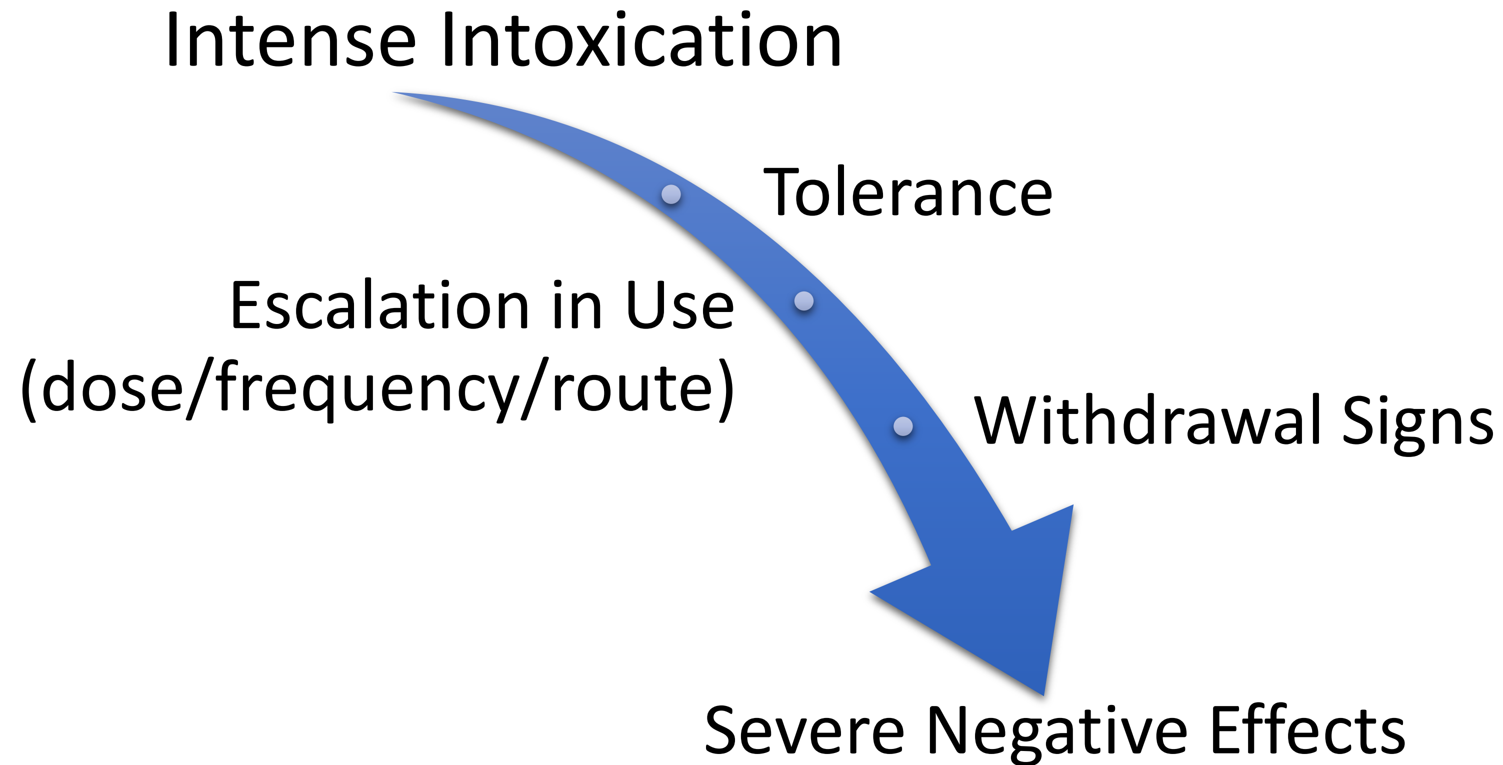
2. https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-misuse-addiction

Cycle of Addiction



3. https://www.ncbi.nlm.nih.gov/books/NBK424849/figure/ch2.f3/

Opioid Use Disorder



3. SAMHSA, 2016

Results of Neuroadaptive Changes

Binge & Intoxication	Feeling euphoric	Feeling good	Escaping dysphoria
Withdrawal & negative effects	Reduced energy	Reduced excitement	Depressed, anxious, restless
Preoccupations & anticipation	Looking forward	Desiring drug	Obsessing and planning to get drug

4. Volkow ND, et al. N Engl J Med. 2016; 374:363-371.

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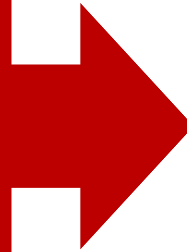
Risks Associated With OUD

- Infectious Disease (ID)
  - HIV, Hep A, Hep B, Hep C
  - Abscess, Blood Infection, Endocarditis
- Overdose Death
- Criminal Behavior & Recidivism
- Loss of Job
- Breakdown of Relationships
- Homelessness



Harm Reduction Strategies

- Needle Exchange (Kits)
- Safe Sex Education & Materials
- Vaccinations & Testing (HIV/Hep C)
- Safer Use Practices
- Naloxone Distribution
- Drug Testing Opportunities
- Drug Court Options
- Detoxification & Drug Treatment
- Housing & Vocational Services

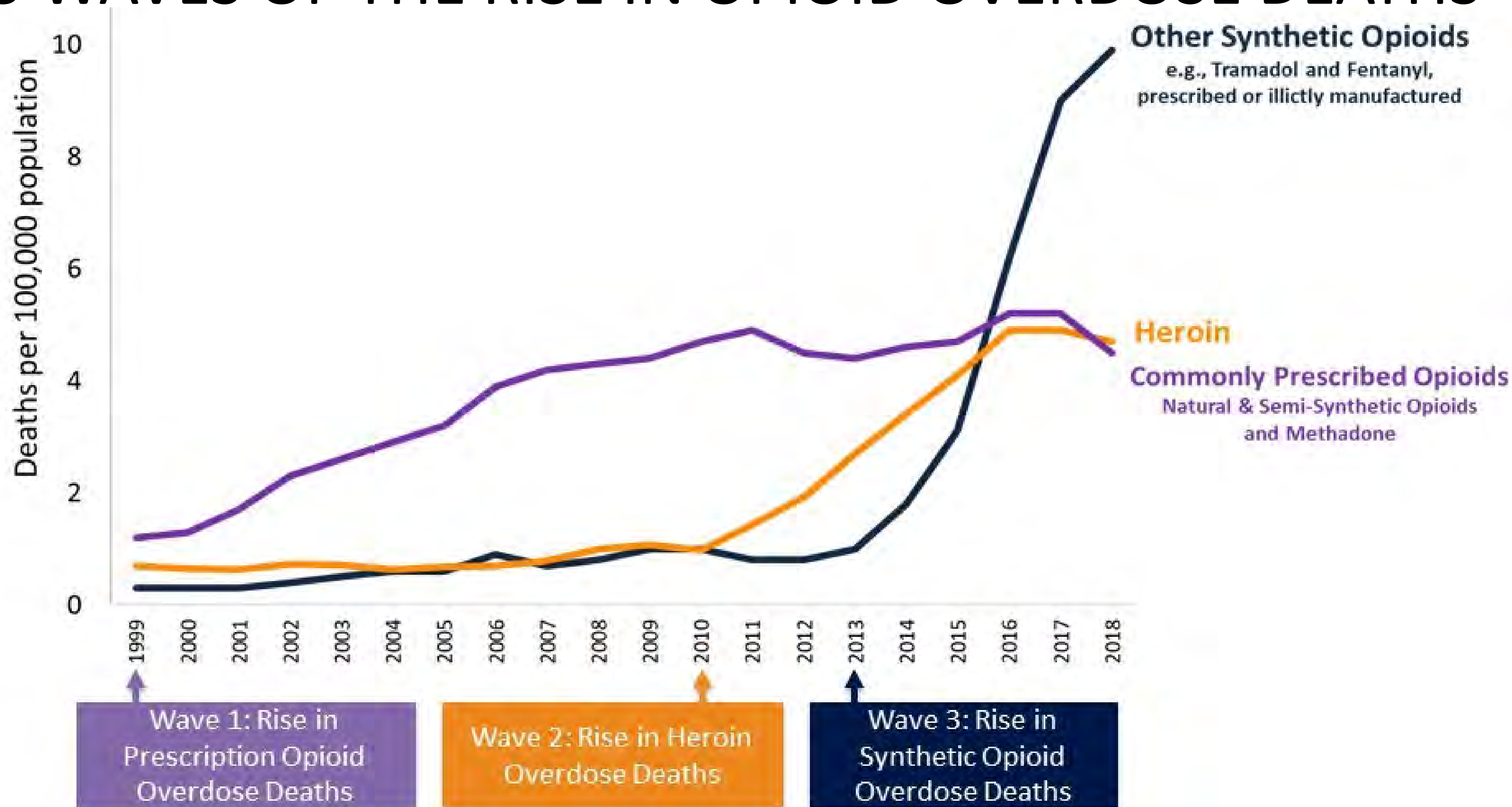
Harm Reduction Practices

- Never use alone, have naloxone, & plan for overdose
- Never share needles/syringe/tourniquet
- Include abstinence days in schedule
- Buy what & when intending to use (consider testing substances)
- Stay fed and hydrated
- Maintain sleep schedules
- Avoid mixing substances
- Carry condoms

ASSESS FOR RISK OF OVERDOSE

- History of overdose
- Prescribed > 50 MME daily
- Prescribed or concomitant use of benzodiazepines or alcohol
- Chronic liver or kidney disease
- Illicit drug use
- Post-incarceration or abstinence
- Using alone

3 WAVES OF THE RISE IN OPIOID OVERDOSE DEATHS



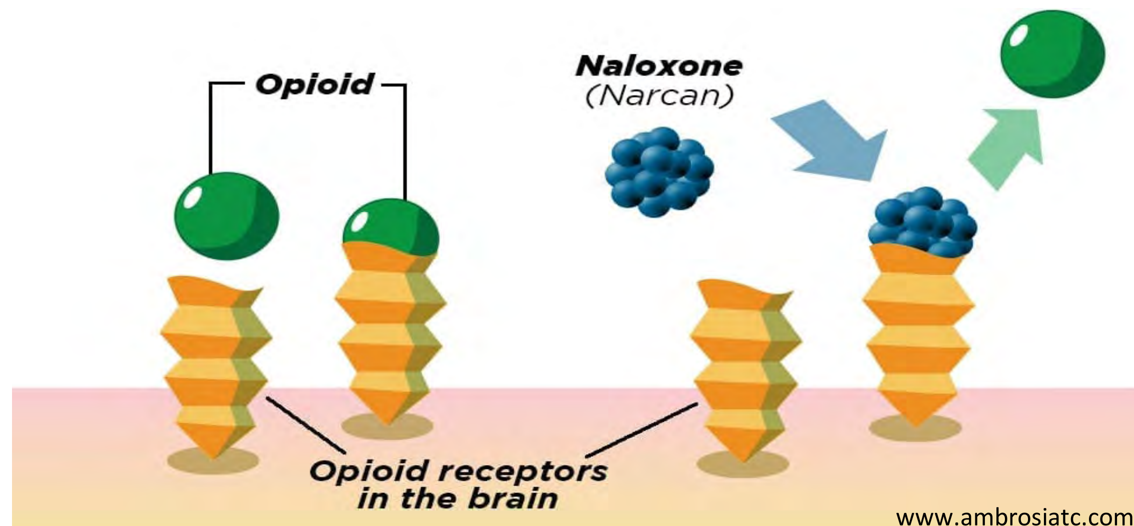
SOURCE: National Vital Statistics System Mortality File.

Overdose Reversal Agent

Naloxone

NALOXONE (NARCAN®)

- Complete opioid antagonist, high affinity for mu receptor
- Short-acting, lasts 30-90 minutes
- Rapid-onset, within 2-5 minutes
- No risk of overdosing from naloxone (may repeat multiple doses)



NALOXONE

Medscape.com

Single-step Nasal Spray (Narcan®)

2 (4mg) doses per box

www.health.harvard.edu

Multi-step Nasal Spray

1 (2mg) doses per box

mms.mckesson.com

Intramuscular Injection

Single (0.4mg) or multi-dose vials

https://naloxoneautoinjector.com/

Auto-Injector (Evzio®)

2 (2mg) prefilled auto-injectors per box

California Naloxone Protocol

- CE Requirement
- Screen Recipient
- Educate Recipient
- Provide Fact Sheet
- Consented Notification
- Document & Maintain Records (3 yrs)

Resources:

https://www.pharmacy.ca.gov/licensees/naloxone_info.shtml

http://prescribetoprevent.org/wp2015/wp-content/uploads/OpioidSafetyFocusOnNaloxone_Pharmacists_AUG.18_final-with-links.pdf

Opioid Use Disorder Treatment

"Most Valuable Resource"

Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63, Executive Summary. HHS Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020. Available from https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006

ASSESS FOR OPIOID USE DISORDER

National Institute on Drug Abuse (NIDA) Quick Screen

"How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reason?"

NIDA-modified ASSIST (Alcohol, Smoking, and Substance Involvement Screening Test)

DAST-10 (Drug Abuse Screening Test)

TAPS (Tobacco, Alcohol, Prescription Medications, and Other Substance Use)

DSM-5

Goals of OUD Treatment

- Achieve and maintain physical, psychological, and social well-being
- Reduce risky behaviors
- Reduce → eliminate drug use

Non-Pharmacologic Treatment Strategies

Psychosocial

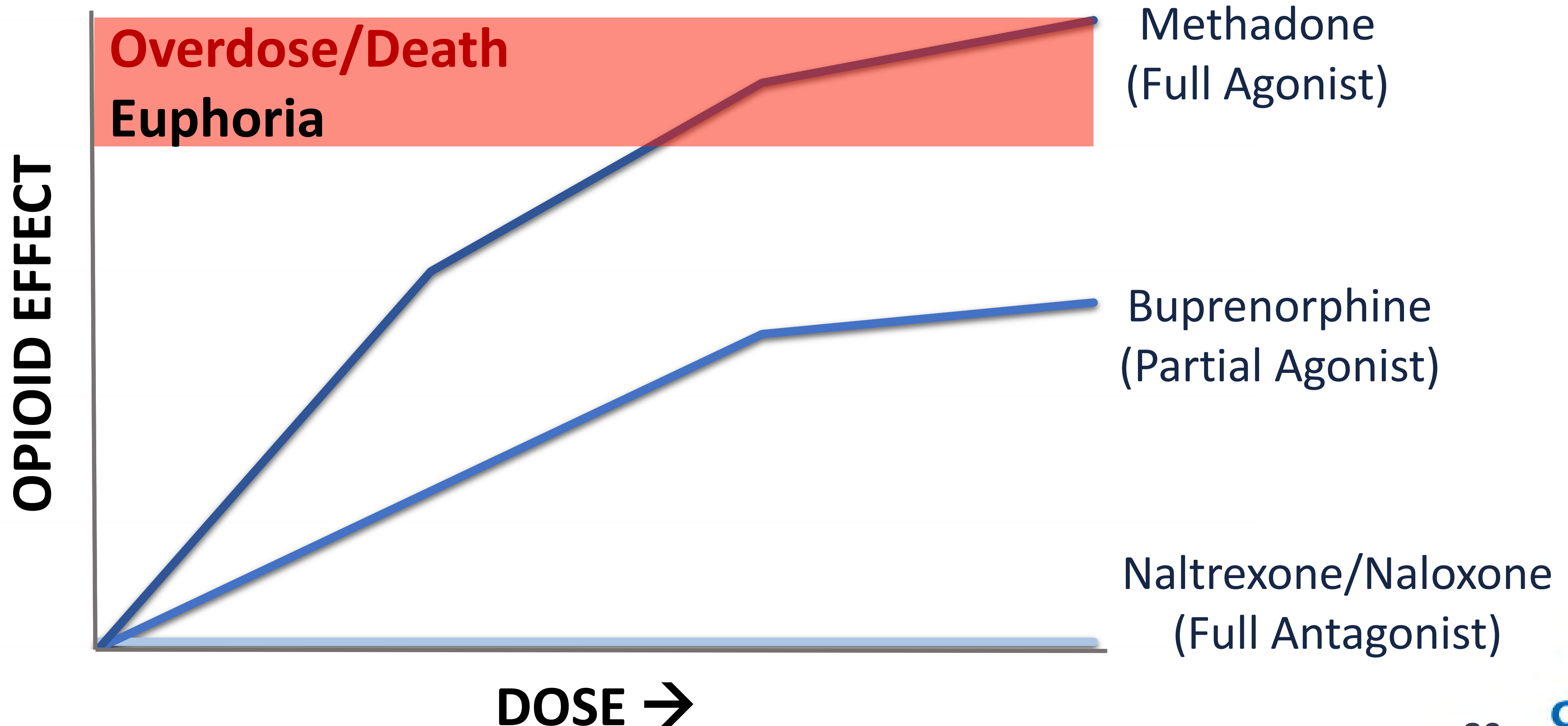
- Abstinence based 12-step program
- Cognitive behavioral therapy (CBT)
- Family counseling
- Drug-free living

PHARMACOLOGIC TREATMENT STRATEGIES

Medication Strategies

- Opioid agonist: Detoxification
- Opioid agonist: Maintenance therapy
- Opioid antagonist: Overdose reversal
- Opioid antagonist: Relapse prevention

OUD PHARMACOLOGIC TREATMENT EFFECTS



OUD Pharmacologic Treatment Efficacy

Opioid **Agonist** Maintenance is MOST Effective

- Reduced risk of overdose deaths by 70%
- Retention in treatment
- Reduction of drug use
- Reduced emergency health services
- Reduce infection rates for HIV and Hepatitis C by 50%
- Reduction of high-risk injecting
- Reduction of high-risk sexual behaviors
- Slowing progression of HIV
- Reduced criminal offences and associated cost

9. Weber R, et al. BMJ. 1990;301:1362-1365.
10. Larney S, et al. BMJ Open. 2018;8:e025204.
11. Lawrinson P, et al. Addiction. 2018;103:1484-1492.
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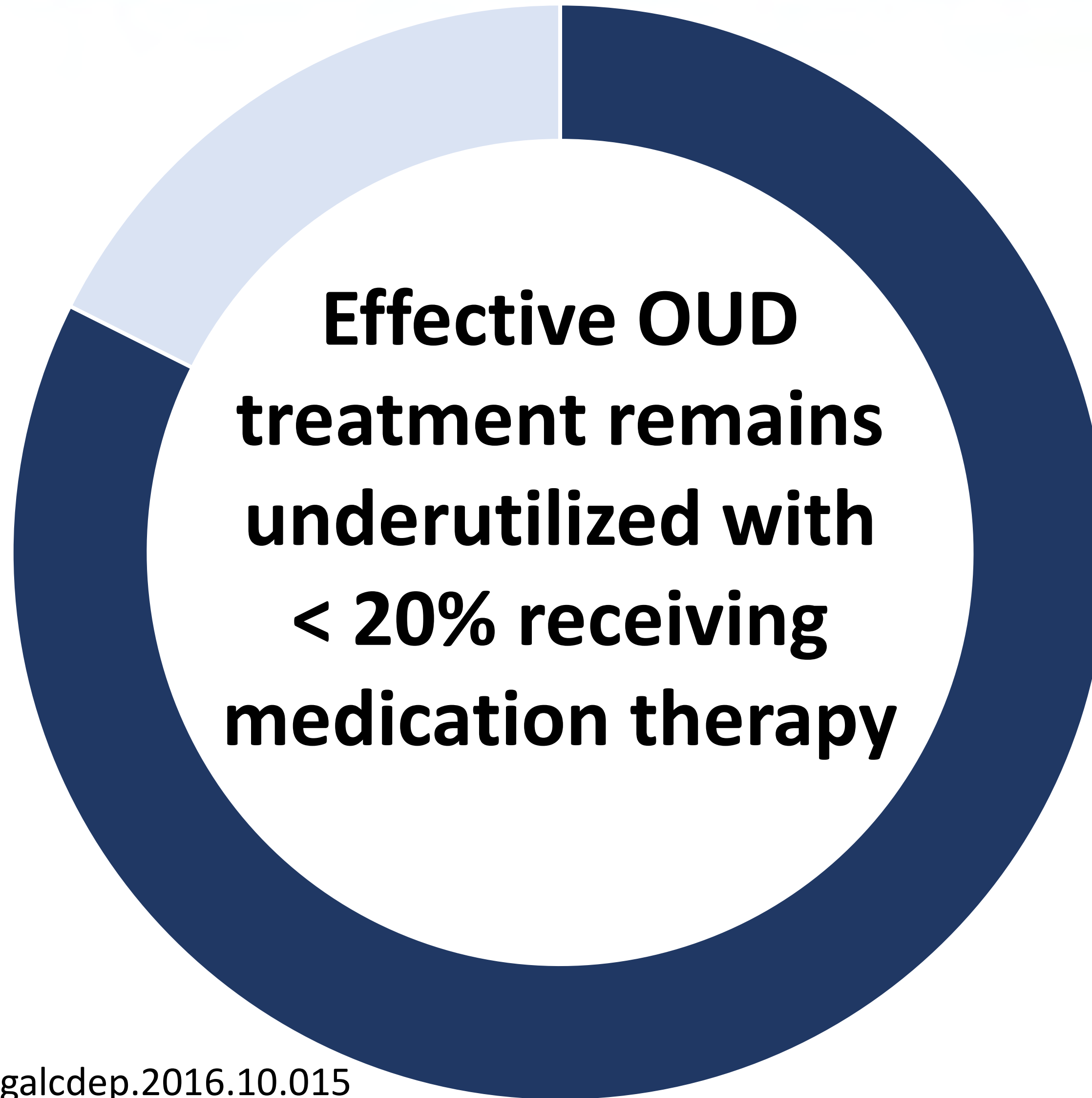

13. http://dx.doi.org/10.1016/j.drugalcdep.2016.10.015

Opioid Agonist Treatment

Methadone

Buprenorphine

METHADONE

Mechanism of Action:

- Synthetic complete mu-receptor agonist

Pharmacokinetics

- Long-acting (up to 60 hours)
- Steady-state ~ 5 days
- Highly protein bound & lipophilic
- Metabolism CYP450 3A4, 2B6, 2D6

METHADONE

Contraindications

- Acute asthma or severe COPD

Precautions/Warnings

- Respiratory depression, concurrent benzodiazepine/alcohol dependence, QTc prolongation/cardiac arrhythmia, unintended ingestion (lock box!), Neonatal abstinence syndrome (NAS), physical dependence, sedation

Side effects

- Overdose, QT interval prolongation (may require ECG monitoring), constipation, nausea, sexual dysfunction, sweating, weight gain, edema

METHADONE

Drug Interactions

- CYP450 inducers: rifampin, efavirenz, nevirapine, lopinavir, ritonavir, carbamazepine, phenobarbital, phenytoin
- CYP450 inhibitors: ciprofloxacin, cimetidine, fluconazole, paroxetine, sertraline
- QTc prolongation: tricyclic antidepressants, venlafaxine, antiarrhythmics
- CNS depression: benzodiazepines, barbiturates, gabapentin, pregabalin

METHADONE FOR OUD / PAIN

Comparator	OUD Treatment	Pain Treatment
Prescriber Requirement	DEA-X practicing in OTP*	DEA required
Dispensing	Dispensing/Administration through a certified OTP	Regular C-II prescription Dispensed by pharmacy
Frequency of Dosing	Once daily	Three times daily
Typical Formulation	Oral solution	Oral tablet
Prescription Drug Monitoring Program	Not reported to CURES	Reported to CURES

*OTP = Opioid Treatment Program

METHADONE

Induction

- Initiate 10 to 30mg
- Reassess 3-4 hours after initial dose
- Additional 10mg on first day, if withdrawal symptoms are present

Day 1

weekly

Stabilization

- Increase by 5 – 10mg every 7days depending on response

Thereafter

Maintenance

- 60 to 120mg

Buprenorphine (Subutex®, Sublocade®, Probuphine®)

Mechanism of Action

- Partial agonist with high mu-receptor affinity ("ceiling effect") & slow dissociation
- Antagonist at kappa-receptors

Pharmacokinetics

- Bioavailability requires avoidance of first-pass metabolism
- Long-acting (24-42 hours sublingual)
- Highly protein bound; lipophilic

Buprenorphine / Naloxone (Suboxone®, Bunavail®, Zubsolv®)

Buprenorphine Co-formulated with Naloxone

- Naloxone component
  - Full opioid antagonist,
  - Low bioavailability SL/oral
    - Bioavailable nasally/IV
- Abuse deterrent
- Preferred formulation
- Not recommended in pregnancy (prefer buprenorphine alone)

Buprenorphine / Naloxone

Precautions / Warnings

- Precipitated withdrawal- induction, respiratory depression, concurrent benzodiazepine/alcohol dependence, unintended ingestion, sedation, dependence, NAS

Adverse Effects

- Opioid withdrawal, oral discomfort, constipation, vomiting, insomnia, sweating

Drug Interactions

- Strong CYP450 inhibitors/inducers- clinically monitor and consider adjusting when necessary (over-sedation/withdrawal)

BUPRENORPHINE FOR OUD / PAIN

Comparator	OUD Treatment	Pain Treatment
Prescriber Requirement	DEA-X or X-number Waiver	DEA required
Dispensing	C-III; Dispensing by OTP or pharmacy – written Rx	Regular C-III prescription; Dispensed by pharmacy
Frequency of Dosing	Once daily*	Two - Three times daily
FDA-approved Formulations	B/N- SL film/tablet B/N- Buccal film B- Subcutaneous monthly B- Subdermal implant Q 6 months	SL/buccal tablets/films Transdermal patch
Prescription Drug Monitoring Program	OTP-NOT reported to CURES; Pharmacy-reported to CURES	Reported to CURES

Buprenorphine Formulations

Sublingual Tablet	Subcutaneous Depot	Subdermal Implant
https://www.drugs.com /buprenorphine-images.html	www.indivior.com	probuphine.com
Sublingual tablets once daily	SUBLOCADE® 300mg, 100mg once monthly	PROBUPHINE® Each insertion lasts 6 months
Dispensed by OTP or pharmacy	Administered abdominally by healthcare provider REMS: pharmacy & provider certification www.SublocadeREMS.com	Inserted inside upper arm by healthcare provider REMS: attend 8h training including insertion & removal probuphinerems.com

Buprenorphine / Naloxone Formulations

Suboxone® SL Tab/Film	Bunavail® Buccal Film	Zubsolv® SL Tablet
	medscape.com	drugs.com/zubsolv-images.html
	Equivalent Dosing	
8 / 2mg	4.2 / 0.7 mg	5.7 / 1.4 mg
Off-label instructions for cutting or splitting dose (up to 2 – 3 times daily)	Dissolve on inside upper cheek	Dissolve under tongue
4 generic strips available	Brand name	Brand name

BUPRENORPHINE / NALOXONE TRANSMUCOSAL

Start 10-12 h after last short-acting opioid use or >24 h for long-acting
Mild-moderate withdrawal symptoms before 1st dose (COW-Score ≥ 8)

Induction — Day 1

- Initiate 2-4mg (with/without naloxone)
- Reassess 2 hours after initial dose
- May dose up to 8mg total on Day 1

Stabilization — Day 2-4

- Switch to combination buprenorphine/naloxone
- Reassess withdrawal symptoms, may increase dose by 4/1mg

Maintenance — Thereafter

- Continue or increase to effective dosing (typically 16/4mg daily)

BUPRENORPHINE LONG-ACTING SUBCUTANEOUS

SUBLOCADE® Conversion

Maintenance
- Transmucosal 8-24mg daily

At least 7 days

Subcutaneous Induction
- Inject 300 mg once monthly

2 months

Subcutaneous Maintenance
- Inject 100 mg once monthly
- May increase to 300 mg (monitor LFTs)

Thereafter

Buprenorphine Long-Acting Implant

PROBUPHINE® Conversion

Maintenance
- Transmucosal ≤ 8 mg daily

≥ 3 weeks

Subdermal Implant
- REMS Certified HCP inserts 4 rods
- Upper inside of arm

6 months

Second Subdermal Implant
- REMS Certified HCP removal of 4 rods
- Insert 4 new rods into alternate arm

6 months

Comparing Opioid Agonist Treatments

Methadone

- ✓ Most universal insurance coverage
- ✓ May benefit patients needing daily dosing supervision in OTP
- ✓ May benefit previous office-based treatment program relapses
- X Only available from OTP, frequent visits required
- X Higher abuse potential
- X Higher overdose risk

Buprenorphine

- ✓ Increasing insurance coverage
- ✓ Improves access, with waiver, through office-based treatment & prescription
- ✓ Longer lasting formulations available
- ✓ Less cravings/withdrawals with intermittent non-adherence
- ✓ "ceiling effect" reduces overdose risk
- X Higher risk of precipitated withdrawal
- X Potentially higher cost

Opioid Antagonist Treatment

Naltrexone

NALTREXONE

Not scheduled by DEA

Physicians, NPs, and PAs may prescribe oral or XR-naltrexone

Indications

- Opioid Use Disorder: Abstinence maintenance/Relapse prevention
- Alcohol dependence

Mechanism of Action

- Complete opioid antagonist – will induce withdrawal
    - Block the effects of opioids

NALTREXONE XR (VIVITROL®) INJECTABLE

Contraindications

- Current or anticipated opioid use for pain, opioid use within preceding 7-10 days, severe hepatic impairment

Precautions / Warnings

- Pregnant/planning on becoming pregnant, increased risk of overdose death, hepatitis risk (monitor LFT at baseline and during treatment), depression & suicidality, emergency pain treatment needs

Adverse Effects

- Insomnia, injection site pain, hepatic enzyme elevations, nasopharyngitis

NALTREXONE XR (VIVITROL®)

Other Comments

- Often initiated at release from incarceration
  - Specialty drug courts
  - Detoxification → sober-living facility

- Provide safety alert materials to patient
  - Wallet card, wrist band, dog tag

https://www.orpca.org/

Naltrexone SR (Vivitrol®) Injectable

Administration

Abstinence
- No opioid use

7 – 14 days

Naloxone Challenge
- May trial an oral dose of naloxone
- Baseline LFT evaluation

Prior to first dose

Intramuscular Injection
- Remove from refrigeration 45 min
- IM gluteal injection into alternating buttock

Every 4 weeks or monthly

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Naltrexone Treatment

Advantages

- ✓ No sedation or overdose risk
- ✓ No diversion risk
- ✓ Legend drug without restrictions to specialty providers
- ✓ Blocks effects of opioid agonists, thereby reinforcing abstinence
- ✓ Additional indication for alcohol dependence disorder

Disadvantages

- X Lower rates of retention in treatment programs relative to opioid agonist treatment
- X Can precipitate withdrawal if administered too early in abstinence
- X Complicates emergency pain management
- X Increased risk of overdose death with opioid use following treatment discontinuation

EVIDENCE

- All 3 OUD treatments superior to placebo in reduced illicit opioid use[15,16]
- No difference with methadone mod-high (>80mg) or buprenorphine mod-high (>16mg) in retention, opioid-use, or mortality[15]
- Methadone low-dose superior to buprenorphine low-dose in retention; no difference in mortality[15]
- Continued treatment methadone/buprenorphine superior to medically supervised withdrawal in return to use and mortality[5]
- Buprenorphine shows lower return to use & higher treatment initiation rates vs. naltrexone XR; no significant difference in return to use when initiated on naltrexone XR[17]

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PHARMACIST QUESTION #1

Which of the following patients should you discuss naloxone with?

A. TF is a 54 yr-old who is prescribed Norco 5/325- 1 tablet orally twice daily as needed for chronic back pain. TF comes in every other month to pick up fills of 30 tablets.

B. MA fills a prescription for Oxycontin 10 mg orally every 12 hours and Percocet 5/325mg 1 every 6 hours as needed for pain.

C. RM is prescribed a 10-day supply of oxycodone/apap 5/325mg- 1 tablets orally every 8 hours as needed for pain following a cesarian section.

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What is the recommended strategy to avoid precipitating withdrawal during induction?

A. Buprenorphine should be initiated within 4 hours of the last dose of heroin.

B. Buprenorphine should be started only after the patient is experiencing significant opioid withdrawal symptoms.

C. Patients should abstain from opioid use for at least 7 days before initiating buprenorphine.

D. Buprenorphine is a low-risk medication for precipitating withdrawal.

PHARMACIST QUESTION #4

What is TRUE regarding evidence surrounding OUD treatment?

A. Maintenance treatment leads to superior outcomes compared to detoxification.

B. Maintenance therapy with methadone 80mg is superior to buprenorphine 16mg.

C. Naltrexone XR is non-inferior to methadone or buprenorphine in mortality outcomes.

D. Treatment retention is superior with buprenorphine compared to methadone.

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A. Vaccination history review
B. Naloxone distribution
C. Safe-sex education
D. Needle distribution
E. All of the above

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Which of the following medications can be dispensed by the pharmacy for OUD treatment?

A. Methadone
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C. Naltrexone XR
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What is the most effective form of treatment for OUD?

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B. Medically supervised detoxification
C. Opioid-agonist therapy within an opioid treatment program
D. Naloxone therapy

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