Opioid Addiction Treatment ECHO

For Providers and Primary Care Teams

Medication Treatment for Opioid Use Disorder

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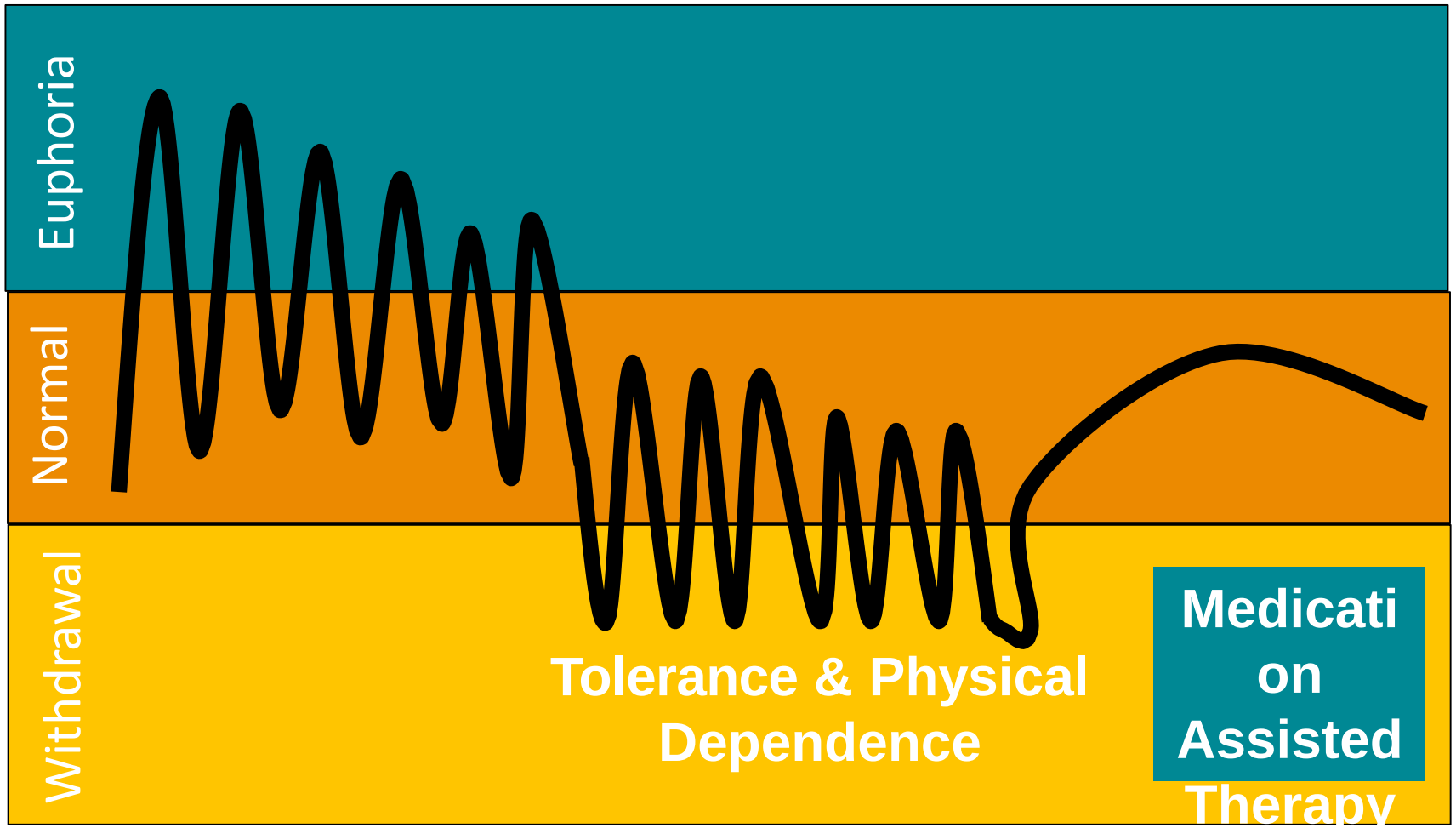
Disclosures

Joe Merrill, Charles Morgan, and Ann Griepp, Miriam Komaromy and Olawale Ojo have nothing to disclose.



Acute Use

Chronic Use

Alford, Boston University, 2012

MAT vs MOUD

- Historically, pharmacological treatment for opioid use disorder was referred to as “Medications for Addiction Treatment (MAT),” but more recently it has been determined that the more appropriate term is “Medications for Opioid Use Disorder (MOUD).”

- MAT connotes short term treatment
- MOUD involves a combination of a medications that targets the brain, and psychosocial interventions (e.g., counseling, skills development) aimed at improving treatment outcomes

Medications for Opioid Use Disorder

- Buprenorphine (sublingual and implantable)
- Naltrexone (oral and extended release injectable)
- Methadone

"Detox" has no long-term effect on outcomes; it is medication maintenance that saves lives and reduces relapse

Pharmacotherapy for Opioid Addiction: **Methadone**

- Most effective
  - ↑ survival, treatment retention, employment
  - ↓ illicit opioid use, hepatitis and HIV infections, criminal activity
- Cost-effective
  - Every dollar invested generates $4-5 in savings
- Highly regulated, dispensed at Opioid Treatment Programs (OTP)
  - Supervised daily dosing with take-home doses if stable
  - Counseling, urine testing
  - Psychiatric, medical services often not provided
  - **Illegal** to prescribe methadone **for addiction** in general practice

Pharmacotherapy for Opioid Addiction: **Methadone**

Daily, observed dosing

- Full opioid agonist
- Onset within 30-60 minutes
- Long-acting: Daily dosing effective for addiction
- Dose 20-40 mg for acute withdrawal
- >80 mg for craving and "blockade"
- To evaluate stability, ask about take-home doses
- **Multiple** medication interactions

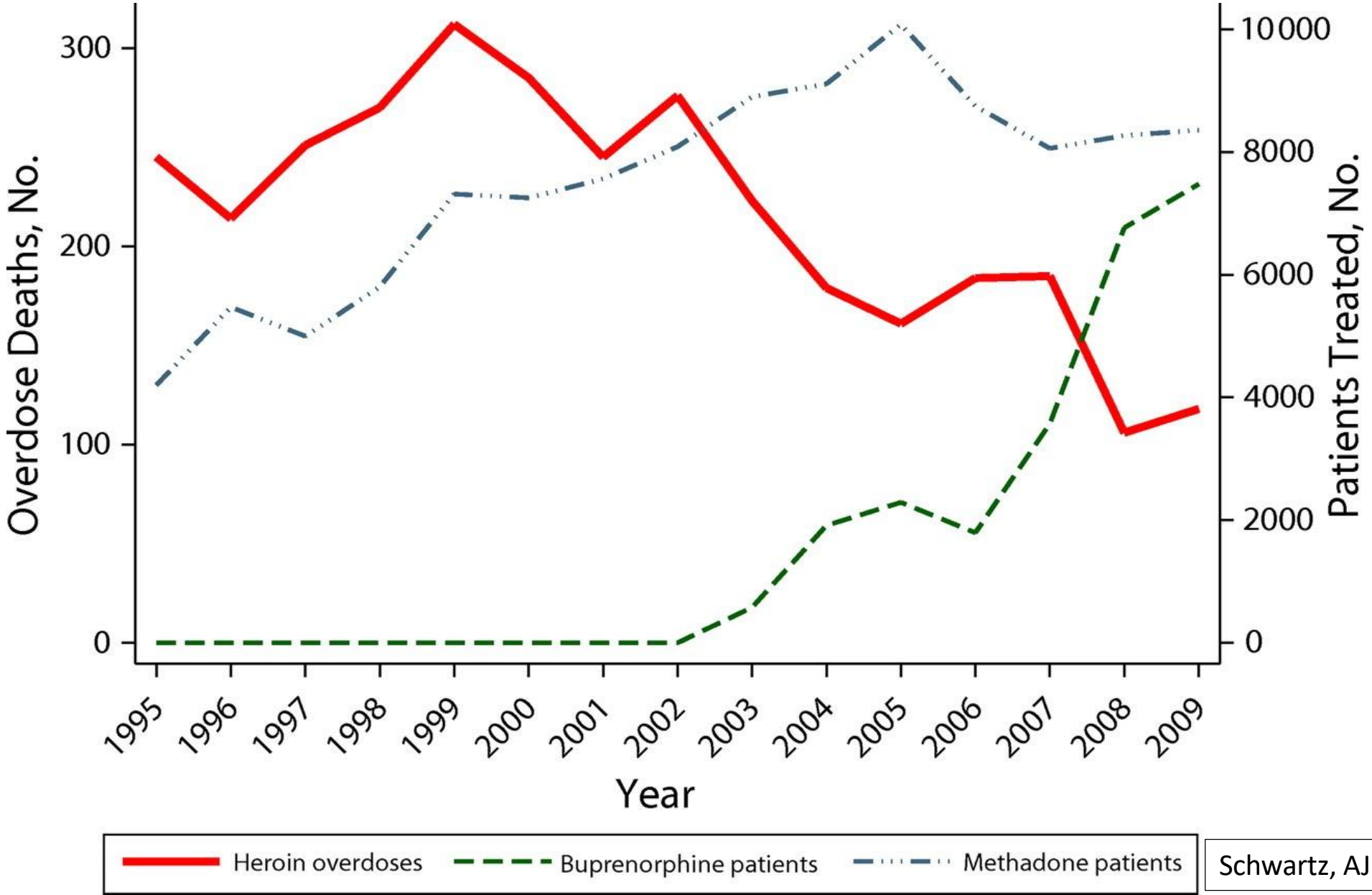
Advise staying in treatment until social, medical, psychiatric, legal, and family issues are stable.

- "Detox" therapy has no long-term effect on outcomes
- Longer duration, higher dose treatment most effective
- For some patients, methadone therapy should be lifelong, as risk of relapse is high after cessation

Pharmacotherapy for Opioid Addiction: **Buprenorphine**

- 2000 Federal Drug Addiction Treatment Act ("DATA-2000"):
  - Made office-based addiction treatment by physicians legal
  - Must complete 8-hour training and obtain federal waiver
- 2002: Suboxone (buprenorphine/naloxone) FDA approved
  - Outcomes much superior to psychosocial treatment alone
  - Longer treatment duration is more effective

- Compared to methadone:
  - Similar abstinence from illicit opioids and decreased craving
  - Lower retention in treatment
  - Can be prescribed in general practice, lowering barriers to treatment

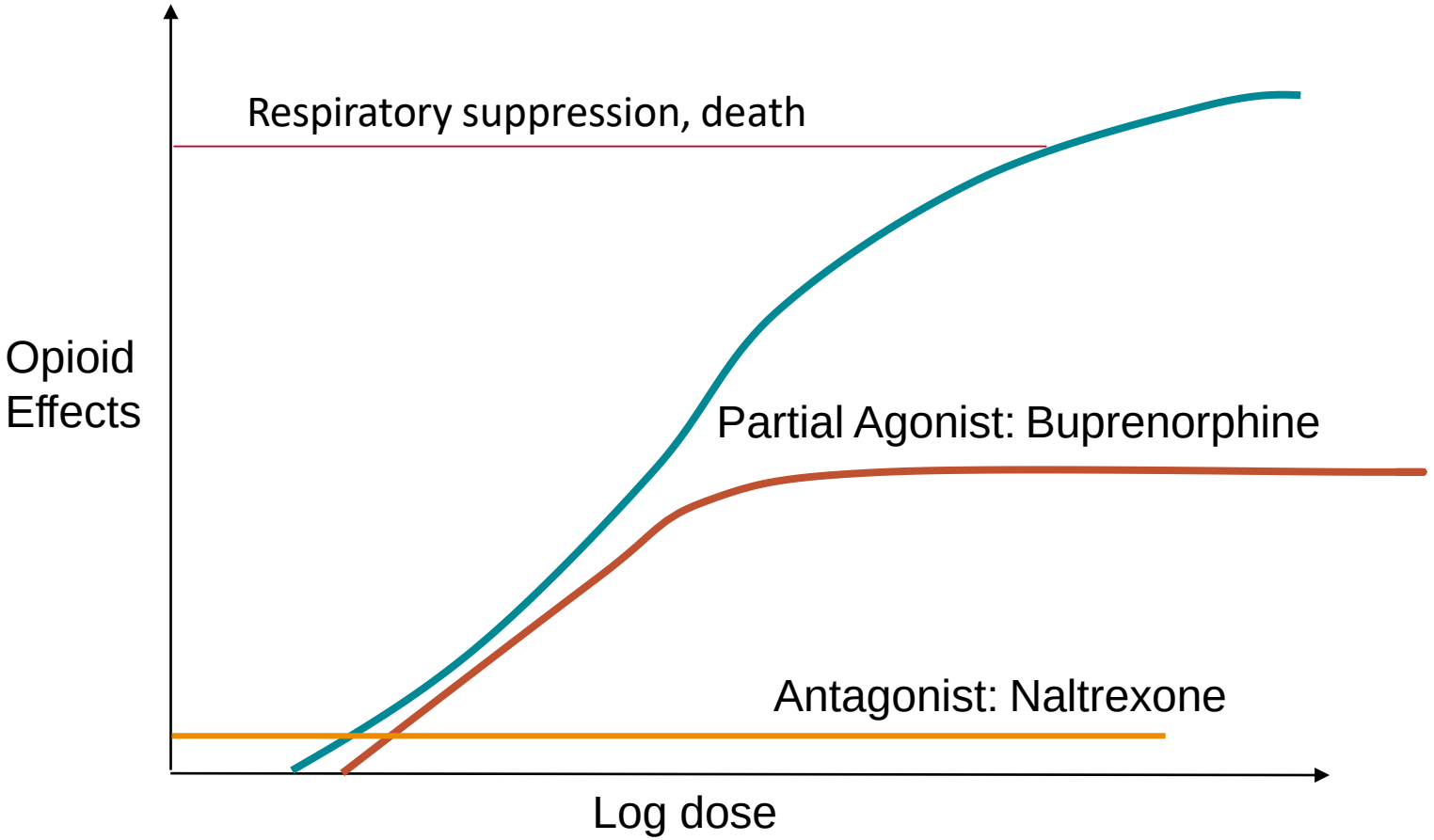


Schwartz, AJPH, 2012

Pharmacotherapy for Opioid Addiction: **Buprenorphine**

- Partial opioid agonist, so safer than methadone
- High mu receptor affinity, so blocks other opioids
- Formulations
  - Sublingual- Formulated with naloxone - abuse deterrent
  - Implant- Probuphine- stable patients on ≤8 mg buprenorphine
  - Extended release subcutaneous injectable (Sublocade)
- Can precipitate withdrawal if full agonist are still in the body
- Requires induction after patient enters mild-moderate withdrawal

Why is Overdose Potential Low with Buprenorphine?



Agonist: Methadone, Heroin, etc.

Buprenorphine in Primary Care

- Advantages of buprenorphine in primary care:
  - Setting built for chronic disease management
  - Reduces the stigma of addiction treatment
  - Facilitates management of mental health and medical co-morbidities and preventive care
  - Important tool when problems arise during chronic opioid therapy
  - Public health benefit: increases local access to lifesaving care
- Highly gratifying form of treatment!

DATA 2000 Waivers

The Drug Addiction Treatment Act of 2000 (DATA 2000) permits physicians who meet certain qualifications to treat opioid dependency with narcotic medications approved by the FDA – including buprenorphine – in treatment settings other than OTPs.

Must receive waiver (known as "DATA Waiver") to prescribe. "Qualifying physician" must be

- Licensed under state law
- Registered with DEA to dispense controlled substances
- Qualified by training/certification
  - Addictions/addictions psychiatry certification OR
  - Approved 8 hour training course
- Capable of referring patients to counseling and other services

DATE: Support for Patients and Communities Act (October 2018)

- Regulations have not been updated, but many of the provisions are effective immediately

Nurse Practitioners/Physician's Assistants/Other Providers

- Comprehensive Addiction and Recovery Act (CARA): NP and PA can also receive waivers
  - Clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives, also eligible through October 1, 2023. NP and PA eligible permanently
- Must meet/maintain all state law requirements for prescribing and receive 24 hours of approved training

"Qualified Practice Setting"

- Provides professional coverage for patient medical emergencies during hours when the practice is closed.
- Provides access to case management services for patients, including referral and follow-up services for programs that provide or financially support medical, behavioral, social, housing, employment, educational, or other related services (Medication Assisted Treatment, not "Medication")
- Uses health information technology if it is already required in the practice setting.
- Is registered for their state prescription drug monitoring program where operational and in accordance with federal and state law (INSPECT program)
- Accepts third-party payment for some services, though not necessarily for buprenorphine-related services and not necessarily all third-party payers
- Have adopted a "diversion control plan"

Patient Limits

- Default: 30 for first year, then apply to increase
- If there is additional credentialing OR Qualified Practice Setting, then Physician can have 100 immediately
- Physicians can increase to 275 after one year at 100
  - Disclaimer: no opinion is offered as to the wisdom or practicality of this approach
- Increase to 275 requires one year at the lower limit, additional credentialing (certification in addiction medicine or addiction psychiatry) AND proof of a Qualified Practice Setting
- Increase to 275 is good for a three year period, must file to renew

Emergencies (“72 hour rule”)

Non waivered practitioners can administer or dispense (but not prescribe) in hospitals (not limited to ED), if the following conditions are met:

- If a primary medical problem other than opioid dependency
  - Given to prevent opioid withdrawal that would complicate the primary medical problem
- Not more than one day’s medication may be administered or given to a patient at one time
- Treatment may not be carried out for more than 72 hours
- The 72-hour period cannot be renewed or extended

New Policy-Jan 14th 2021

- As of January 2021, only 66,000 physicians and another 25,000 prescribers like NPs or PAs have an X-waiver

- Any physician with a DEA license to treat up to 30 in-state patients with buprenorphine.
- Hospital-based physicians will be exempted from the 30-patient cap
- Doctors can still treat up to 275 patients if they undergo the training and receive a separate waiver.
- It does not impact nurse practitioners or physician assistants, who will still need to apply for separate waivers to earn buprenorphine prescribing privileges.

How to Apply/More information

- https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver
- ASAM Summary of 2018 law: https://www.asam.org/docs/default-source/advocacy/hr6_09-28-18-final-opioid-sec-by-sec_bipart-bicam.pdf?sfvrsn=49d048c2_2

Naltrexone

- Opioid antagonist that blocks other opioids
- Does not lead to physical dependence, or to withdrawal when stopped
- Causes acute withdrawal in opioid-dependent patients
- Can be used in office-based settings without added training
- Effective in alcohol use disorder treatment
- Two formulations available:
  - Oral ReVia 50 mg PO daily
  - Injectable Vivitrol 380 mg IM monthly

Naltrexone for Opioid Use Disorder

- Requires opioid abstinence prior to initiation, a major barrier since most treatment-seeking patients are actively using opioids
- Russian studies show benefit in population where opioid substitution therapy is not available
- Recent study (Lancet 2018) found that relapse events were higher with extended release naltrexone when compared to buprenorphine – most or all of the difference in relapse was due to induction failure with extended release naltrexone
  - In patients successfully initiated on naltrexone, relapse rates were similar compared to buprenorphine

Summary:
Medications for Opioid Use Disorder

- Prescription opioid and heroin epidemics are major public health problems
- Medications are an essential component of evidence-based treatment
- Methadone and buprenorphine are the most effective pharmacotherapies for opioid use disorder
- Naltrexone can also be used, but patients must go through an opioid-free period (7-10 days) prior to induction
- Primary care teams can play an important role in treatment of opioid use disorders and prevention of overdose

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COVID RELATED CHANGES TO PRACTICE

Can a practitioner working in an Opioid Treatment Program (OTP), admit a new patient with opioid use disorder (OUD) to an OTP using telehealth (including use of telephone, if needed)?

a. Yes
b. No

Federal law requires a complete physical evaluation before admission to an OTP.
SAMHSA has made the decision to pre-emptively exercise its authority to exempt OTPs from the requirement to perform an in-person physical evaluation exclusively to OTP patients treated with buprenorphine.

This exemption does not apply to new OTP patients treated with methadone. For new OTP patients that are treated with methadone, the requirements of an in-person medical evaluation will remain in force.

Can a practitioner working in an Opioid Treatment Program continue to treat an existing OTP patient using methadone via telehealth (including use of telephone, if needed)?

a. Yes

b. No

Yes, a practitioner may continue treating an existing patient of the OTP with methadone via telehealth and in accordance with SAMHSA's OTP guidance issued on March 16, 2020, assuming applicable standards of
care are met.

Can an OTP dispense medication (either methadone or buprenorphine products) based on telehealth (including telephone, if needed) evaluation?

a. Yes

b. No

Yes. Under the current national health emergency, OTPs can provide medication under blanket
exception: up to 14 doses for clinically less stable patients and 28 doses for clinically stable patients (clinical stability and ability to safely manage medication must be determined by the clinical team and documented in the patient's medical record).