



Opioid Addiction Treatment ECHO

For Providers and Primary Care Teams





Medication Treatment for Opioid Use Disorder

Developer: Joe Merrill, MD, University of Washington,
Charles Morgan MD, and Anne Griep MD, Western New York Collaborative
And Miriam Komaromy, MD, University of New Mexico

Reviewer/Editor: Miriam Komaromy, MD, The ECHO Institute™

Updated by/Presenter: Gabriela Williams, PharmD, Eskenazi Health



Disclosures

Joe Merrill, Charles Morgan, and Ann Grieppe,
Miriam Komaromy and Gabriela Williams have
nothing to disclose.

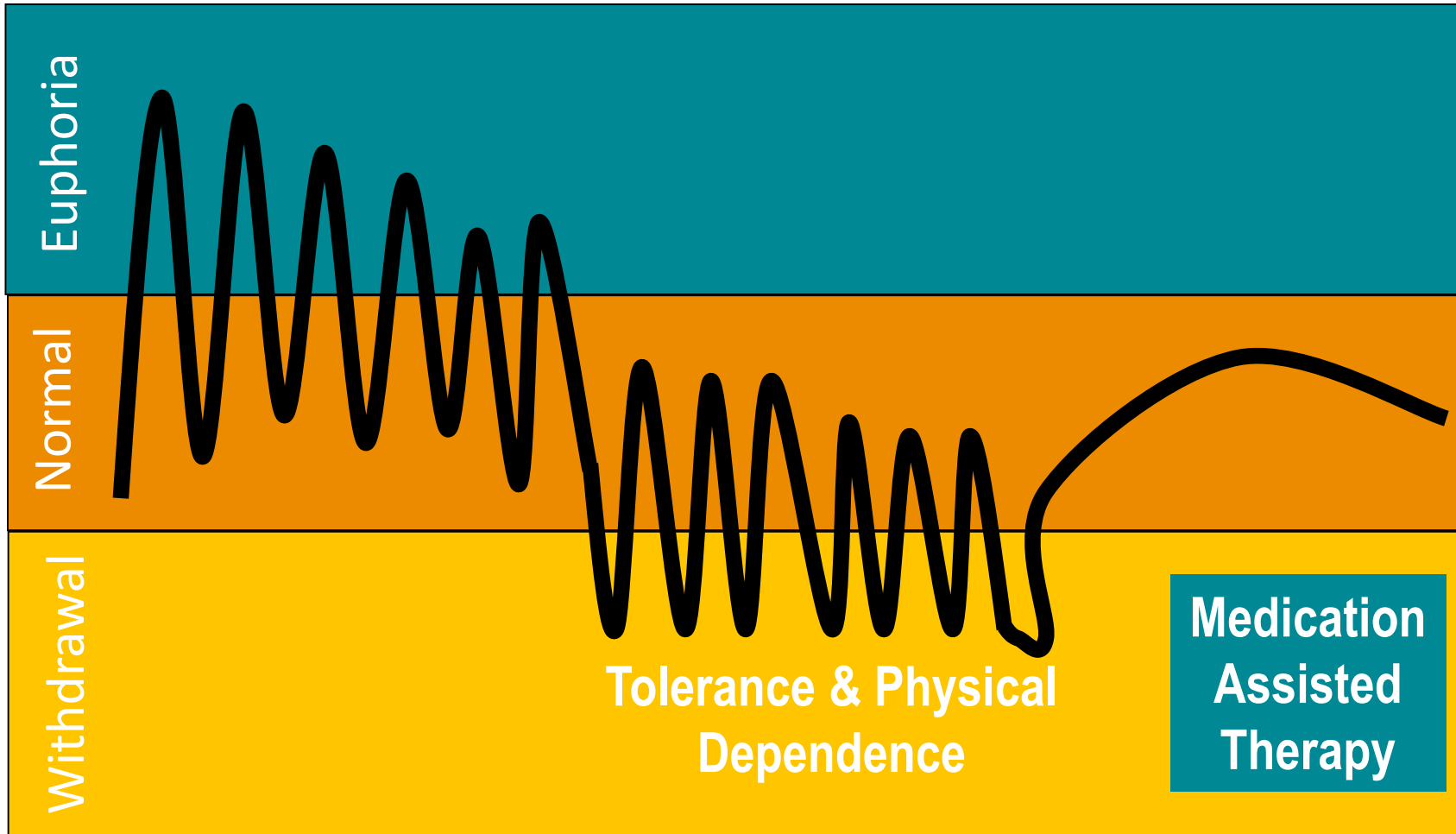




Medications for Opioid Use Disorder

- 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





Acute Use

Chronic Use

Alford, Boston University, 2012



Pharmacotherapy for Opioid Addiction: **Methadone**

- Most effective
 -  survival, treatment retention, employment
 -  illicit opioid use, hepatitis and HIV infections, criminal activity
- 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
- Cost-effective
 - Every dollar invested generates \$4-5 in savings



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

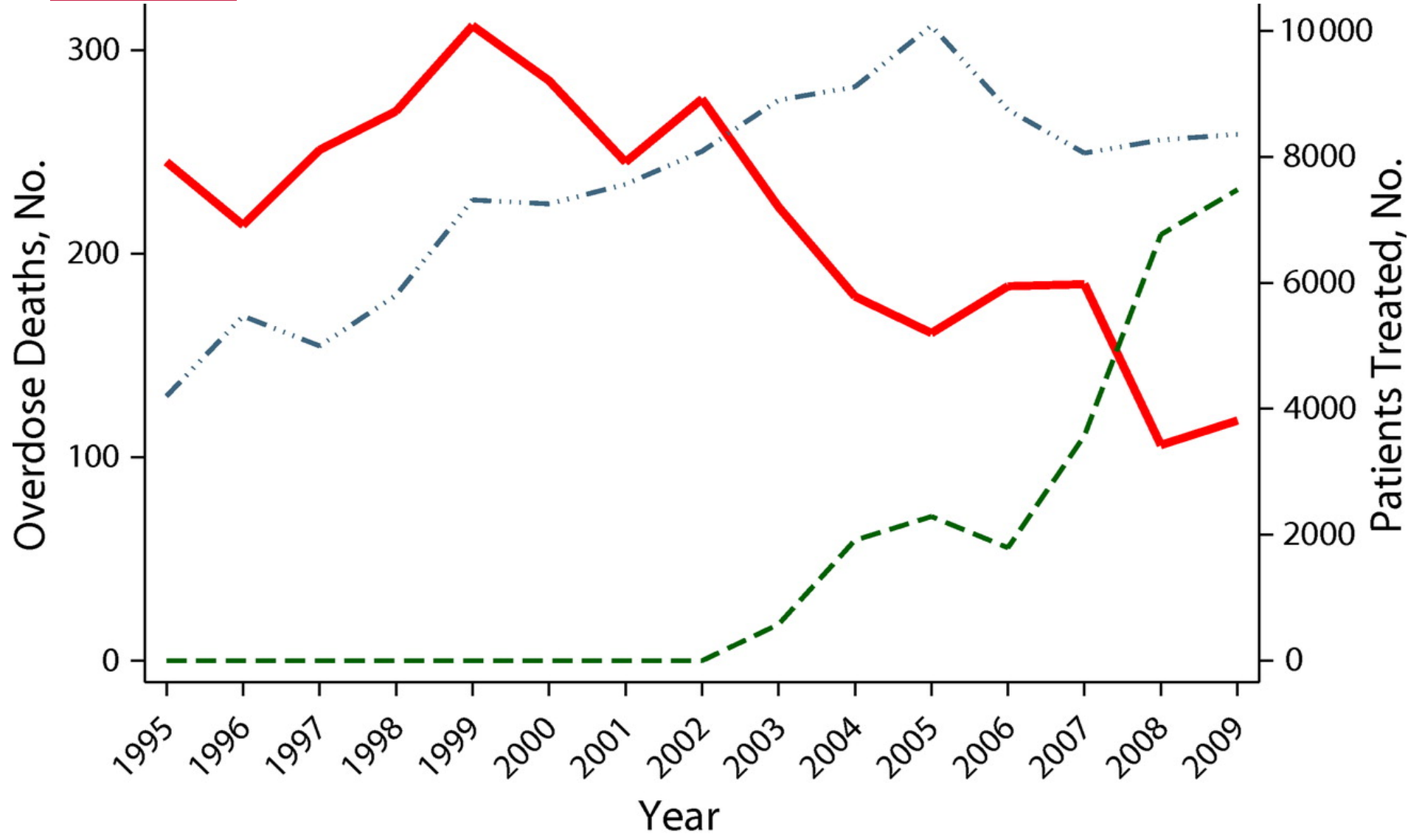
Advise staying in treatment until social, medical, psychiatric, legal, and family issues are stable.

- “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



— Heroin overdoses - - - Buprenorphine patients - · - - Methadone patients

Schwartz, AJPH, 2012



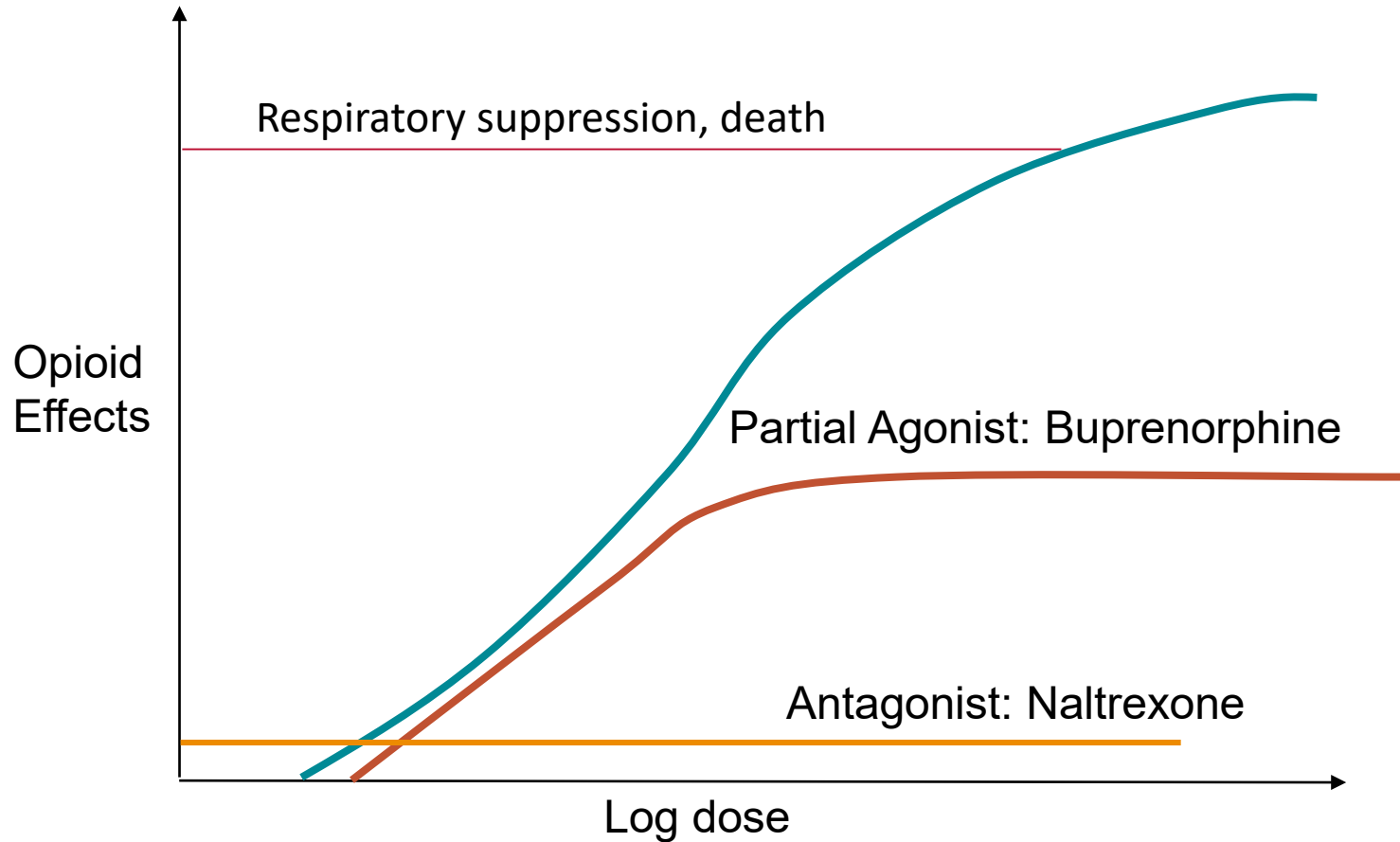
Pharmacotherapy for Opioid Addiction: **Buprenorphine**

- Partial opioid agonist, so safer than methadone
- High mu receptor affinity, so blocks other opioids
- Formulated with naloxone - abuse deterrent
- Sublingual dosing and newer implant (Probuphine) and extended release subcutaneous injectable (Sublocade)
- Can precipitate withdrawal in tolerant patients
- Requires induction after patient enters mild-moderate withdrawal
- Implant approved for stable patients on ≤ 8 mg buprenorphine
- Extended release subcutaneous injectable approved in those initiated on transmucosal buprenorphine 8-24mg/day after a minimum of 7 days





Why is Overdose Potential Low with Buprenorphine?



Agonist: Methadone,
Heroin, etc.

Partial Agonist: Buprenorphine

Antagonist: Naltrexone

Respiratory suppression, death

Opioid
Effects

Log dose



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

UPDATE: 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
 - UPDATE: 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
- Limit of 30 patients
 - UPDATE: Seems to increase to 100, for NP/PA working in Qualified Practice Setting
 - Waiting on regulations
 - ASAM expects the regulations to increase to 100 for NPs/PAs in QP Setting
 - Open question: Indiana requires collaborative arrangement with physician to review 5% of charts with a prescription. Does the collaborating physician also need waiver? (Probably, but nothing in the law)



“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
 - As far as I can tell, if is no additional credentialing or qualified practice setting, limit is still 30
- New law: 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



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



References:

[J Addict Med.](#) 2014 Sep-Oct;8(5):299-308. doi: 10.1097/ADM.0000000000000059.

Unobserved "home" induction onto buprenorphine.

[Lee JD¹](#), [Vocci F](#), [Fiellin DA](#)

[A comparison of **buprenorphine induction** strategies: patient-centered **home**-based inductions versus standard-of-care office-based inductions.](#)

Cunningham CO, Giovanniello A, Li X, Kunins HV, Roose RJ, Sohler NL.
J Subst Abuse Treat. 2011 Jun;40(4):349-56

[Statement of the American Society Of Addiction Medicine Consensus Panel on the use of **buprenorphine** in office-based treatment of opioid addiction.](#)

Kraus ML, Alford DP, Kotz MM, Levounis P, Mandell TW, Meyer M, Salsitz EA, Wetterau N, Wyatt SA; American Society Of Addiction Medicine..
J Addict Med. 2011 Dec;5(4):254-63. doi:

[Collaborative care of opioid-addicted patients in primary care using **buprenorphine**: five-year experience.](#)

Alford DP, LaBelle CT, Kretsch N, Bergeron A, Winter M, Botticelli M, Samet JH.
Arch Intern Med. 2011 Mar 14;171(5):425-31.



[Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence.](#)

Mattick RP, Breen C, Kimber J, Davoli M.

Cochrane Database Syst Rev. 2014

NIDA (2016). Understanding Drug Abuse and Addiction: What Science Says. Retrieved January 2, 2017, from <https://www.drugabuse.gov/understanding-drug-abuse-addiction-what-science-says>

[Psychosocial combined with agonist maintenance treatments versus agonist maintenance treatments alone for treatment of opioid dependence.](#)

Amato L, Minozzi S, Davoli M, Vecchi S.

Cochrane Database Syst Rev. 2011 Oct 5;(10):CD004147

[Lancet.](#) 2003 Feb 22;361(9358):662-8.

1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: a randomised, placebo-controlled trial.

[Kakko J](#)¹, [Svanborg KD](#), [Kreek MJ](#), [Heilig M](#).

[Am J Public Health.](#) 2013 May;103(5):917-22. doi: 10.2105/AJPH.2012.301049. Epub 2013 Mar 14.

Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995-2009.

[Schwartz RP](#)¹, [Gryczynski J](#), [O'Grady KE](#), [Sharfstein JM](#), [Warren G](#), [Olsen Y](#), [Mitchell SG](#), [Jaffe JH](#)



[Cochrane Database Syst Rev.](#) 2008 Apr 16;(2):CD006140. doi: 10.1002/14651858.CD006140.pub2.

Sustained-release naltrexone for opioid dependence.

[Lobmaier P¹](#), [Kornør H](#), [Kunøe N](#), [Bjørndal A](#)

[Lancet.](#) 2011 Apr 30;377(9776):1506-13. doi: 10.1016/S0140-6736(11)60358-9.

Injectable extended-release naltrexone for opioid dependence: a double-blind, placebo-controlled, multicentre randomised trial.

[Krupitsky E¹](#), [Nunes EV](#), [Ling W](#), [Illeperuma A](#), [Gastfriend DR](#), [Silverman BL](#).

[Lancet.](#) 2018 Jan 27;391(10118):309-318.. doi: 10.1016/S0140-6736(17)32812-X.

Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial.

[Lee JD](#), [Nunes EV Jr](#), [Novo P](#), [et al.](#)



[Collaborative care of opioid-addicted patients in primary care using buprenorphine: five-year experience.](#)

Alford DP, LaBelle CT, Kretsch N, Bergeron A, Winter M, Botticelli M, Samet JH.
Arch Intern Med. 2011 Mar 14;171(5):425-31.

[Prev Med.](#) 2015 Nov;80:10-1. doi: 10.1016/j.ypmed.2015.04.002. Epub 2015 Apr 11.

Vermont responds to its opioid crisis.

[Simpatico TA](#)¹

Yale School of Medicine (2019). ED-Initiated Buprenorphine. Retrieved April 22, 2019 from <https://medicine.yale.edu/edbup/>