Opioid Use Disorder Treatment Integrated with Primary Care

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DACS provides support to primary care and specialty prescribers in addressing the needs of their patients with substance use disorders and chronic pain management.

All Services are FREE

- Phone consultation for clinical questions provided by expert addiction medicine specialists
- Education and training opportunities related to substance use disorders and chronic pain management
- Assistance in the identification of substance use and behavioral health resources and referrals that meet the needs of the patients in your community

Funding for DACS is provided by The District of Columbia Government, DC Health, Health Regulation and Licensing Administration (HRLA), Pharmaceutical Control Division (PCD). DACS is administered by the University of Maryland School of Medicine staff and faculty.

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Conflict of Interest

- No commercial, financial or advisory relationships

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Learning Objectives

1. Review the integration of SUD treatment and primary care
2. Review the Medications for Opioid Use Disorder, including features, initiation, maintenance, and safety
3. Describe the process of buprenorphine initiation as well as stabilization and maintenance
4. Describe how to take a patient history and evaluation
5. Discuss the importance of harm reduction
6. Review the steps for completing the online waiver application

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Some reasons why everyone should have x waiver

- Caring for patient in opioid withdrawal
- Patient needs urgent refill for buprenorphine
- Covering for provider who has patient on buprenorphine
- Patient doing well on buprenorphine and wants all care integrated
- Patient had surgery and is having difficulty coming off full opioid agonist
- Patient recovered from major trauma and needs help stopping opioid agonist after 4 weeks of use
- Patient has been on opioid agonist for chronic pain for many years and inquires about switching to buprenorphine (theoretically do not need x number)
- Caring for patient with opioid use disorder who asks for help
- Diagnosed patient with opioid use disorder and you want to immediately help and prevent an overdose death

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Integration of substance use disorder treatment and primary care

- **In 2006, the IOM released a report recommending improvement in coordination of mental health and substance-related services into general health care services:**
- **“Available evidence suggests that integration of mental health and primary care may lead to improved care and quality of life”**
- **“Studies of health delivery, process of care, and health outcomes in integrated clinical settings will be critical to inform the process”**

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What should providers expect from their patients with addiction?

- **Desire to receive care that will improve health**
- **Engagement in care based on trust and rapport**

Press K, Zornberg G, Geller G, Carrese J, Fingerhood M. What patients with addiction disorders need from their primary care physicians: a qualitative study. Substance Abuse 2016; 37:349-55.

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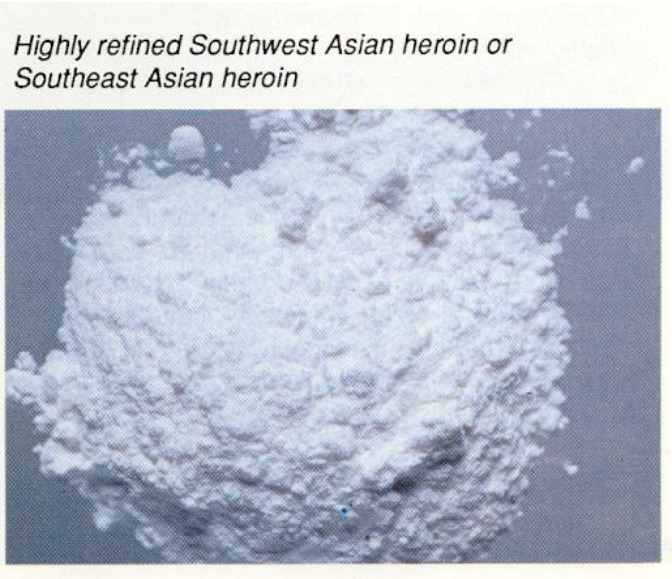
What do patients with addiction need from their providers

- **Knowledge about addiction**
- **Duty to treat**
- **Focus on overall health**
- **Engage patients in care**
- **Treat the full scope of illness (isolation, rejection, creating hope)**

The sap is extracted by slitting the pod



Opiates & Opioids

Opiates **= naturally present in opium**

- **e.g. morphine, codeine, thebaine**

Opioids **= manufactured**

- **Semisynthetics are derived from an opiate**
  - **Heroin from morphine**
  - **Buprenorphine, oxycodone from thebaine**
- **Synthetics are completely man-made to work like opiates**
  - **Methadone**
  - **Fentanyl**

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Narcotic Regulation in US

- **1914- Harrison Narcotics Tax Act**
- **1925- Linder vs United States**
- **1964- Methadone introduced as experimental treatment for opioid addiction**
- **1968- Bureau of Narcotic and Dangerous Drugs formed (changed to DEA in 1973)**

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DSM5- Opioid Use Disorder

- Group 1- **Impaired control**- larger amounts and longer; desire to cut down; great deal of time spent related to using; craving
- Group **2-Social impairment**- failure to fulfill obligations; interpersonal problems; reduction in social, occupational or recreational activities
- Group 3- **Risky use-** use in hazardous situations; continued use despite negative consequences
- Group 4- **Pharmacologic dependence-** tolerance; withdrawal with cessation

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Management of OUD

- Management = Treatment + Prevention
- Management = can be utilized across patient goal

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Options for Treatment

- Medication (MOUD)- methadone, buprenorphine or naltrexone
- Simple detoxification and no other treatment
- Counseling and/or peer support without MOUD
- Referral to short or long term residential treatment

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But here is my bias:

SBIRT

vs

SIT (screen, intervene and treat)

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Intervention- “I have joined your fan club”

- **Interventions and education are effective**
- **Interventions should emphasize health and relationship benefits**

•Use family/friends in a positive way

•Avoid threats- “If you use, you will die”

•Give hope that life can improve

•Acknowledge reasons for use, but…

•Work together to define the benefits of change

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Effective Treatment of Opiate Addiction

NIH Consensus Development Conference
November 17-19, 1997

- **Opiate dependence is a brain-related medical disorder**
- **Treatment is effective-**
  - **"Although a drug-free state represents an optimal treatment goal, research has demonstrated that this goal cannot be achieved or sustained by the majority of opiate-dependent people."**
- **Reduce unnecessary regulation of long-acting agonist treatment programs**
- **Improve training of health care professionals in treatment of opiate dependence**

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MEDICATIONS

NOT MAT

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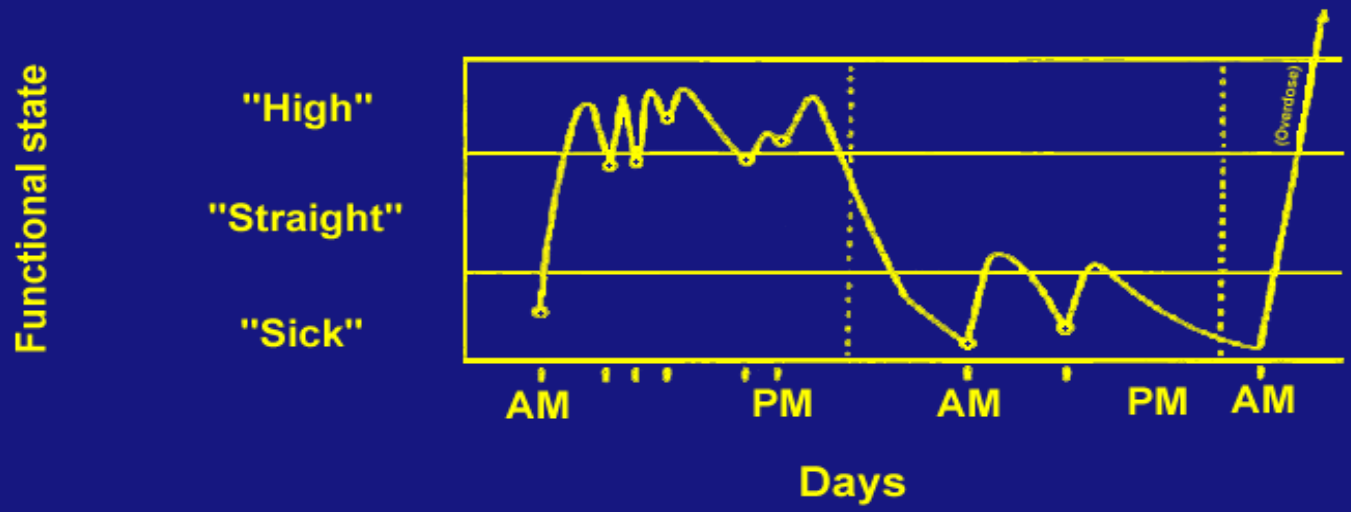
What the patient with opioid use disorder feels…



Diagrammatic summary of functional state of typical "mailine" heroin user. Arrows show the repetitive injection of heroin in uncertain dose, usually 10 to 30 mg but sometimes much more. Note that addict is hardly ever in a state of normal function ("straight").

From "Narcotic Blockade," by V. P. Dole, M. E. Nyswander, and M. J. Kreek, 1966, Archives of Internal Medicine, 118, p. 305.

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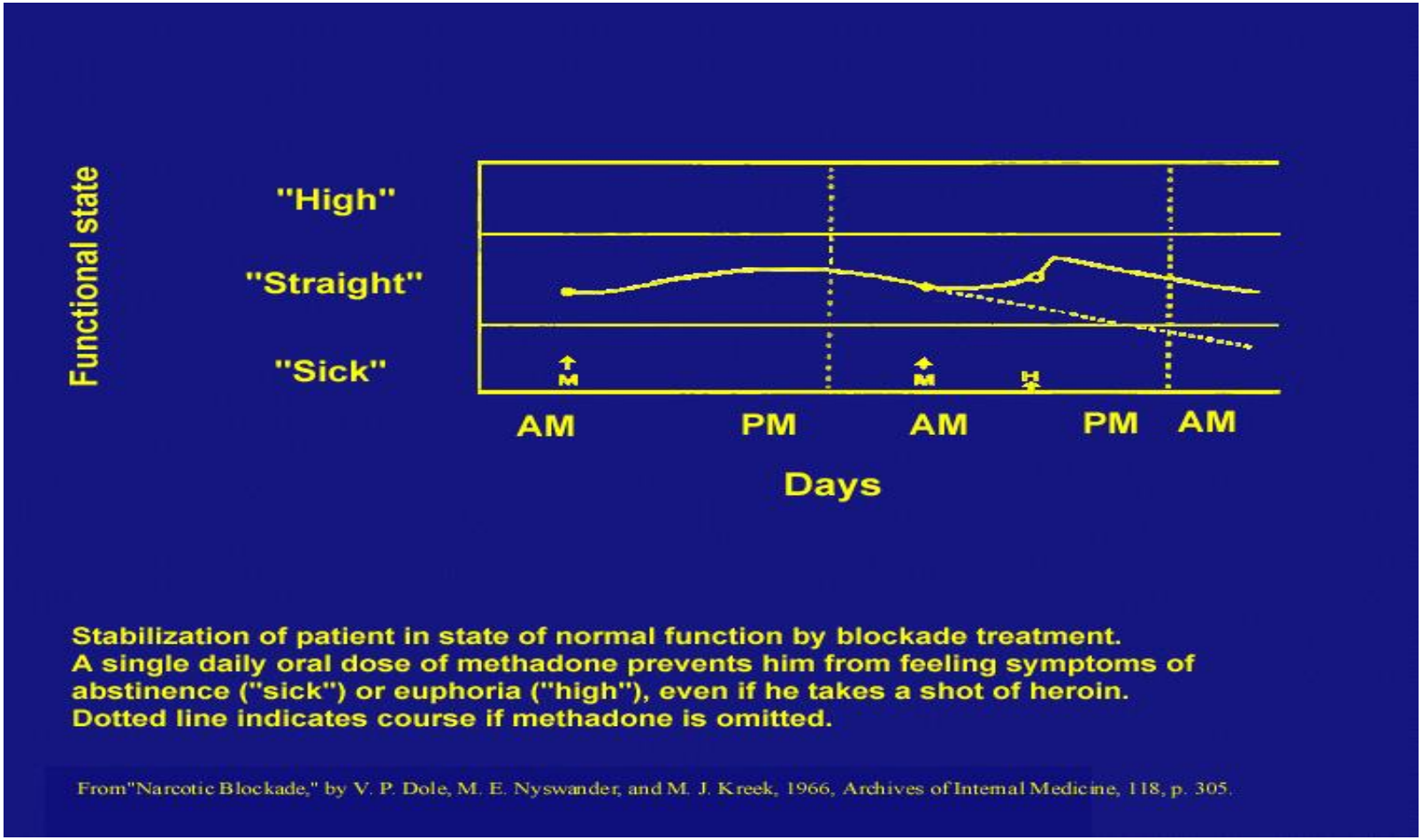
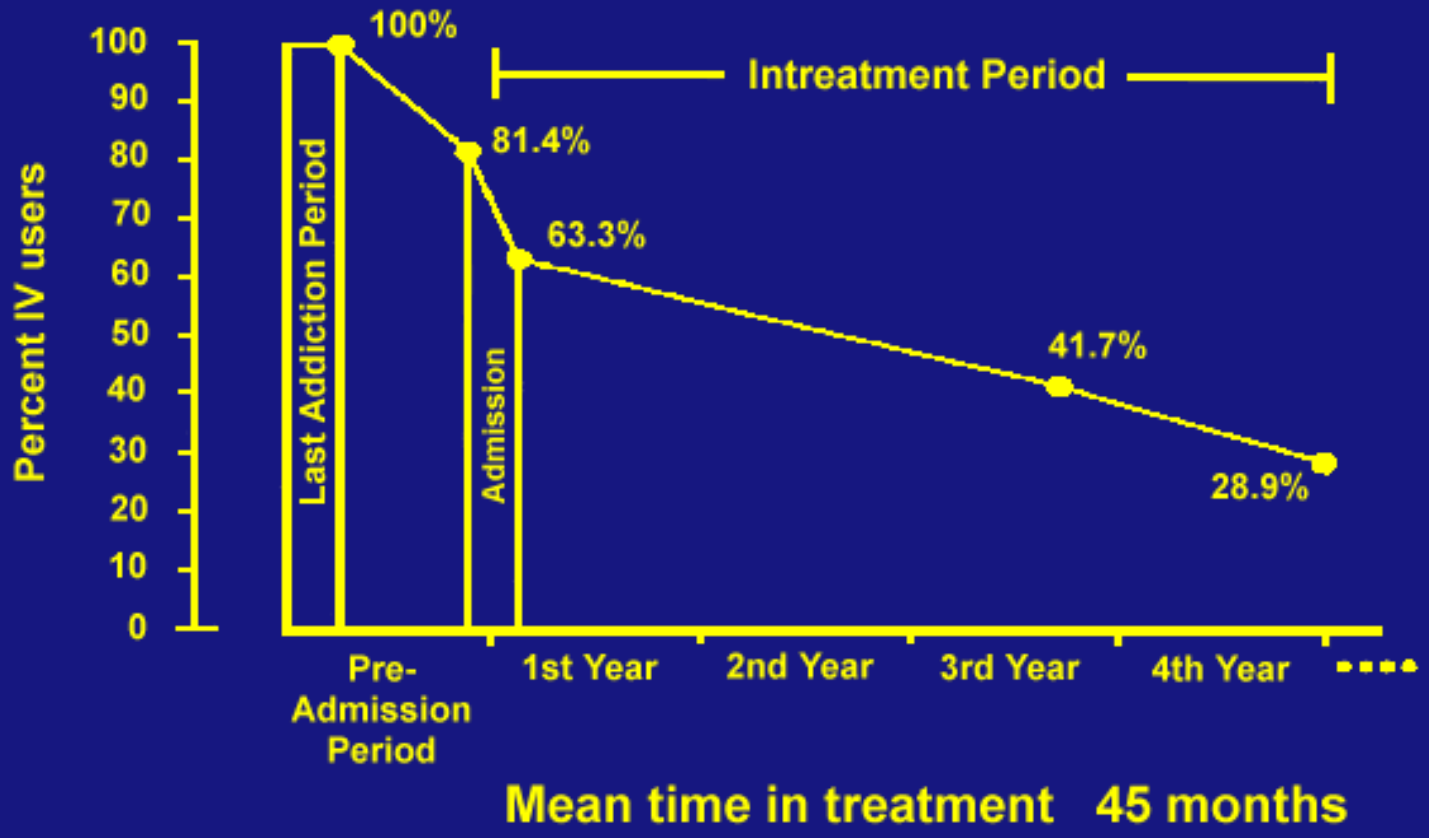
Stabilization by "Blockade Treatment"





Impact of methadone maintenance treatment on intravenous drug use for 388 male methadone patients in six programs.

From the Effectiveness of Methadone Maintenance Treatment (p. 169), by J. C. Ball and A. Ross, 1991, New York: Springer-Verlag. Copyright by Springer-Verlag New York, Inc. Reprinted with permission.

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Goals of Pharmacotherapy

Mitigate withdrawal	Prevent or manage withdrawal symptoms
Reduce drug use	Reduce drug use and sustain reduction or abstinence
Improve morbidity and mortality	Prevent, reduce and/or manage the physical and social complications of continued opioid use

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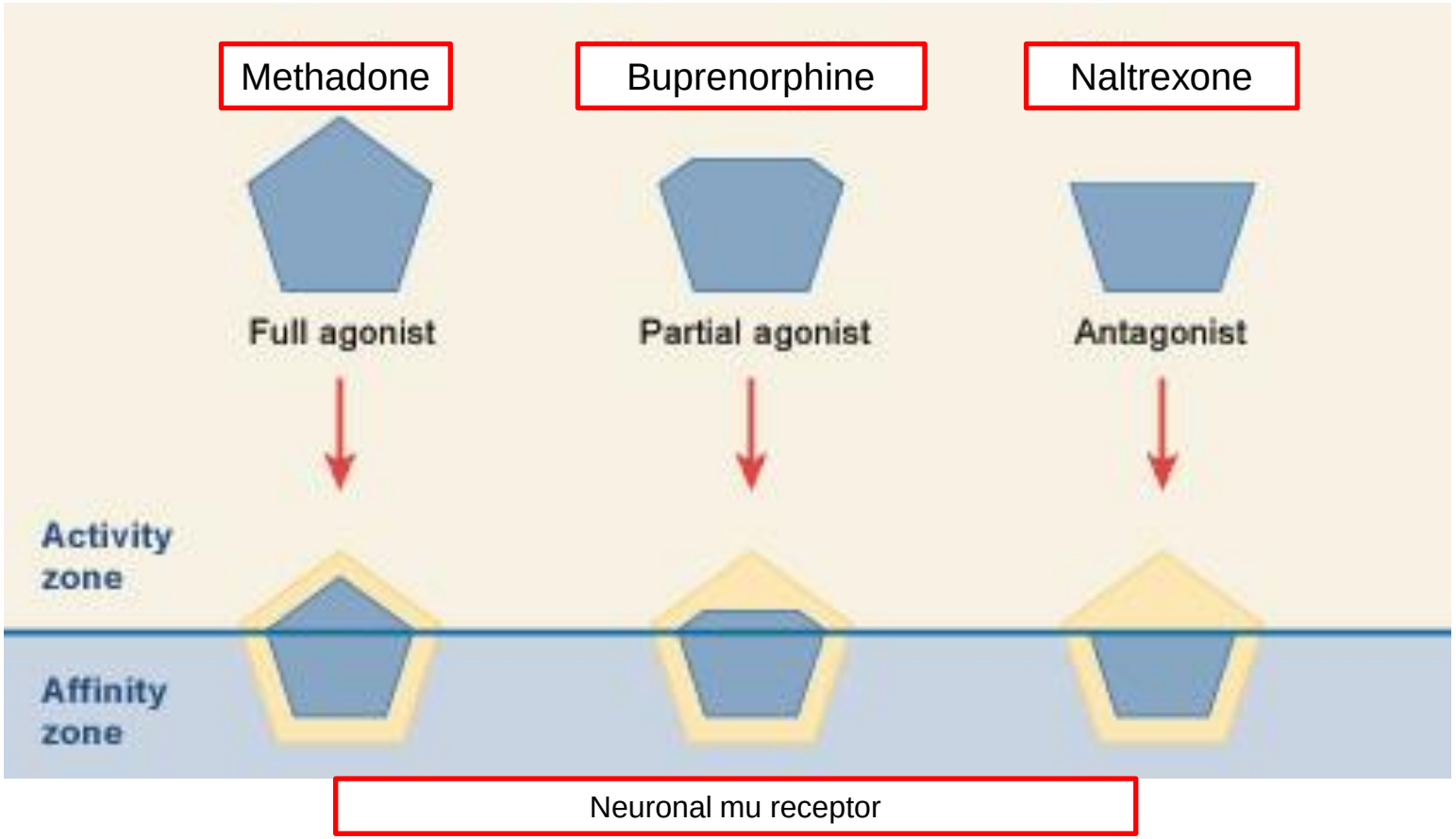
Medications for Opioid Use Disorder



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Drug Abuse Treatment Act (DATA) of 2000

- **Allowed "Qualified" physicians to treat opioid dependence outside methadone facilities**
  1. **Addiction certification from approved organization, or**
  2. **Physician in clinical trial of qualifying medication, or**
  3. **Complete 8-hour course from approved organization**
- **DEA issues (free) to qualifying physicians a new DEA number to use medication for opioid dependence**
- **As of today, only one medication formulation is approved for this use**

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Opioid Treatment: Changing Approach

Methadone Clinic	Buprenorphine
• **Criteria:** **Withdrawal** **12 months use**	• **Criteria:** **DSM IV** **No time criteria**
• **Dose regulated**	• **MD sets dose**
• **Age > 18**	• **Age > 16**
• **Limited take homes**	• **Take homes (30 days)**
• **Services “required”**	• **Services must be “available”**

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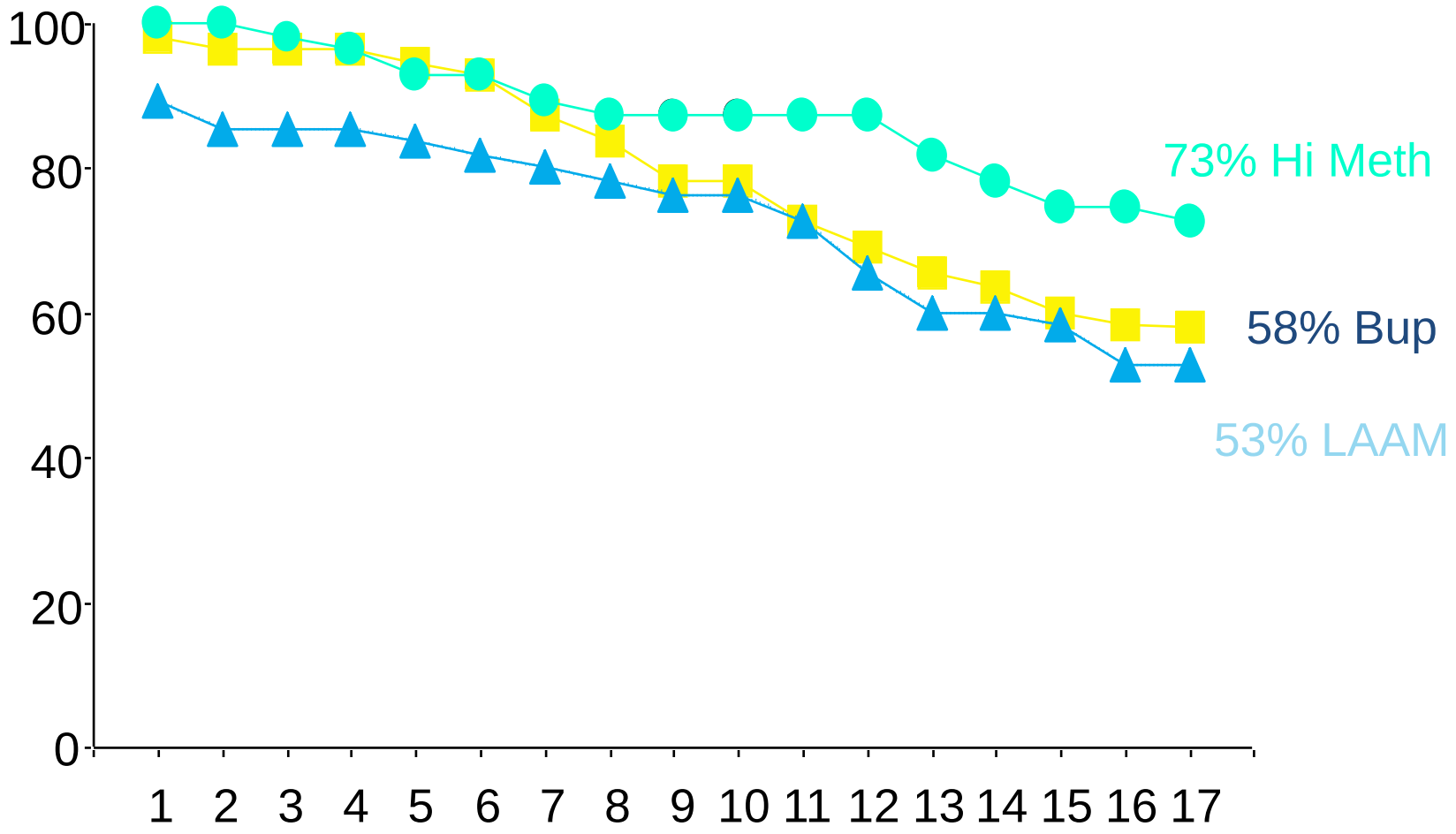
Buprenorphine, Methadone, LAAM: Treatment Retention



Johnson RE, et al NEJM 2000

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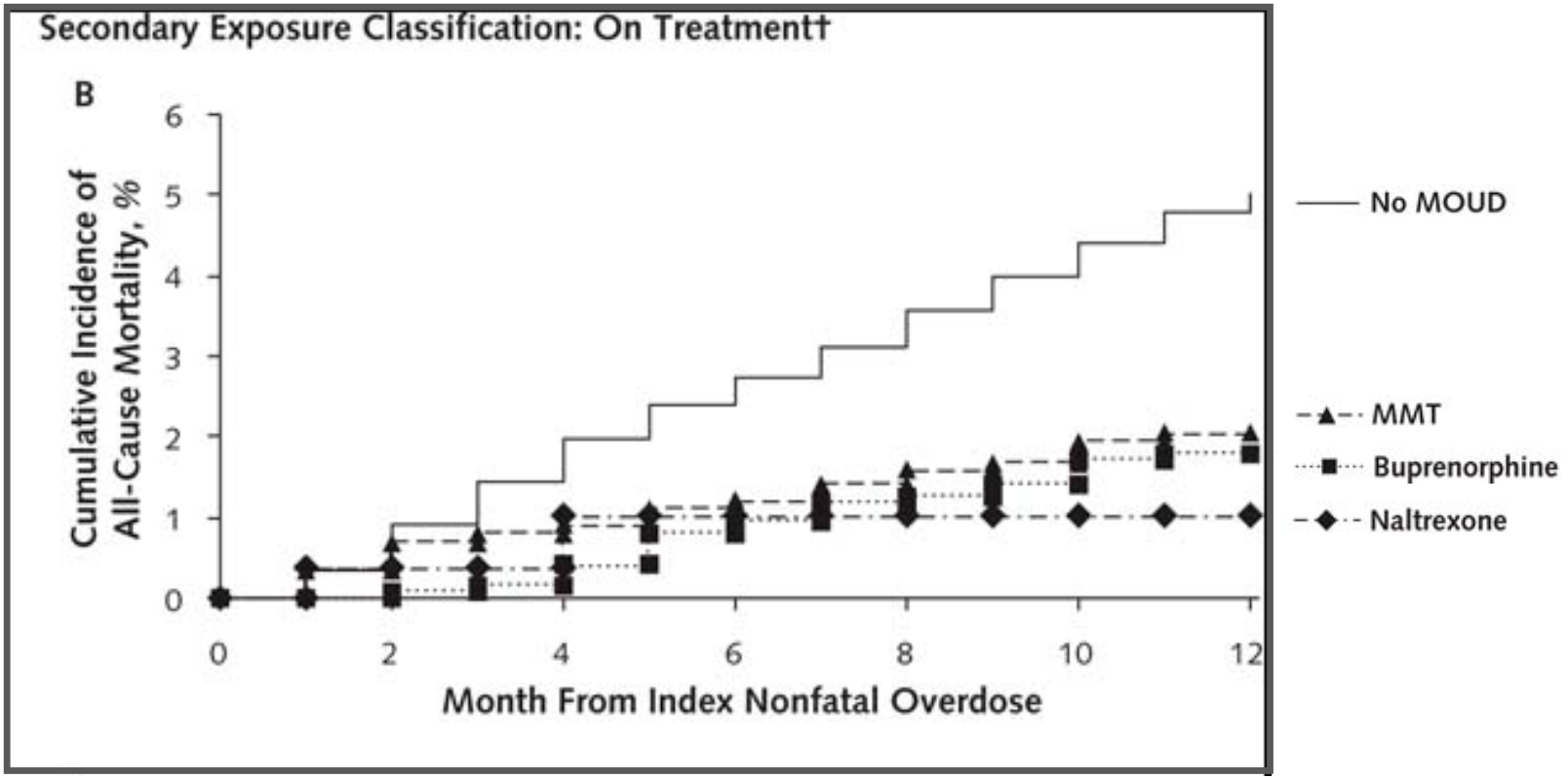
MOUD Decreases Mortality



Larochelle, Annals of Internal Medicine 2018

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Major Features of Methadone

***Full Agonist* at mu receptor**

Long acting

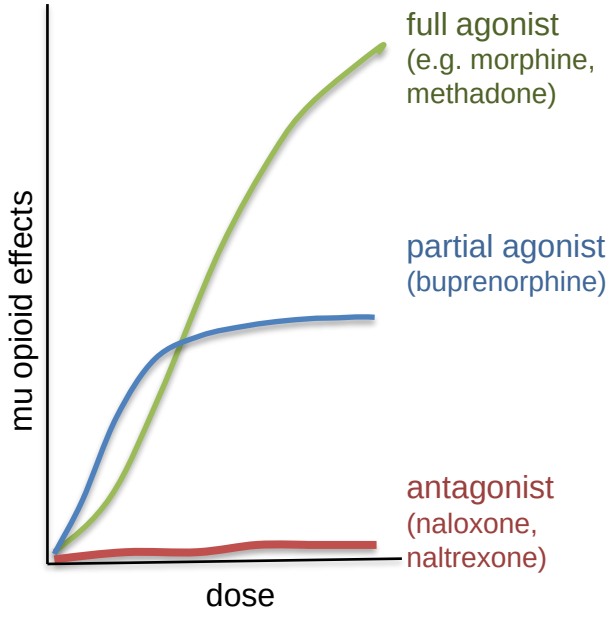
- Half-life ~ 15-60 Hours

Weak affinity for mu receptor

- *Can be displaced by partial agonists (e,g. burprenorphine) and antagonists (e.g.naloxone, naltrexone),* which can both precipitate withdrawal

Monitoring

- Significant respiratory suppression and potential respiratory arrest in overdose
- QT prolongation



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Methadone Initiation

- Require dispensing at "Opioid Treatment Program"
  - Medical assessment
- Dosing
  - Starting dose of 30mg
  - Liquid
  - Federal law requires that the initial dose be ≤30 mg and not exceed 40 mg in 1st day

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Methadone Maintenance

- Initial Dose Increase
  - Doses ↑ 5-10 mg every 7d
  - Can take 4d for full effect
- Maintenance Dosing
  - ↑ 60-120mg/d based on response (no craving, withdrawal, euphoria)
  - Higher dosing associated with better efficacy
  - Can go up to >200mg
- Federal law regulates take-home schedule in first two years of therapy

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Methadone Safety

Side effects:

Common: **constipation, lightheadedness, dizziness, sedation, nausea, vomiting, sweating**

Rare: **EKG abnormalities, psychosis, pruritis, sexual dysfunction or decreased libido, amenorrhea, weight gain, edema, seizures, hypotension**

Drug Interactions:

Metabolized primarily by CYP3A4

Inducers ↓ methadone effect

Inhibitors ↑ toxicity

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Major Features of Naltrexone

Full Antagonist at mu receptor

- Competitive binding at mu receptor

Long acting

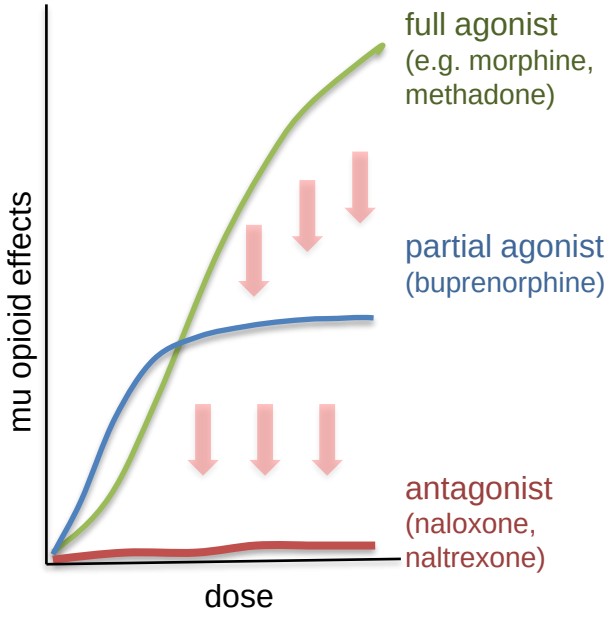
- Half-life:
  - Oral ~ 4 Hours
  - IM ~ 5-10 days

High affinity for mu receptor

- *Blocks* other opioids
- *Displaces* other opioids
  - Can precipitate withdrawal

Formulations

- *Tablets: Revia®: FDA approved in 1984*
- *Extended-Release intramuscular injection: Vivitrol®: FDA approved in 2010*



SAMHSA, 2018

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Naltrexone Formulations/Dosing

Oral naltrexone 25mg x1d, then 50mg/d

Long acting injectable naltrexone (Vivitrol®) 380mg once q4 wks

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Naltrexone Initiation

- Start ≥7 days after last opioid use
  - ≥14 days with long acting opioids (buprenorphine, methadone)
  - Can precipitate severe opioid withdrawal
- Strategies
  - Negative urine screen
  - Challenge with naloxone before administering XR-NTX

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Major Features of Buprenorphine

Partial agonist at mu receptor

- Comparatively minimal respiratory suppression and no respiratory arrest when used as prescribed

Long acting

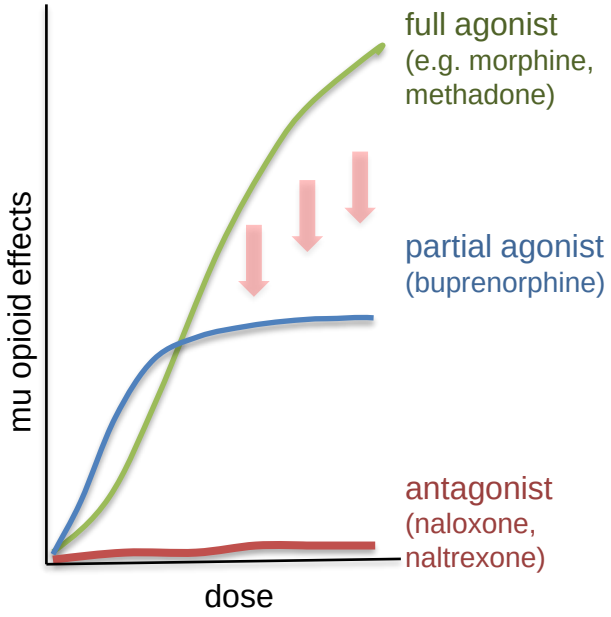
- Half-life ~ 24-36 Hours

High affinity for mu receptor

- *Blocks* other opioids
- *Displaces* other opioids
  - Can precipitate withdrawal

Slow dissociation from mu receptor

- *Stays on receptor for a long time*



SAMHSA, 2018
Orman & Keating, 2009

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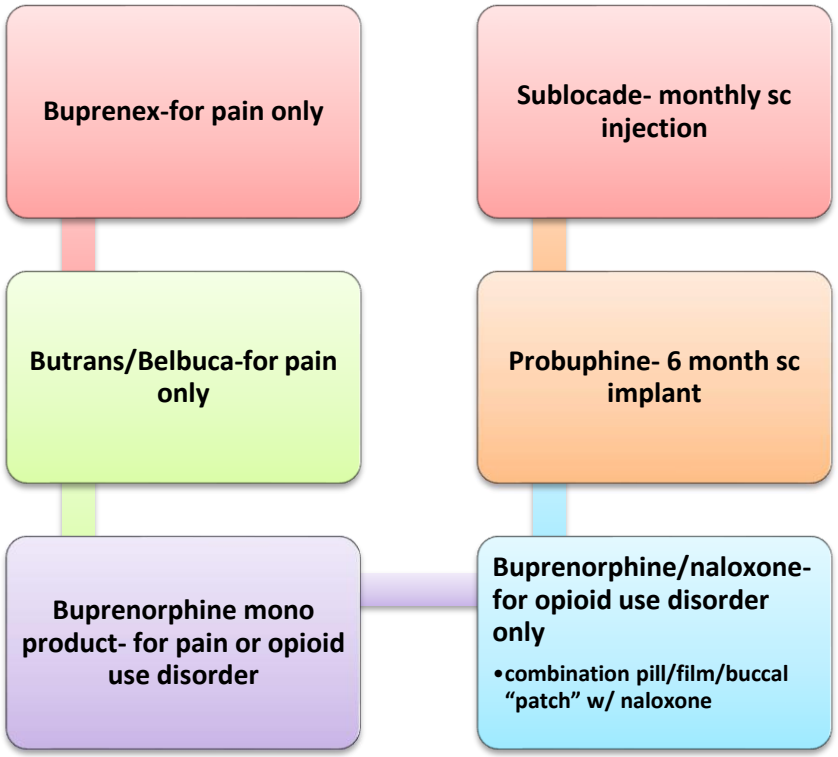
Buprenorphine Formulations



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Stop using this term:

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Buprenorphine Common Adverse Effects

- Headaches
  - Management: aspirin, ibuprofen, acetaminophen (if there are no contra-indications)
- Nausea
  - Management: Consider spitting the saliva out after adequate absorption instead of swallowing.
- Constipation
  - Management: Stay well-hydrated, Consume high-fiber diet, Consider stool softeners, laxatives, naloxegol
- Xerostomia (Dry mouth) –
  - Complications: Gingivitis, Periodontitis
  - Management: Stay well-hydrated, Maintain good oral hygiene

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Precipitated Withdrawal

- Because of its high affinity for mu opioid receptors, buprenorphine can displace other agonists (such as heroin, methadone) that are already present and occupying the receptors

- The sudden change from full-agonist to partial-agonist activation of opioid receptors can cause sudden and severe withdrawal symptoms (precipitated withdrawal)

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MOUD

	Methadone	Buprenorphine (Oral)	Naltrexone (IM)
Mechanism of Action	Full Agonist on Opioid Receptor	Partial Agonist on Opioid Receptor	Antagonist on Opioid Receptor
Dosing	80mg-100mg (Usual Dose)	4-32mg	380mg Depot Injection
Advantages	▪ Provided in a highly structured supervised setting where additional services can be provided on-site and diversion is unlikely ▪ Maybe effective for individuals who have not benefited sufficiently from partial agonists or antagonists	▪ Improved safety due to partial agonism ▪ Availability in office-based settings	▪ No addictive potential or diversion risk ▪ Available in office-based settings ▪ Option for individuals seeking to avoid any opioids

Schuckit, 2016

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Starting Buprenorphine

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Obtaining History

Ask about all substances:

Prescribed and non-prescribed

Age at first use

Determine patterns of use over time:

Frequency

Amount

Route

Assess recent use

In the last 2 weeks

Most recent use

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Previous Treatment

- Prior treatment attempts
  - What type?
  - What age?
  - What happened?
  - What was your experience?
  - What was the outcome?

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Clinical Opiate Withdrawal Scale (COWS)

- Resting Pulse
- Sweating
- Restlessness
- GI Upset
- Tremor
- Pupil Size
- Bone or Joint Aches
- Yawning
- Anxiety or Irritability
- Gooseflesh
- Runny Nose or Tearing Eyes

Wesson and Ling, 2003

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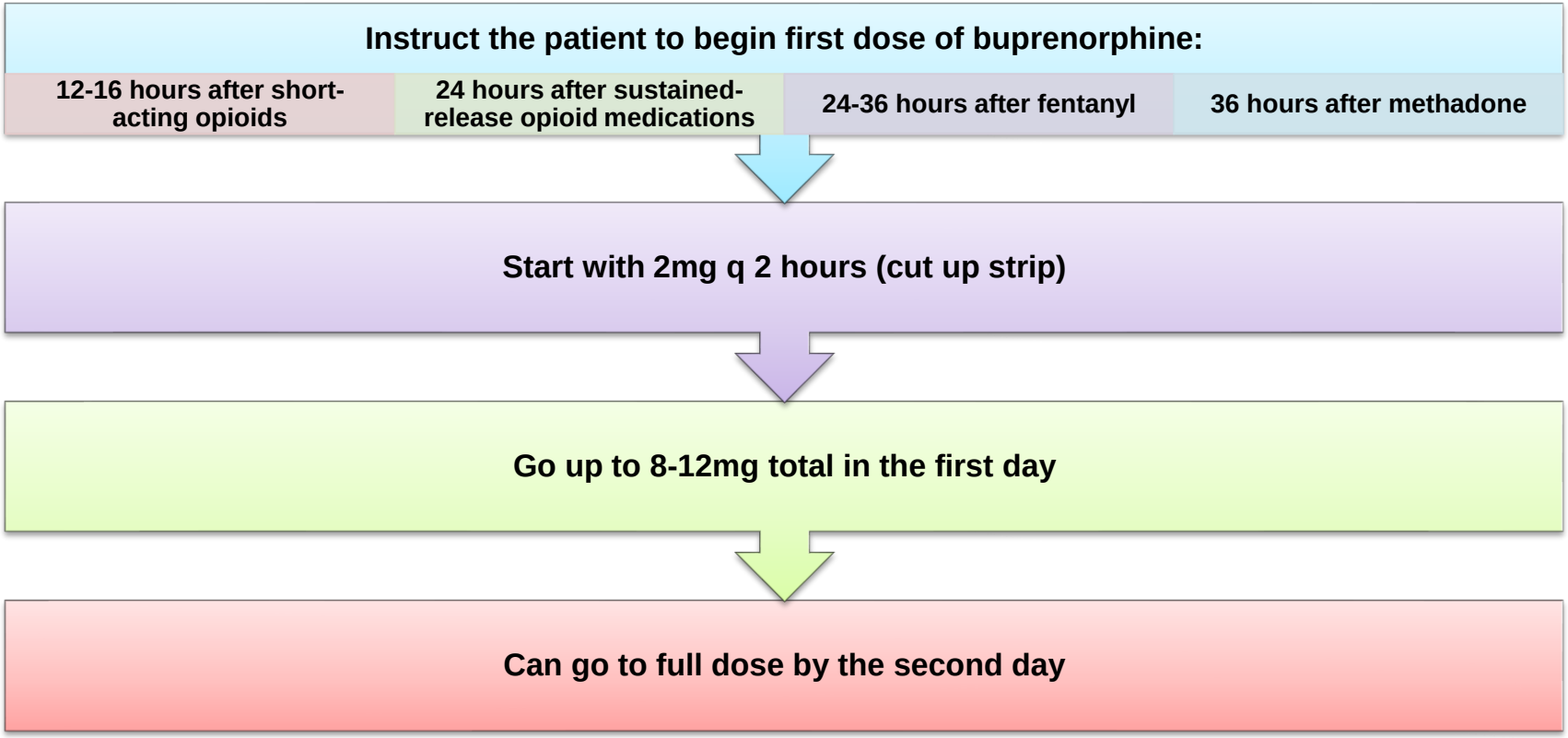
To Avoid Precipitated Withdrawal



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Buprenorphine/Naloxone Instructions

Moisten mouth before taking film

Hold sublingual film/tablet (for 2 to 8 minutes) until completely dissolved

Do not swallow or spit

If administering 2 films/tablets at the same time, place the second under the tongue on the opposite side. Try to avoid having the films/tablets touch as much as possible

Don't drink, eat, or smoke until 10 min after taking bup

Risk for OD:

- Offer naloxone

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Maintaining Buprenorphine

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Treatment Duration

Evidence supports long term maintenance

- Studies up to 16 weeks show high relapse rates with medication withdrawal
- Improved retention rates in treatment with extended buprenorphine maintenance

Continue maintenance as long as patient is benefitting from treatment

Kakko et al., 2003
Weiss et al., 2011

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Monitoring Efficacy

- Urine toxicology
  - Testing is not meant to "catch" the patient
  - Positive UDS results
    - Reflect only recent drug use
    - Cannot determine exposure time, dose, or frequency of use
    - Should not lead to a discharge from treatment
    - Opportunity for discussion

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Monitoring Adherence

Urine testing for norbuprenorphine (metabolite)

Check PDMP

Pill/strip counts

Ask your patient!

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Urine Toxicology Time Limits

Amphetamine	2-4 days
Benzodiazepines	1-10 days
Cocaine	1-3 days
Heroin/morphine	1-3 days
Methadone	1-4 days
Marijuana	1-30 days
PCP	3-30 days

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MOUD in Pregnancy

Buprenorphine	Methadone

▪ Similar efficacy as methadone
▪ Same rates of adverse events, NAS, as methadone
▪ Improvement over methadone:
  ▪ Lower risk of overdose
  ▪ Fewer drug interactions
  ▪ Milder withdrawal symptoms in NAS
  ▪ Reduced morphine dosing for NAS
  ▪ Significantly shorter hospital stay
	▪ More structure- better for patients in unstable situations
	  ▪ Decreased risk of diversion
	▪ More long-term data on outcomes

Fischer et al., 1998, 1999
Jones et al., 2010;
Kakko et al., 2008;
Kraft et al., 2017

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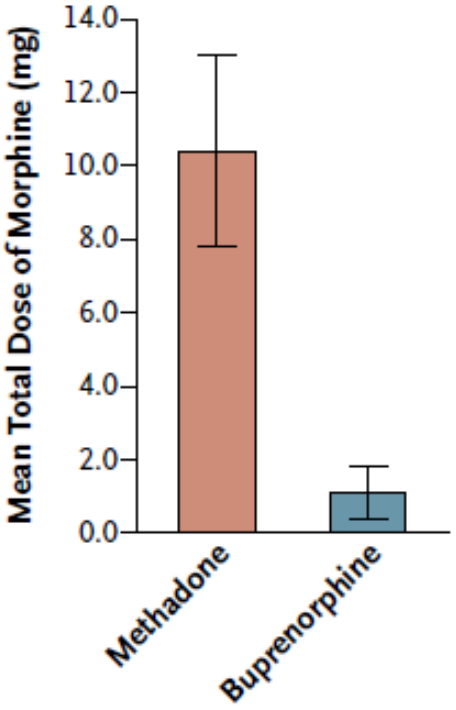
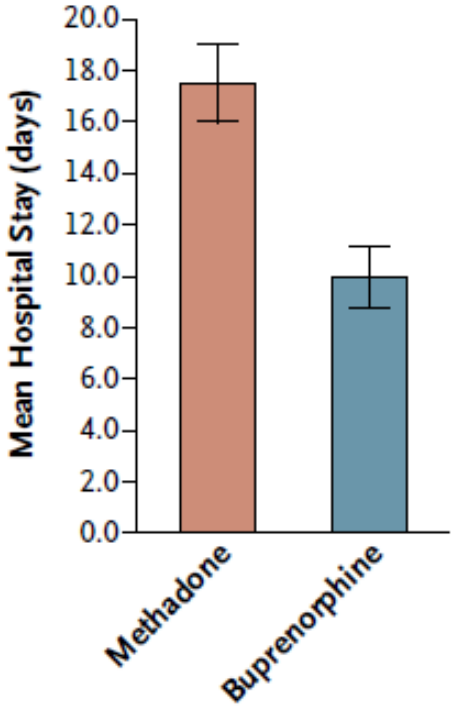
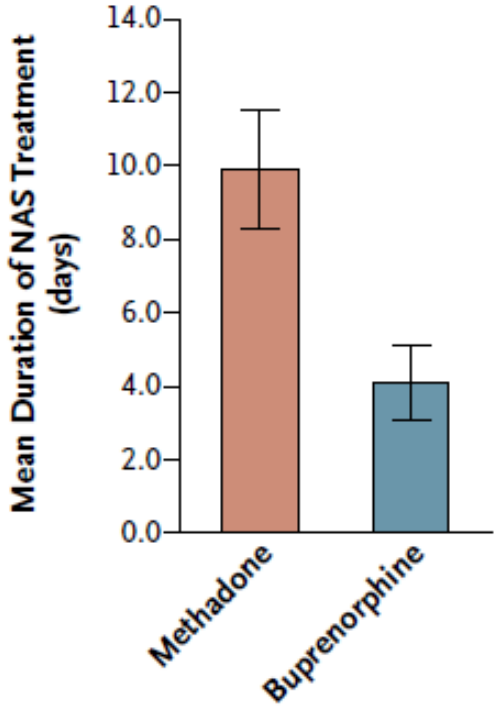
Maternal Opioid Treatment:

MOTHER Study







Jones et al., 2010

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Optimal Management

Medications alone are efficacious and should never be delayed for individuals without access to counseling or therapy

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But don’t I need to provide a counselor?

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Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence:*A 2-Phase Randomized Controlled Trial*

Roger D. Weiss, MD; Jennifer Sharpe Potter, PhD; David A. Fiellin, MD et. al. Arch Gen Psych 2011; 68:1238-1246

- **Multicenter randomized clinical trial- n=653**
  - **In both phases patients randomized to standard medical management(SMM) or SMM plus counseling**
  - **In both phases (3 &12 weeks of buprenorphine), separate counseling did not change outcomes**

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Support groups?

“You’re not in recovery if you’re on medication”

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So now I am convinced (maybe) I should prescribe in my primary care setting…

- Prescribing is the easy part
- The conversation is the art of medicine (and the fun)

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SHAME

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Self-esteem

- **You- "The best thing you can do for yourself is stop using drugs"**
- **Patient- "I don't deserve the best, what else can I do?"**

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Coping

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Visit openers:

What have you done today to make the world a better place?

What have you done today to make today better than yesterday?

Give me an update for your fan club

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What if ?

- **My patient's urine drug screen is positive for…**
- **My patient's urine drug screen is negative for buprenorphine**
- **My patient misses an appointment**
- **My patient asks for a refill early**
- **My patient has an overdose**

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Recovery is about progression (not linear), not perfection

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Quotes from patients on buprenorphine

“I feel normal”

“I wake up not sick”

“I have my life back”

- **Treatment in normal medical settings:**
  - **Encourages continuity of medical care**
  - **Encourages relationship building**
  - **Legitimizes opioid use disorder as a treatable, chronic illness**

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Fingerhood M, King V, Brooner R, Rastegar D. A comparison of characteristics and outcomes of opioid dependent patients initiating office-based buprenorphine or methadone maintenance treatment. Substance Abuse. 2014; 35:122-6.

Characteristics

Characteristic	BUP n=252	METH n=252	P value
Abused Substances			
Heroin	83%	86%	0.39
Opioid Rx	29%	9%	<0.001
Cocaine	53%	55%	0.73
Benzodiazepines	9%	23%	<0.001
Injection drug use	61%	69%	0.051
HIV infection	14%	8%	0.023
Chronic pain	18%	12%	0.063
Recent criminal charges	43%	50%	0.129

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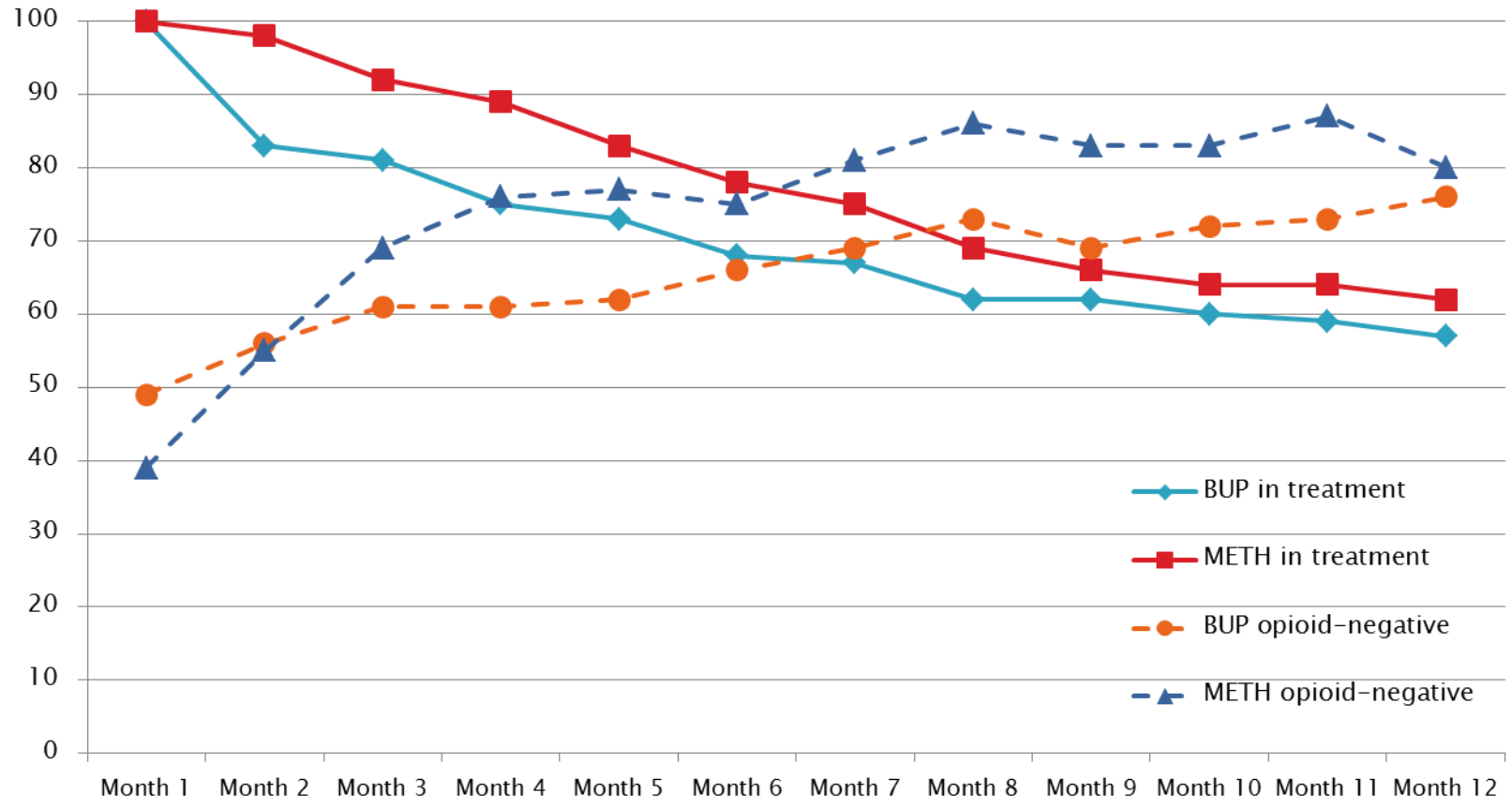
Percentage of patients in treatment at each month and percentage of those in treatment who were opioid-negative. (BUP – buprenorphine, METH – methadone).



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Integrated buprenorphine cost study

Hsu YJ, Marsteller JA, Kachur SG, Fingerhood MI. Integration of buprenorphine treatment with primary care: Comparative effectiveness on retention, utilization and cost. Pop Health Managem. 2019; 22:292-9.

- **Maryland Medicaid Priority Partners beneficiaries who received a script for buprenorphine and no buprenorphine script in previous 3 months**
- **Only first episodes analyzed**

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Buprenorphine cost study

	CCP n=137	Non-CCP n=992	
6 month retention	80.3%	59.2%	p<.001
Any ED visit 12 months	63.5%	60.4%	NS
Any acute hospital stay 12 months	15.3%	18.9%	NS
Total cost 12 months mean	$10,785	$12,210	P<.001

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Harm Reduction

- The practice of reducing the negative consequences of drug use in people who are not ready, or not able to abstain from drug use completely
  - Needle and syringe programs
  - Safe injection practice counseling
  - Overdose education and naloxone distribution

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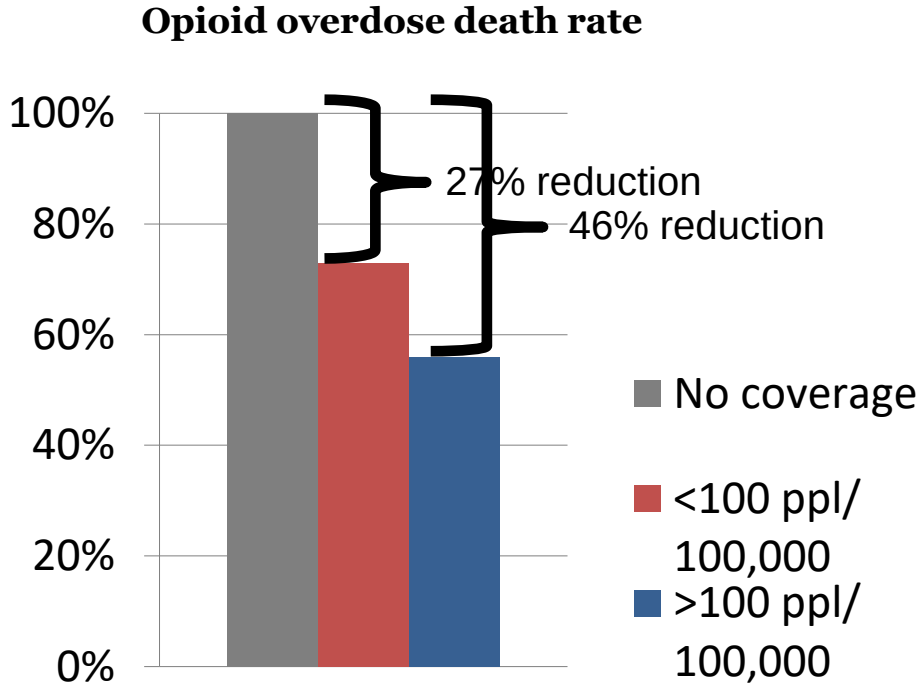
Naloxone Distribution Reduces Deaths Due to Overdose



Adapted from Alex Walley's slide, CRIT/FIT Program 2014

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Terms to avoid	Alternatives	Why?
Addict *User* *Substance or Drug Abuser* *Junkie* *Alcoholic/Drunk* *Substance Dependence*	• **Person with…(OUD, AUD, SUD)** • **Person with opioid addiction…** • **Patient** • **Person in recovery**	• Person-first language • Shows that a person "has" a medical problem, rather than "is" the problem • Avoids negative associations, punitive attitudes, and blame
Clean/Dirty	**For toxicology screen results:** • **Testing negative/positive**	•Accurate terminology consistent with a medical disorder
Opioid Substitution Therapy/ Replacement Therapy	• **Opioid agonist therapy** • **Evidence-Based medication for OUD** • **Pharmacotherapy**	• Avoid misconception medications substitute for another drug/addiction
Medication Assisted Treatment (MAT)	• **Medication to treat OUD** • **Pharmacotherapy for OUD**	• "Assisted treatment" -undervalues the role of medication -unlike other medical disorders

National Institute of Drug Abuse. https://www.drugabuse.gov/nidamed-medical-health-professionals/health-professions-education/words-matter-terms-to-use-avoid-when-talking-about-addiction. Accessed 04/22/2020.

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Patient vignette 1

- **EB is a 72 F seen for initial visit. She has a history of chronic pain in hips and knees. Her previous provider will no longer prescribe oxycodone as for the past 2 months her 30 day script ran out after 2 weeks. Tearful and fearful that providers won't help her. Cannot take NSAIDs. She admits that she often takes oxycodone when she is upset.**
- **She lives alone in senior housing apartment; 2 daughters- both with difficulties (medical and social). Non-smoker; no alcohol.**

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Patient vignette 1 outcome

- **After spending time building rapport and making sure she knew my goal was to work with her, I explained I would not prescribe her oxycodone.**
- **She was open to undoing isolation, treating mood and trying buprenorphine.**
- **Almost immediately, physically more active (no longer dwelling on when next dose of pain medication is and does she have enough), remains on low dose buprenorphine, never running out before she should, with improved pain.**

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Patient vignette 2

- **KL is a 65F retired nurse who had right total knee replacement complicated by joint infection requiring prolonged course of antibiotics, hardware removal with spacer and finally replacement of hardware. She has been on oxycodone 15 mg four times daily for 4 months.**

- **She sees orthopedics in f/u and is told she should not be on any further opioids as she is now 2 weeks out since the last surgery. She is told to take ibuprofen.**

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Patient vignette 2 outcome

- **I receive a call from the police that KL had died from an apparent opioid overdose**
- **I find out from her son that she had gone into severe opioid withdrawal and bought opioids on the street.**

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Patient vignette 3

- **28F seen for first visit. Able to review in CRISP/PDMP- multiple ER visits for back pain and one opioid overdose, and many filled scripts for oxycodone from many providers. Had abnormal PAP 3 years ago. History of HIV (not addressed) and hypertension (has elevated BP today)**
- **Her agenda- getting script for oxycodone. My agenda- getting her engaged in medical care and treatment for opioid use disorder**

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Patient vignette 3 outcome

- **After 3 months - seen her 7 times**
- **Doing well on buprenorphine/naloxone. No back pain. Urine drug screens all negative since the first visit.**
- **On medication for hypertension; adherent with HAART for HIV; had PAP done. No ER visits.**
- **Mood/self-esteem much improved. Better relationship with family. Working part-time.**

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X waiver by the numbers

- 30- how many patients can be treated with taking 5 minutes to apply
- 100- how many patients can be treated if you have taken 8 hour training for physicians or 24 hours for non-physicians
- 275- how many patients can be treated after one year of being able to prescribe for 100 patients

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BUPRENORPHINE Waiver Notification Form

Entering a 30 Patient Notification

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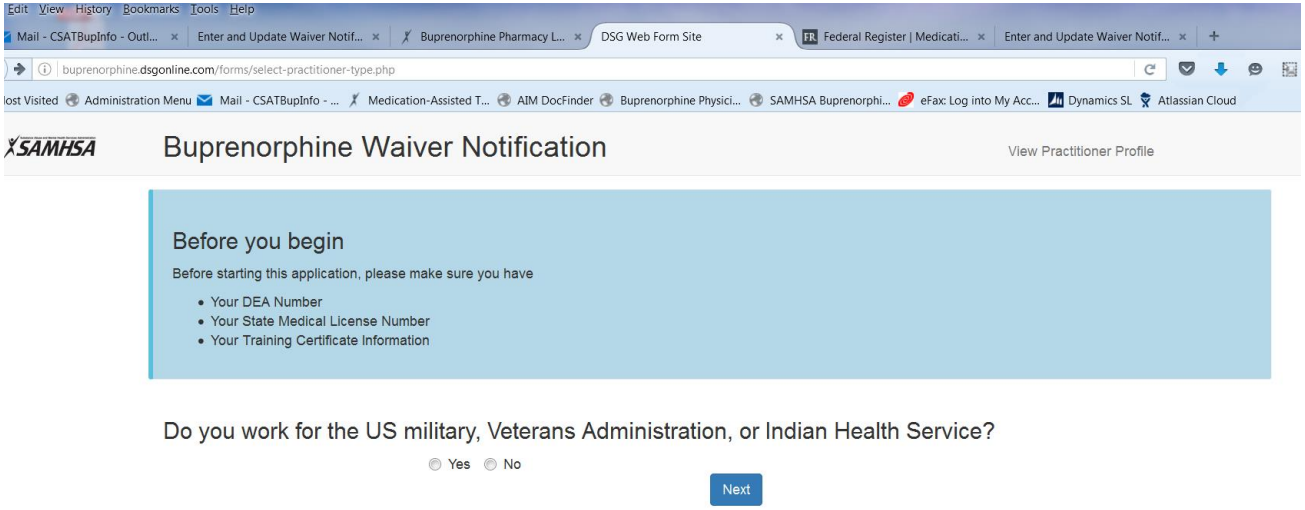
Submitting a 30 Patient Notification Form Online



Answer the question yes or no and click the Next button.

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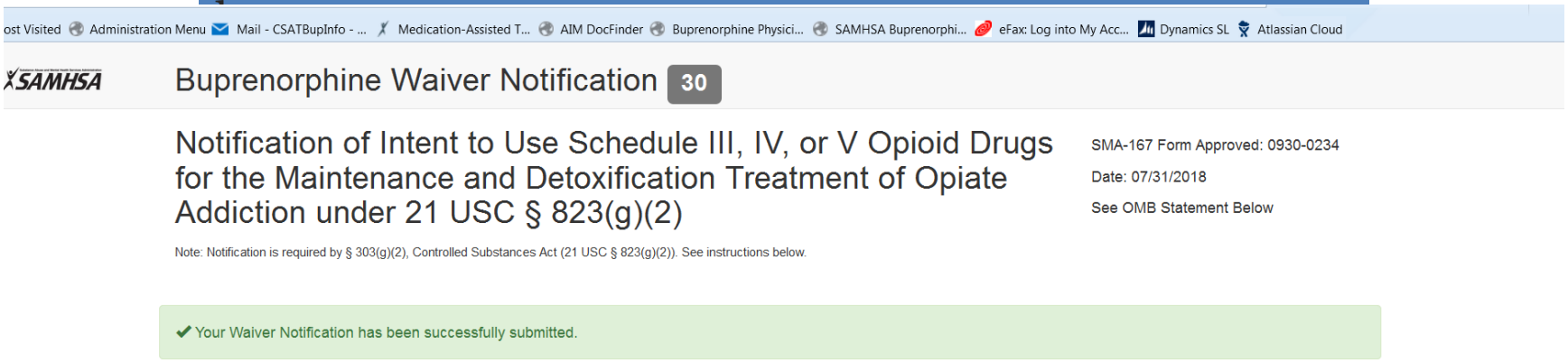
When the Notification is submitted successfully you will receive a confirmation.
If it has not, an error message will indicate what needs to



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DACS provides support to primary care and specialty prescribers in addressing the needs of their patients with substance use disorders and chronic pain management.

All Services are FREE

- Phone consultation for clinical questions provided by expert addiction medicine specialists
- Education and training opportunities related to substance use disorders and chronic pain management
- Assistance in the identification of substance use and behavioral health resources and referrals that meet the needs of the patients in your community

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1-866-337-DACS (3227) • www.DistrictACS.org