EMergency Department-Initiated **B**uprenorphin**E** for Opioid Use **D**isorder (EMBED)

Yale SCHOOL OF MEDICINE

Agenda

- Introductions
- Didactic (Why & How)
  - Break
- Small Group Cases & Discussion
  - Break
- EBM Update & Resource Review
- Q&A

DISCLOSURE:

- EMBED is a 5-year UG3/UH3 NIDA award to develop, disseminate, implement, and test a user-centered decision support system to facilitate ED-initiation of buprenorphine for individuals suffering from opioid use disorder.
- RCT, 20 EDs, 5 healthcare systems; enrollment completed in 2021.
- Currently in dissemination phase.

Methods

EMBED:

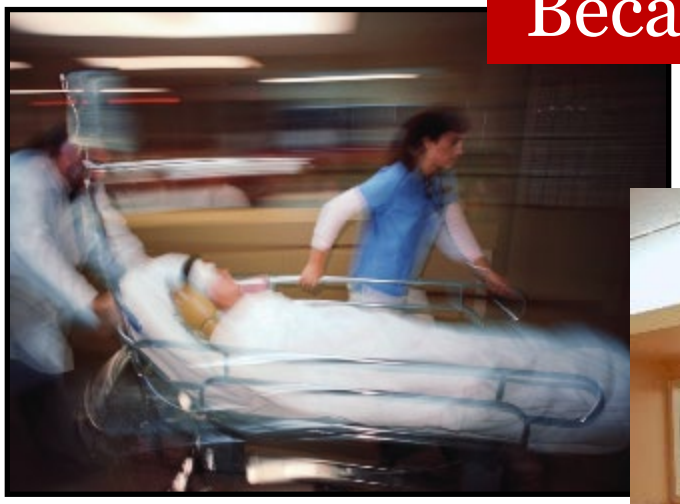
PRAGMATIC TRIAL OF USER-CENTERED CLINICAL DECISION SUPPORT TO IMPLEMENT EMERGENCY DEPARTMENT-INITIATED BUPRENORPHINE FOR OPIOID USE DISORDER

Dr. Ted Melnick

Dr. Gail D'Onofrio

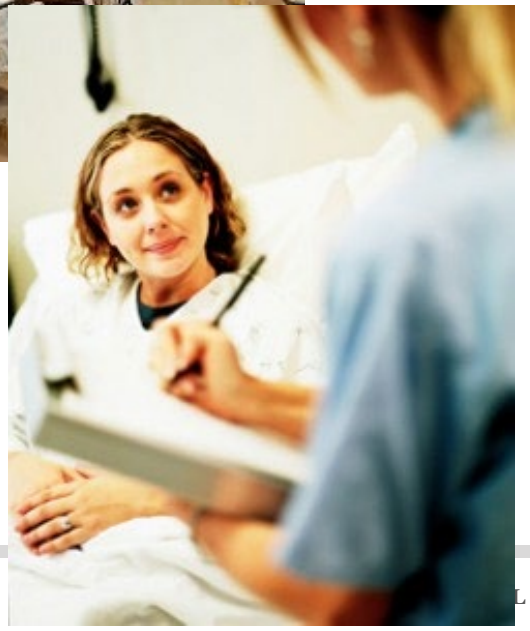
Why focus on the ED?

Because that's where the patients are



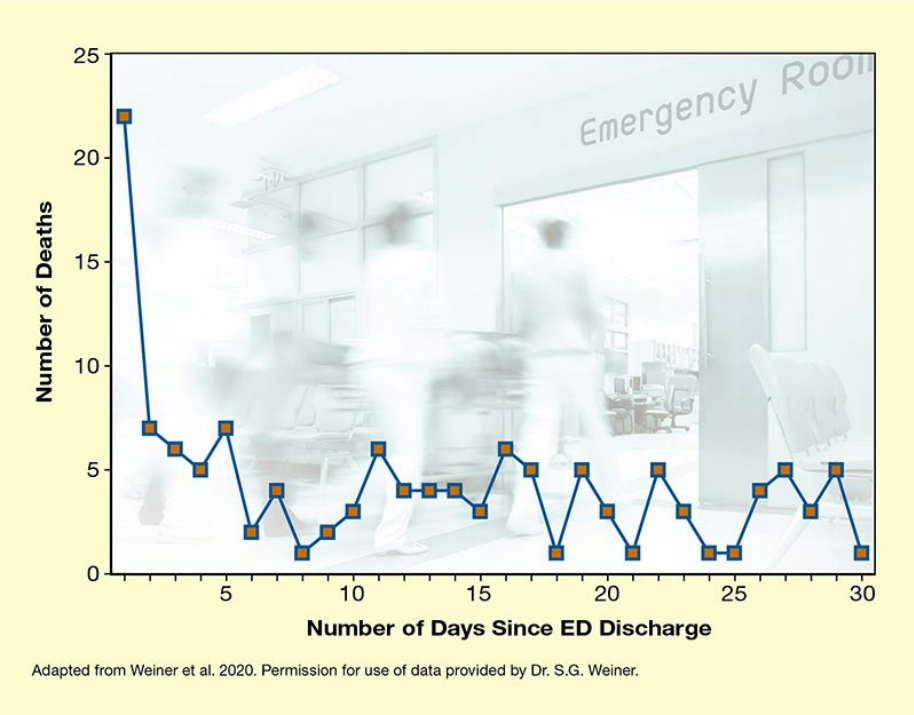
Overdose

Seeking Treatment



Screening

5% post-ED discharge death rate for OUD



Adapted from Weiner et al. 2020. Permission for use of data provided by Dr. S.G. Weiner.

- 1 in 20 patients treated for a nonfatal opioid overdose in an ED died within 1 year of their visit, many within 2 days.
- 2/3's of these deaths were directly attributed to subsequent opioid-related overdoses.

A Randomized Trial of ED-Initiated Interventions for Opioid Dependence

Research

D'Onofrio, G., O'Connor, P.G., Pantalon, M.V., Chawarski, M.C., Busch, S.H., Owens, P.H., Bernstein, S.L. and Fiellin, D.A.

Original Investigation

Emergency Department–Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence

A Randomized Clinical Trial

Gail D'Onofrio, MD, MS; Patrick G. O'Connor, MD, MPH; Michael V. Pantalon, PhD; Marek C. Chawarski, PhD; Susan H. Busch, PhD; Patricia H. Owens, MS; Steven L. Bernstein, MD; David A. Fiellin, MD

IMPORTANCE Opioid-dependent patients often use the emergency department (ED) for medical care.

OBJECTIVE To test the efficacy of 3 interventions for opioid dependence: (1) screening and referral to treatment (referral); (2) screening, brief intervention, and facilitated referral to community-based treatment services (brief intervention); and (3) screening, brief intervention, ED-initiated treatment with buprenorphine/naloxone, and referral to primary care for 10-week follow-up (buprenorphine).

DESIGN, SETTING, AND PARTICIPANTS A randomized clinical trial involving 329 opioid-dependent patients who were treated at an urban teaching hospital ED from April 7, 2009, through June 25, 2013.

INTERVENTIONS After screening, 104 patients were randomized to the referral group, 111 to

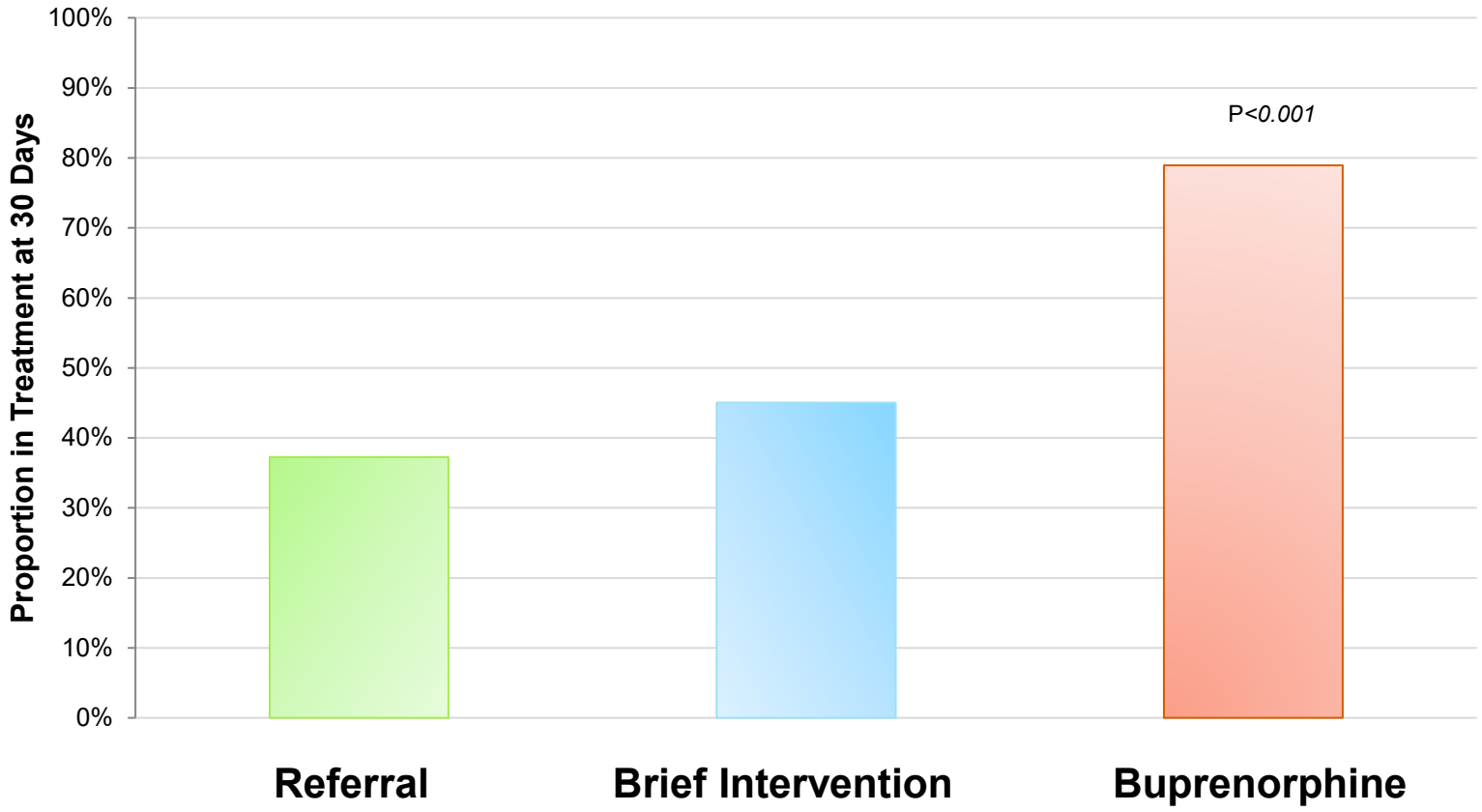
JAMA Report Video and Author Video Interview at jama.com

CME Quiz at jamanetworkcme.
CME Questions p

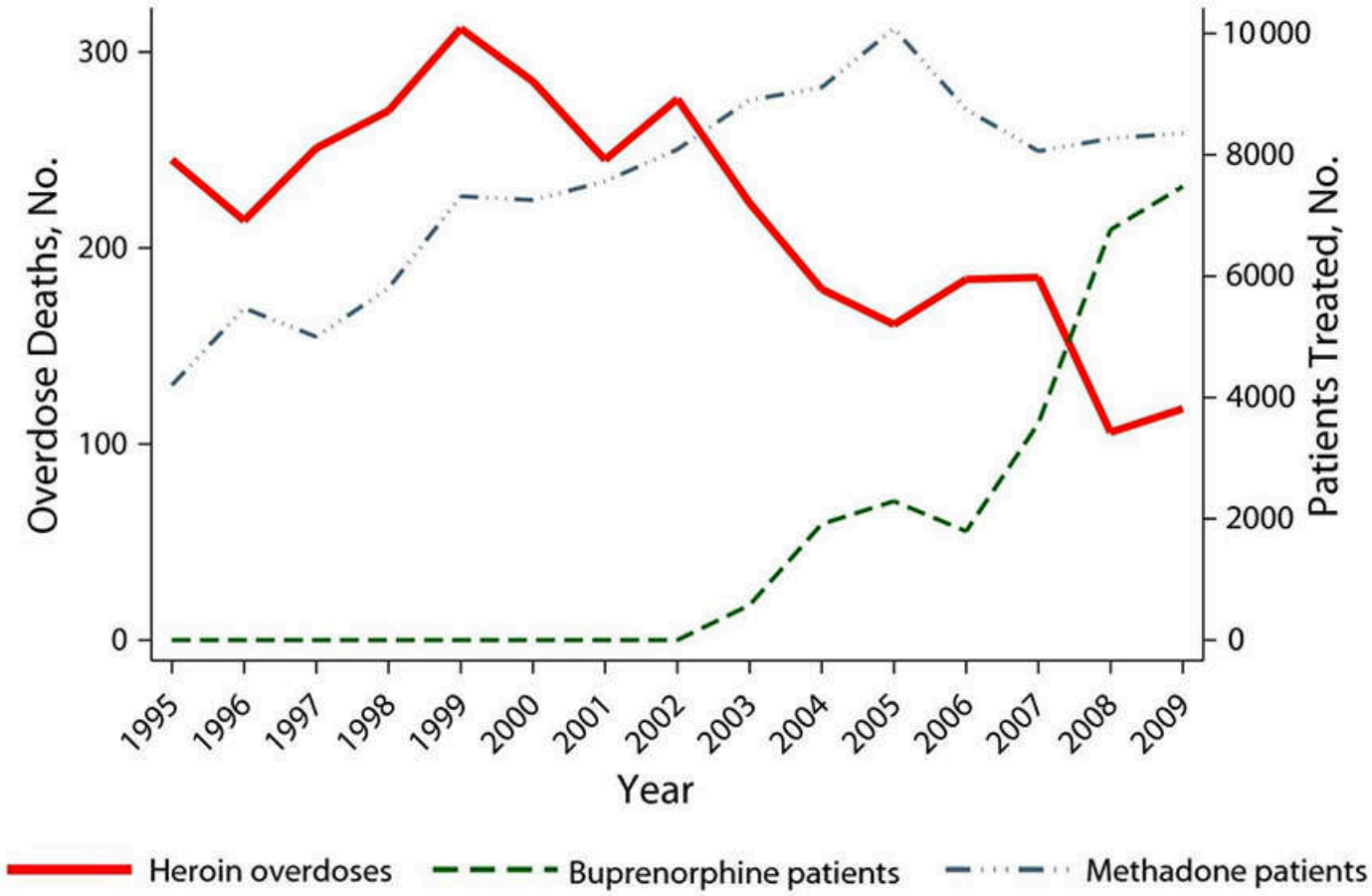
NIDA 5R01DA025991

JAMA. 2015;313(16):1636-1644.

ED-Bup: 2x More Likely to be Engaged in Addiction Treatment at 30 Days



MAT REDUCES HEROIN OD DEATHS

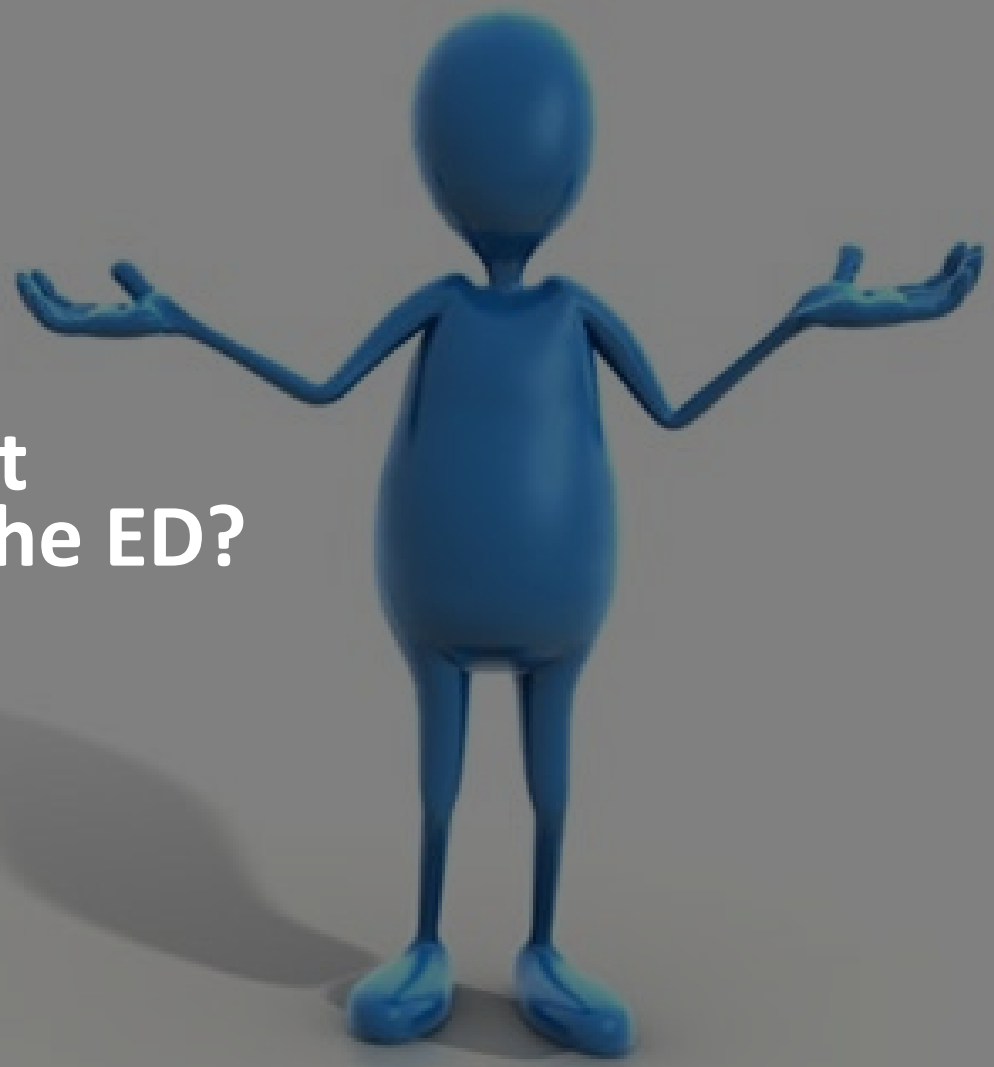


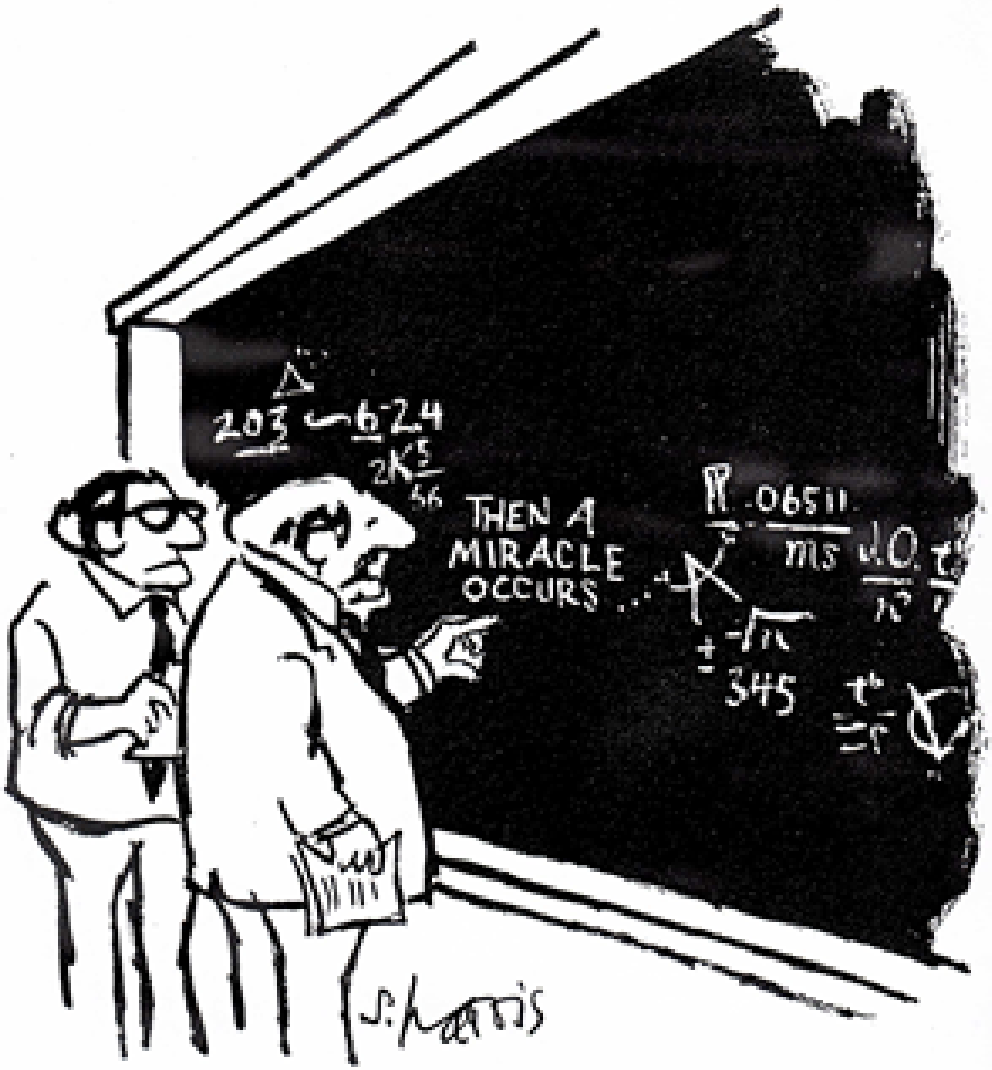
Translating Research into Practice

EDs and Emergency Providers can…

- Identify patients with OUD
- Provide treatment
  - Initiate buprenorphine
  - Overdose education and naloxone distribution
- Directly link patient to continued opioid agonist therapy & preventive services

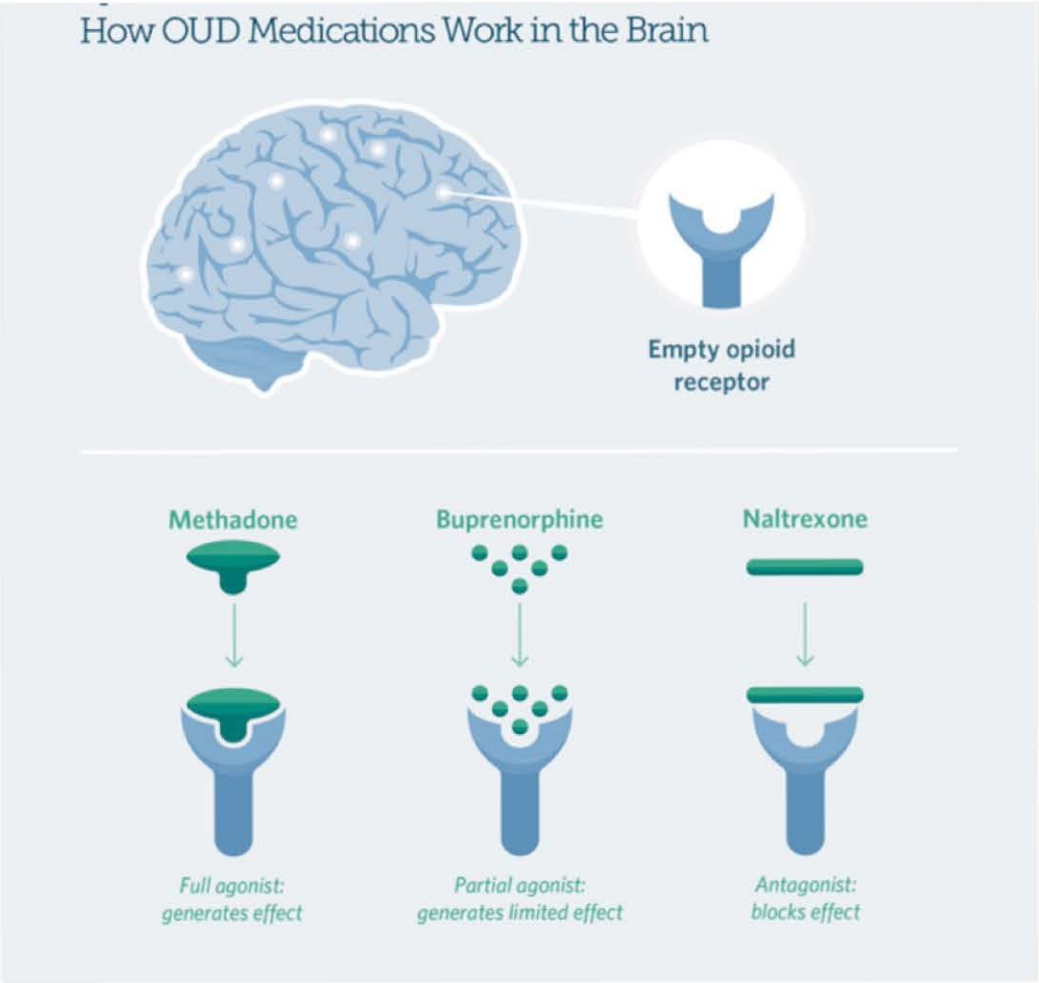
How do I start buprenorphine in the ED?



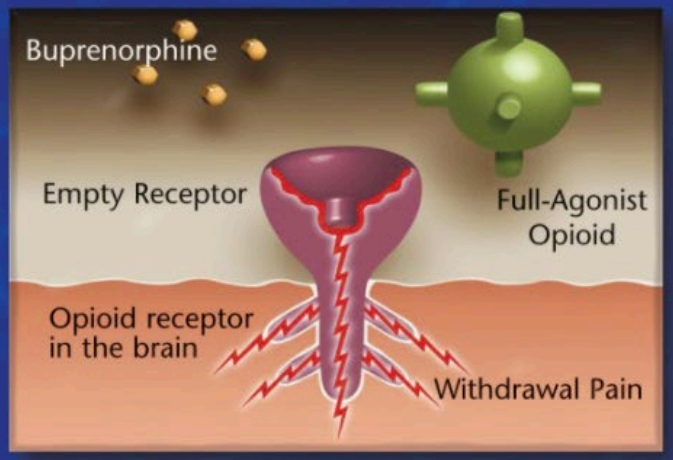


"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."

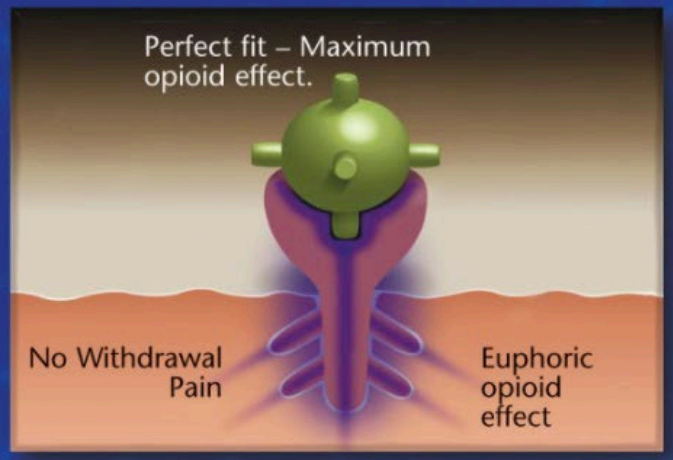
Understanding Buprenorphine:



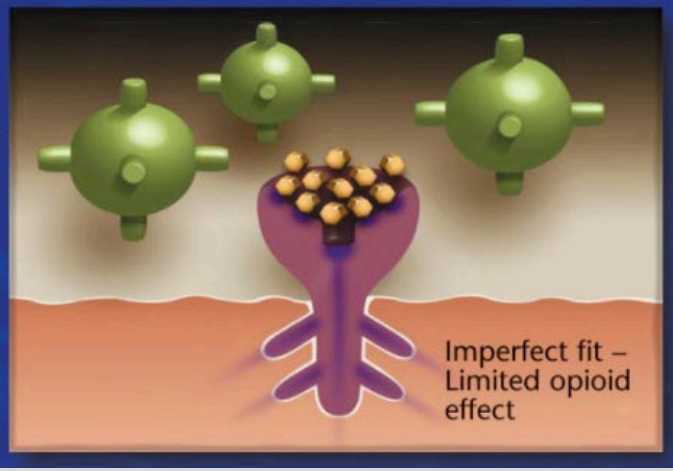
How Buprenorphine Works

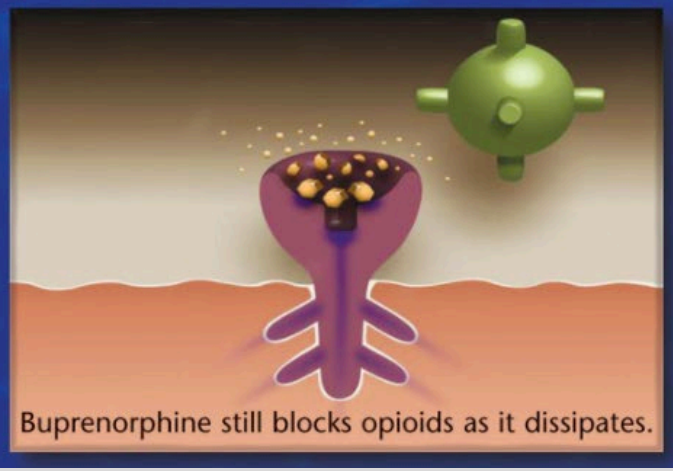


Opioid receptor is empty. As someone becomes ***tolerant*** to opioids, they become less sensitive and require more opioids to produce the same effect. Whenever there is an insufficient amount of opioid receptors activated, the patient feels discomfort. This happens in withdrawal.



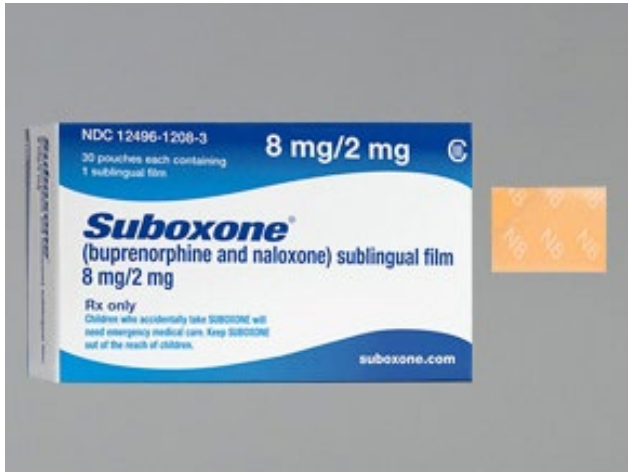
Opioid receptor filled with a full-agonist. The strong opioid effect of heroin and painkillers can cause euphoria and stop the withdrawal for a period of time (4-24 hours). The brain begins to crave opioids, sometimes to the point of an uncontrollable compulsion (addiction), and the cycle repeats and escalates.

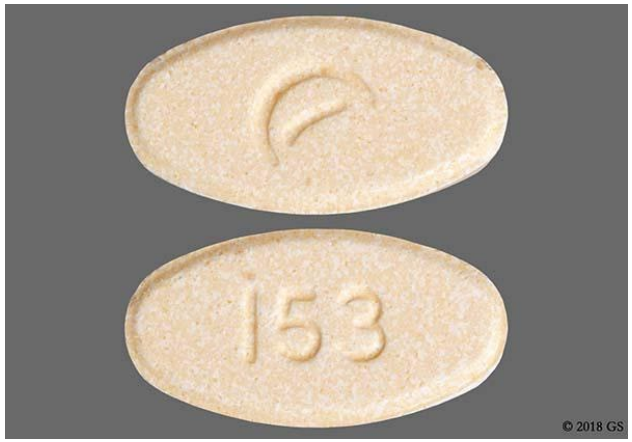




It is NOT simply replacing one drug for another. Buprenorphine treatment decreases withdrawal (dependence) and drug craving without providing an opioid "high."

Suboxone – Buprenorphine/Naloxone





- **Schedule III controlled substance**
- **Combination drug**
- **Sublingual film**
- **Not to be confused with *Subutex* pill**

Buprenorphine Integration Pathway

① ED presentation

-Seeking Treatment
-Screen Positive
-Complication of Drug Use
- Withdrawal
- Overdose
- Infection

-Identified during the course of the visit

② **Assess**

For OUD → Identification of OUD based on DSM-5

For Withdrawal → Clinical Opioid withdrawal Scale (COWS)

③ Treat

BNI Buprenorphine algorithm

④ Discharge & Refer to Treatment

DSM-5 criteria for diagnosis of Opioid Use Disorder

At least 2 criteria must be met within a 12 month period

1. Take more/longer than intended
2. Desire/unsuccessful efforts to quit opioid use
3. A great deal of time taken by activities involved in use
4. Craving, or a strong desire to use opioids
5. Recurrent opioid use resulting in failure to fulfill major role obligations
6. Continued use despite having persistent social problems
7. Important activities are given up because of use.
8. Recurrent opioid use in situations in which it is physically hazardous (e.g. driving)
9. Use despite knowledge of problems
10. Tolerance
11. Withdrawal

Severity

Presence of Symptoms

Mild: 2-3
Moderate: 4-5
Severe: ≥6

Tolerance

It takes a higher dose of a drug to achieve the same level of response achieved initially.

Dependence

① Formally assess for opioid use disorder

② Formally assess the severity of opioid withdrawal (COWS)

③ Assess patient willingness for buprenorphine

④ Provide ED-initiated buprenorphine (ED or home induction)

⑤ Overdose education and naloxone distribution (OEND)

⑥ Provide formal referral for ongoing opioid agonist treatment

COWS

Resting Pulse Rate

80 or below	81-100	101-120	>120
(0)	(1)	(2)	(4)

Restlessness

Sits still	Difficulty siting still	Frequently shifting limbs	Unable to sit still
(0)	(1)	(3)	(5)

Anxiety or irritability

None	Increasing	irritable/ anxious	Cannot participate
(0)	(1)	(2)	(4)

Yawning

None (0)	1-2 times (1)	3 or 4 times (2)	Several per/min (4)

Pupil Size

Normal (0)	Possibly larger (1)	Moderately dilated (2)	Only rim of iris visible (5)

Runny Nose or Tearing

Not present (0)	Stuffiness/ moist eyes (1)	Nose running/ tearing (2)	Constant running/ tears streaming (4)

Tremor

No tremor (0)	Felt-not observed (1)	Slight trem observab (2)

Sweating

No report (0)	Subjective report (1)	Flushed/ observable (2)	Beads of sweat (3)	Streaming down face (4)

Gooseflesh Skin

Skin is smooth (0)	Piloerection (3)	Prominent piloerection (5)

Bone or Joint pain

None (0)	Mild (1)	Severe (2)	Unable to sit still due to pain (4)

GI upset

None (0)	Stomach cramps (1)	Nausea or loose stool (2)	Vomiting or diarrhea (5)	Multiple episodes (5)

Score:
5-12= Mild
13-24= Moderate
25-36= Moderately Severe

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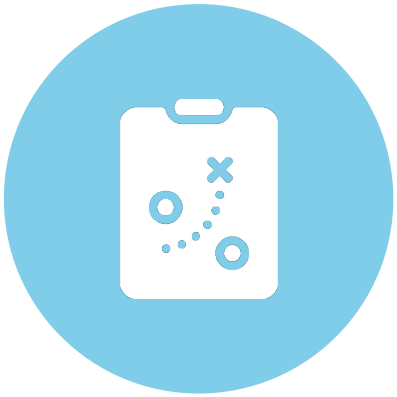
How do you motivate patients to accept treatment?

What makes people take action?

Autonomy (freedom)

Engaging Talk

Hearing Themselves



Making a Plan

Brief Negotiation Interview BNI

Raise The Subject

- Establish rapport
- Raise the subject of drug use
- Assess comfort

Provide Feedback

- Review patient's alcohol and/or drug use and patterns
- Make connection between AOD use and negative consequences; (e.g. impaired judgment leading to injury/unprotected sex/sharing needles)
- Make a connection between AOD use and ED visit

BNI (continued)

Enhance Motivation

Assess readiness to change: One a scale 1 to 10 how ready are you to stop using, cut back or enroll in program???

(Why didn't you pick a lower number?)

Negotiate

- Negotiate goal
- Give advice
- Summarize and complete referral/prescription form
- Thank patient for their time

D'Onofrio G, Pantalon MV, Degutis LC, Fiellin DA, O'Connor PG. Development and implementation of an emergency practitioner-performed brief intervention for hazardous and harmful drinkers in the emergency department. Acad Emerg Med 2005;12:249-256.

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Anyone Can Treat Opioid Withdrawal with Buprenorphine

72-hour rule

Title 21, Code of Federal Regulations, Part 1306.07(b)

Allows to administer (but not prescribe) narcotic drugs for
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d or given to a

- **Patient must return to ED each day for no more than 72 hours**
- **This 72-hour period cannot be renewed or extended.**

Who should **NOT** receive Suboxone?

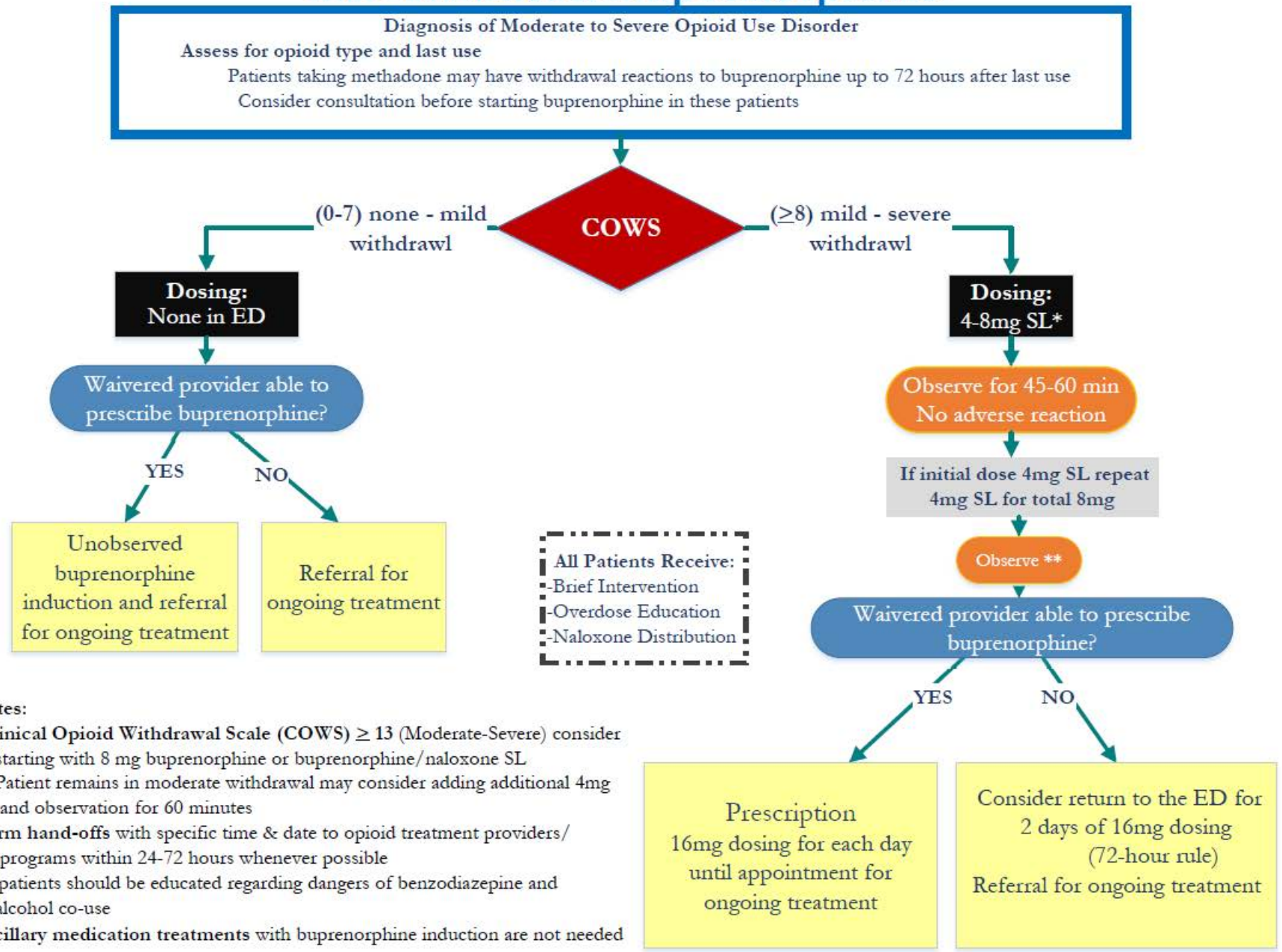
- Pregnant patients
- Allergic reaction to Suboxone
- Active liver disease

What is the key to Initiating Buprenorphine/Naloxone in the ED?

Might not be ready if…..

- **Long acting opioids on board.**
- **Rule of thumb**
  - **Short acting – wait 12 hrs**
  - **Intermediate acting – wait 24hrs**
  - **Long-acting – wait 72hrs**

ED-Initiated Buprenorphine



Notes:

*Clinical Opioid Withdrawal Scale (COWS) ≥ 13 (Moderate-Severe) consider starting with 8 mg buprenorphine or buprenorphine/naloxone SL

** Patient remains in moderate withdrawal may consider adding additional 4mg and observation for 60 minutes

Warm hand-offs with specific time & date to opioid treatment providers/ programs within 24-72 hours whenever possible

All patients should be educated regarding dangers of benzodiazepine and alcohol co-use

Ancillary medication treatments with buprenorphine induction are not needed

Buprenorphine/Naloxone FAQs

1. How do I take it?
2. Can I inject it?
3. Why use suboxone instead of methadone? Is it safer?
4. Can I get a suboxone prescription if I also use Meth, or alcohol or take regular benzos?
5. Does Suboxone impair function? Can patients use it on the job or driving?

A Guide for Patients Beginning Buprenorphine Treatment at Home

Before you begin you want to feel very sick from your withdrawal symptoms

It should be at least . . .

- **12 hours** since you used heroin/fentanyl
- **12 hours** since snorted pain pills (Oxycontin)
- **16 hours** since you swallowed pain pills
- **48-72 hours** since you used methadone

You should feel at least three of these symptoms . . .

- Restlessness
- Heavy yawning
- Enlarged pupils
- Runny nose
- Body aches
- Tremors/twitching
- Chills or sweating
- Anxious or irritable
- Goose pimples
- Stomach cramps, nausea, vomiting or diarrhea

Once you are ready, follow these instructions to start the medication

DAY 1:

8-12mg of buprenorphine

Most people feel better the first day after 8-12mg. (Dosing depends on how early on the first day you started)

Step 1.

Take the first dose	Wait 45 minutes
4mg	45 minutes

- Put the tablet or strip under your tongue
- Keep it there until fully dissolved (about 15 min.)
- Do NOT eat or drink at this time
- Do NOT swallow the medicine

Step 2.

Still feel sick? Take next dose	Wait 6 hours
4mg	6 hours

Most people feel better after two doses = 8mg

Step 3.

Still uncomfortable? Take last dose	Stop
4mg	Stop

- Stop after this dose
- Do not exceed 12mg on Day 1

DAY 2:

16mg of buprenorphine

Take one 16mg dose

Most people feel better with a 16mg dose

16mg

Repeat this dose until your next follow-up appointment

If you develop worsening symptoms while starting buprenorphine before your scheduled outpatient appointment return to the emergency department


BUP

Comfort Medications

① Formally assess for opioid use disorder

② Formally assess the severity of opioid withdrawal (COWS)

③ Assess patient willingness for buprenorphine

④ Provide ED-initiated buprenorphine (ED or home induction)

⑤ Overdose education and naloxone distribution (OEND)

⑥ Provide formal referral for ongoing opioid agonist treatment

Those at Highest Risk for Overdose

- Prior non-fatal opioid overdose
- Opioid use disorder leaving controlled settings (e.g. residential treatments, detoxification, incarceration) who have lowered opioid tolerance
- Prescribed doses of opioid analgesics greater than 90 milligram morphine equivalents (MME) per day
- Taking (co-prescription or co-use) opioids and benzodiazepines
- Alcohol and opioids
- Injecting opioids
- Exposed to high potency opioids (fentanyl, W-18)
- Low levels of physical tolerance (new initiates)
- Sleep disordered breathing (e.g. sleep apnea)

Harm Reduction Strategies

- Carry naloxone
- Never use alone
- Don’t combine opioids with other substances

(alcohol, benzodiazepines or other sedatives)

① Formally assess for opioid use disorder

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How do I set up a program?


Local champions
Community Partners
Leadership Buy-In
Anticipate Barriers
Protocols
Success Stories
Know your Resources

Community Partners

- Is there an OTP, primary care practice, resident clinic, FQHC that will take a “warm handoff”?
  - What services do they offer?
  - Insurance?
  - Waitlist or mandatory waiting period?

- Anyone willing to run a Bridge or Transition Clinic?

Local Champions

- Administration, Faculty, Residents, Nursing…
  - How are you going to get providers waivered?
  - How are you going to get waivered providers to prescribe?
  - Do you need to consider other models?

- Know your allies
  - In the hospital and out
  - Social work/navigators/Health Promotions Advocates
  - Pharmacy!

Anticipate Challenges

- Buprenorphine
  - ~~Waiver Training Requirements~~
  - Formulary/ED Pyxis
  - Local pharmacy

- Patient
  - Insurance
  - Transportation

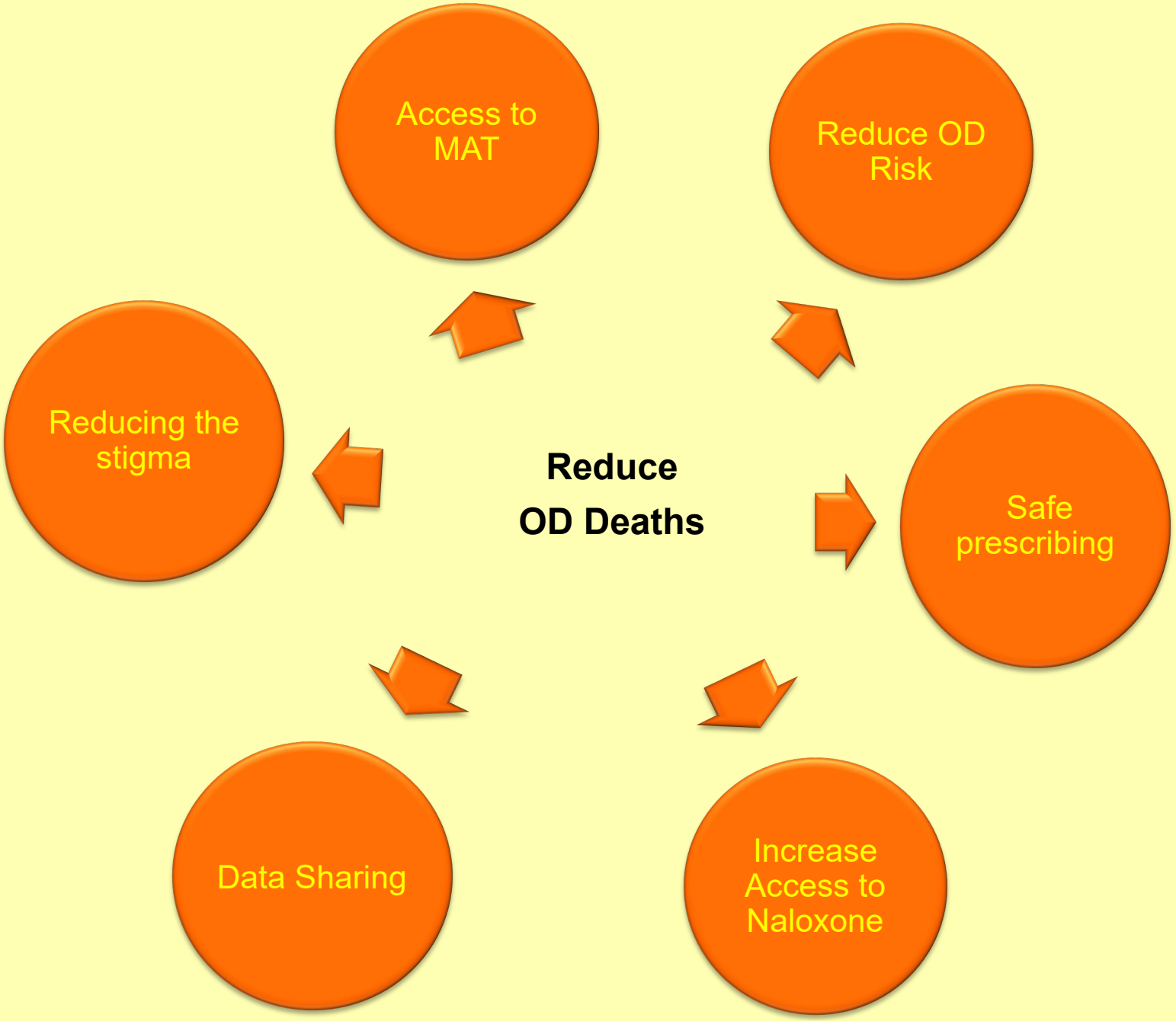
Additional Challenges

- Anticipate resistance, particularly around ANY increased workload across all staff
  - How can you offload some of the work?
  - What motivates different key players?
    - Reducing repeat ED visits or psych holds
    - LOS
    - Patient satisfaction
    - Billing potential

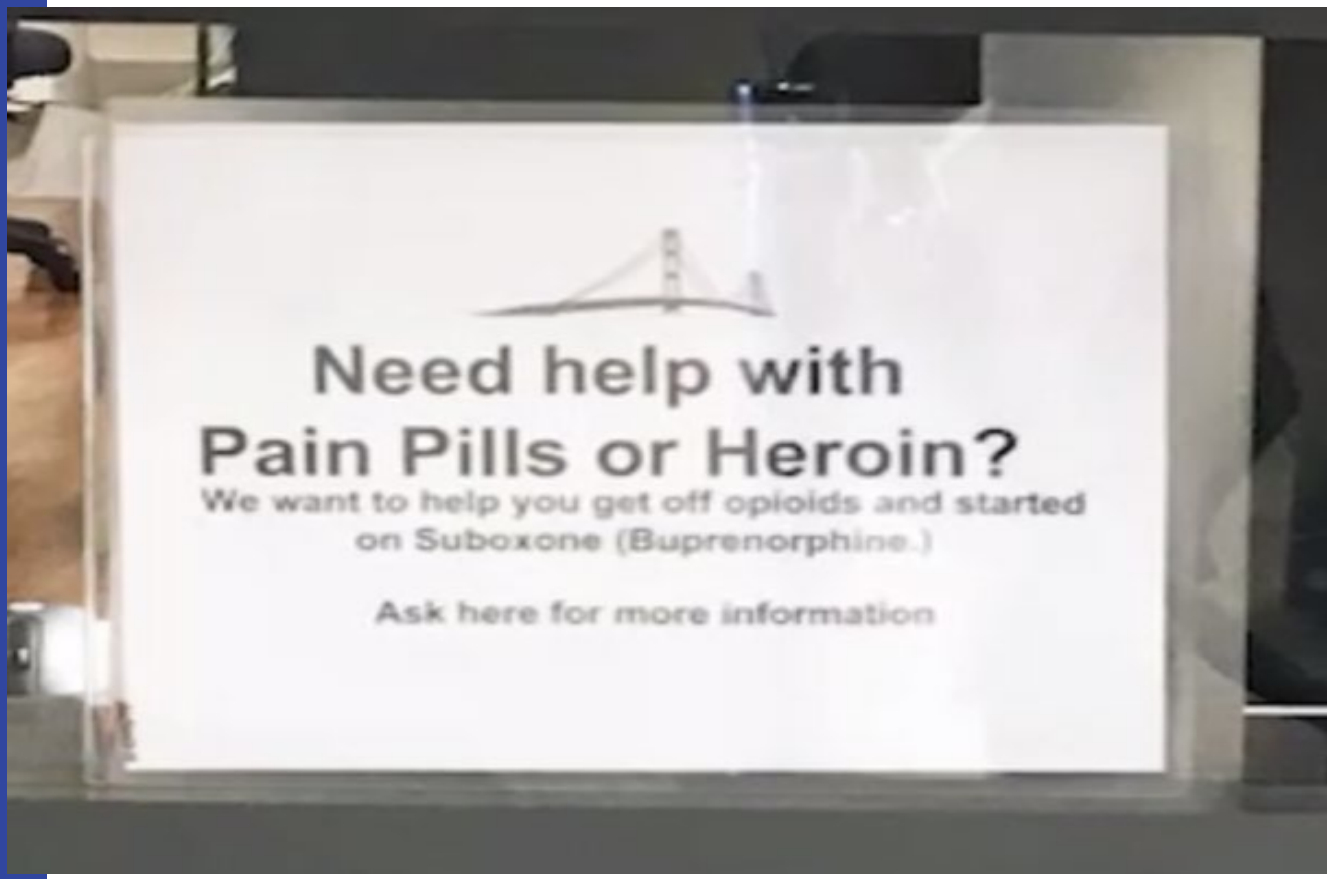
Making Progress

- Engaging stakeholders helps change culture
- It will not happen overnight
- Perfect is the enemy of good
  - Don't wait for a perfect protocol or system!
- Make is as easy as possible for providers and patients

"This is about improving patient care"


Access to MAT
Reduce OD Risk
Reducing the stigma
Reduce
OD Deaths
Safe prescribing
Data Sharing
Increase Access to Naloxone

Barriers & Myths



Emergency Departments — A 24/7/365 Option for Combating the Opioid Crisis

Gail D'Onofrio, M.D., Ryan P. McCormack, M.D., and Kathryn Hawk, M.D., M.H.S.

Concerns, Realities, and Solutions Regarding Opioid Use Disorder and Buprenorphine Treatment in the ED.*

Concern	Reality	Solution
Addiction is a moral failing; patients keep coming back to the ED time and time again.	Addiction is a chronic and relapsing disease that can be effectively treated with opioid-agonist therapies. Emergency physicians often see a skewed sample of patients not in treatment.	Provide patient-specific feedback to ED providers on success stories regarding engagement in treatment.
Providing buprenorphine to patients will lead to diversion.	There is less diversion of buprenorphine than of other opioids. Buprenorphine bought off the street is often used to reduce withdrawal symptoms. Every buprenorphine pill taken is one less opportunity for overdose, complication of injection drug use, or death.	Offer limited supplies, preferably 2–7 days' worth of treatment, until an appointment with a community provider or program can be arranged.
Initiating buprenorphine treatment is complicated, and the ED is already crowded and chaotic.	Buprenorphine is safer and more predictable than many medications used in routine ED practice. Treatment can be accomplished in less time than an urgent care visit.	Integrate protocols electronically into the ED workflow from triage to discharge that engage all providers in order to facilitate a simplified and streamlined process. Identify a cadre of champions available to support new prescribers.
Initiating buprenorphine will increase length of stay.	Initiating buprenorphine will reduce length of stay and reduce the potential for violent behaviors and injury to staff. Buprenorphine markedly reduces withdrawal symptoms in 20–30 minutes.	Streamline protocols and educate staff to achieve times of 60–90 minutes from presentation to discharge, in keeping with urgent care criteria.
There is a lack of referral sites for patients who have initiated buprenorphine treatment.	Most communities have treatment resources of which the ED staff are unaware.	Partner and develop relationships with community resources and local health departments to permit efficient referral and feedback. Hire an ED staff member such as a health promotion advocate, which is helpful and cost-effective.[3]

G D'Onofrio et al. N Engl J Med 2018;379:2487-2490.

Emergency Departments — A 24/7/365 Option for Combating the Opioid Crisis

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Patients will return repeatedly for redosing.	Repeated visits for redosing have not been demonstrated at sites that consistently offer buprenorphine.	Develop treatment plans that are similar to those for other chronic diseases, such as sickle cell disease. Treat withdrawal with buprenorphine and referral.
Patients will flock to the ED for treatment.	Patients with OUD are already in the ED. Sites with ED-initiated buprenorphine do not report an uptake of patients seeking treatment.	Initiate treatment protocols at triage to promote rapid assessment, treatment, and referral.
Many patients don't want treatment anyway.	Some patients, often after an overdose, are not ready for treatment after a brief psychosocial intervention, but discussion may lead to a change in motivation in the future. The ED visit is often a missed opportunity to engage patients who may be contemplating a positive change but need guidance and support.	Introduce harm-reduction strategies such as overdose prevention and naloxone distribution. Establish rapport to facilitate improved outcomes.
Obtaining a waiver to prescribe buprenorphine is too burdensome.	The training required to obtain a waiver can be done all online or as half-day courses coupled with half-day online services. Most training is free and similar to other required learning and counts toward CME requirements for specialty certification, recertification, and licensing in many states.	Identify resources online and at institutions using the SAMHSA and ASAM websites. Offer faculty development days or group learning events.

G D'Onofrio et al. N Engl J Med 2018;379:2487-2490.

Opportunity

Embrace science based treatments

Engage emergency practitioners

Change the trajectory of the opioid epidemic

Questions?

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