



**EMBED: Pragmatic Trial of User-Centered Clinical  
Decision Support to Implement Emergency  
Department-Initiated Buprenorphine  
for Opioid Use Disorder**

Ted Melnick MD, MHS

Gail D'Onofrio MD, MS

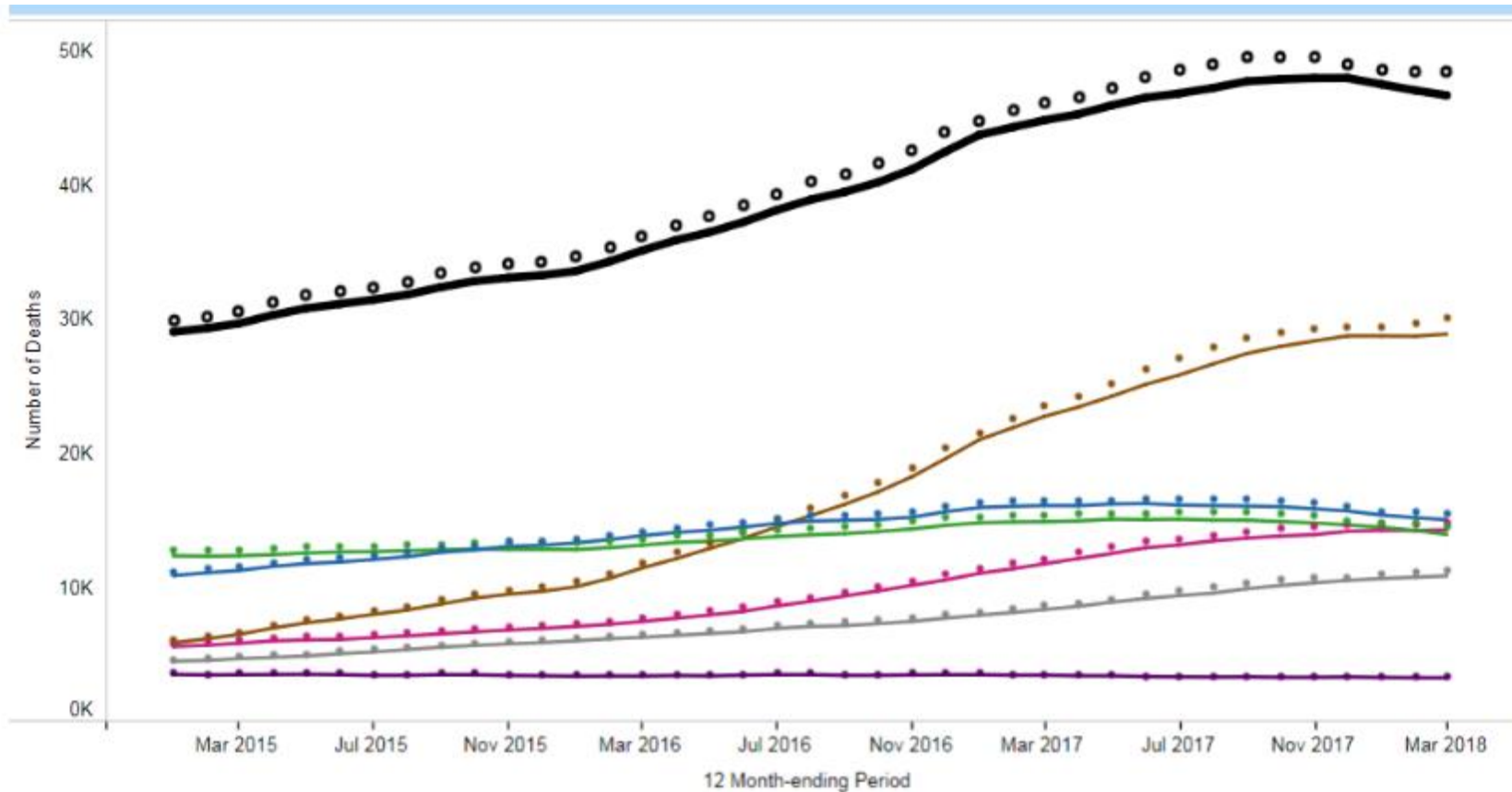


**EMERGENCY**

**The 24/7/365-day Option**

**To Fight the Opioid Crisis**

# US Overdose Deaths



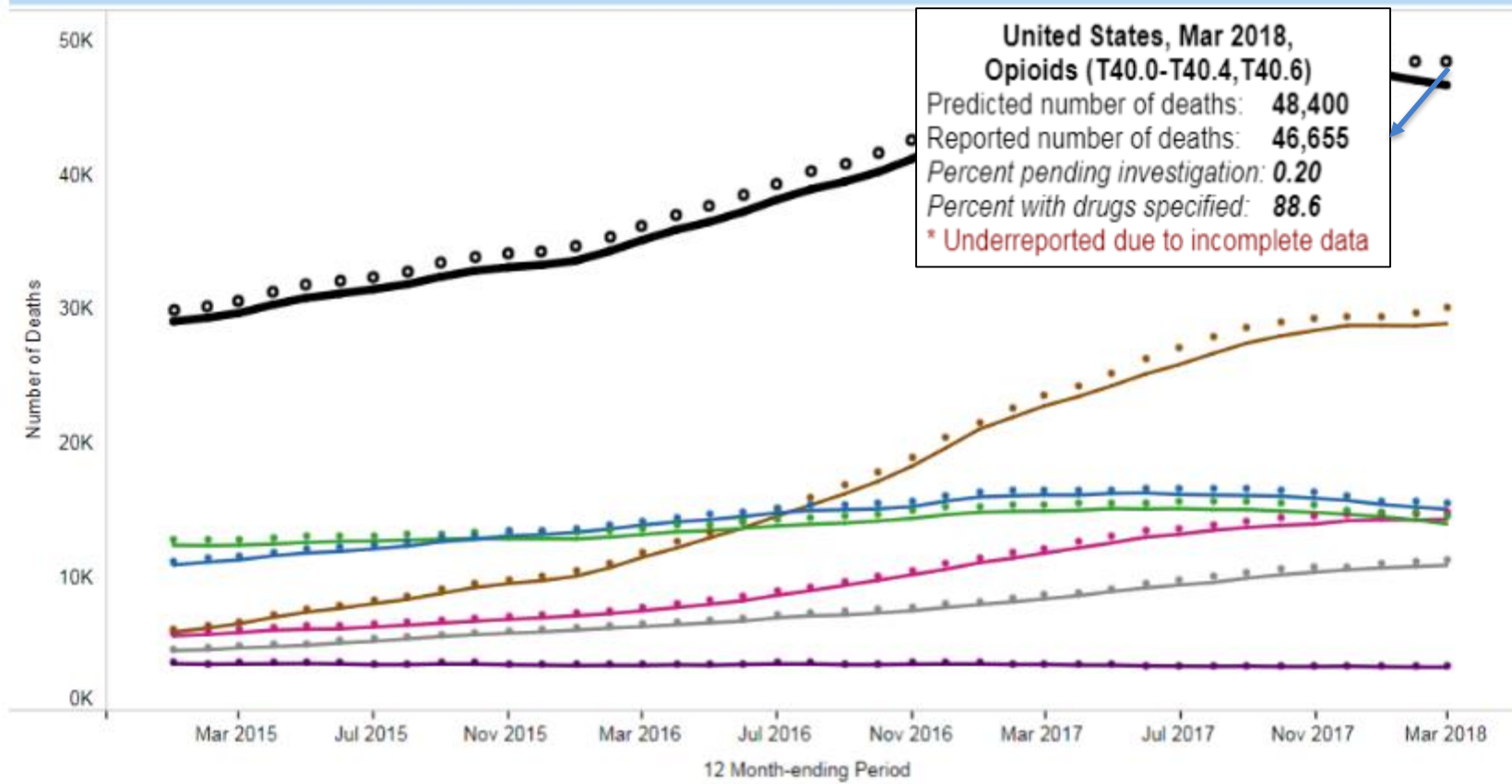
## Legend for Drug or Drug Class

- Opioids (T40.0-T40.4, T40.6)
- Heroin (T40.1)
- Natural & semi-synthetic opioids (T40.2)
- Methadone (T40.3)
- Synthetic opioids, excl. methadone (T40.4)
- Cocaine (T40.5)
- Psychostimulants with abuse potential (T43.6)

- Predicted Value
- Reported Value



# US Overdose Deaths

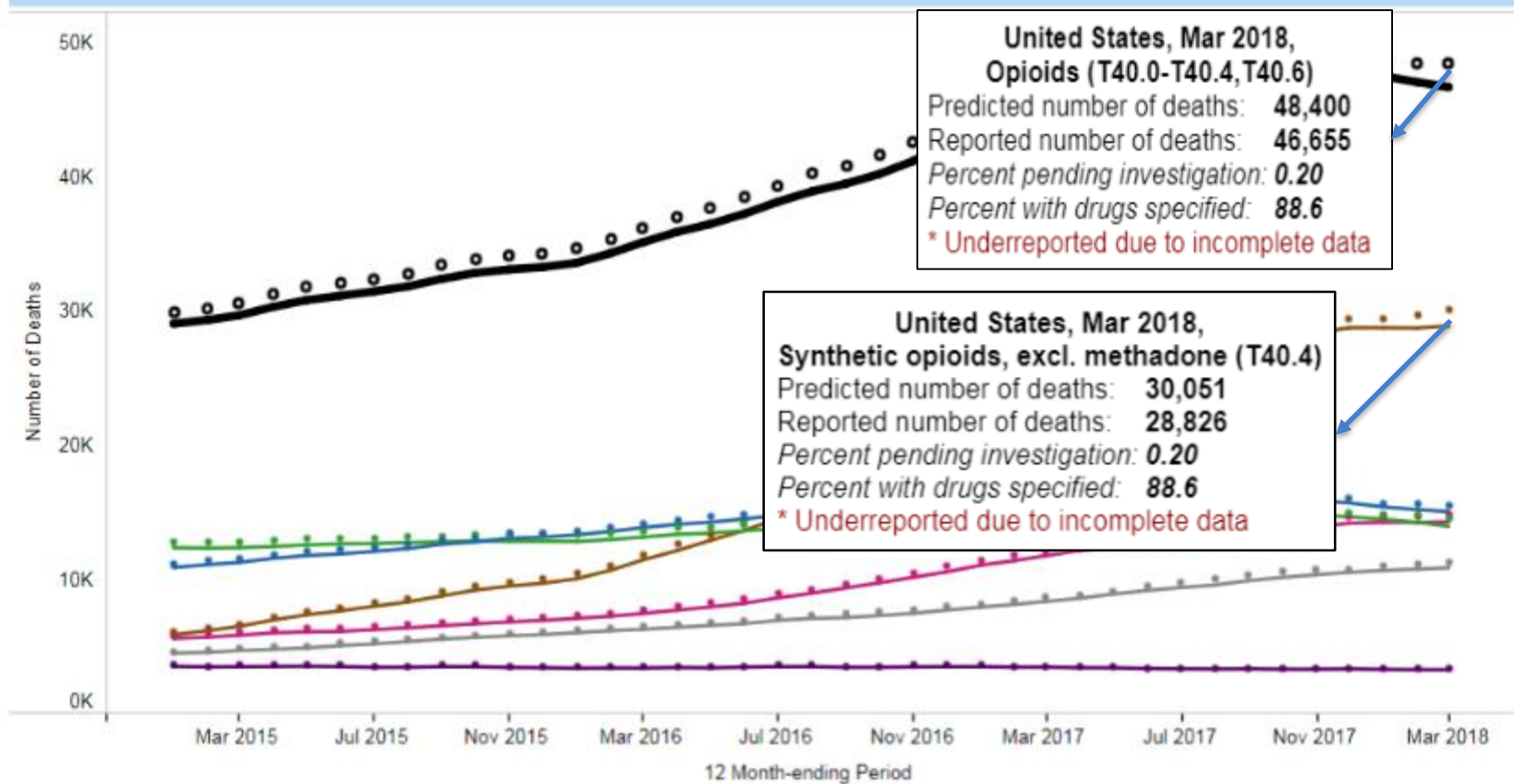


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# Front Page News

## Sunday, August 19, 2018

**Trump Tax Cut Pays Dividends For the G.O.P.**  
**Donors Who Received Windfall Give Back**

By JIM TANEYBURY  
 AND MICHAEL TACKETT  
 WASHINGTON — Republicans are struggling to make the full-scale Trump tax-cut bill a lasting issue with voters as the mid-term congressional elections but the cuts are helping the party in another crucial way: sending tens of millions of dollars in campaign donations from the wealthy conservative and corporate interests that benefited handsomely from it.

Millions and corporations that raised millions of dollars as tax cuts are pouring some of that windfall into the Congressional Leadership Fund, a super PAC directly aligned with Senate Minority Leader Mitch McConnell's efforts to win re-election in conservative congressional districts with its campaign strategy attacks on the Democratic candidates vying to wrest control of the House.

The fund's donors include the conservative, Sheldon Adelson, who has given \$30 million, and where company, Las Vegas Sands, reported a nearly \$70 million windfall from its tax cut earlier this year. Timothy Mellon, chairman and majority owner of Pan Am Systems, a privately held contractor of companies that includes rail, aviation and marketing services, who has contributed \$10 million. Other notable donors include the hedge fund manager and a cofounder of other corporations, executive and financial fund manager.

Just over a quarter of the group's donations have come

Continued on Page 27

**FOUR AMMUNITION**  
**It Redefined U.N. in an Era Of Turbulence**

By ALAN COVIELL  
 Kofi Annan, Ghana's diplomat and politician diploma from Ghana who became the seventh secretary general of the United Nations, proposing himself and his organization as the world's conscience and moral arbiter despite bloody deaths that remained his record as a peacekeeper, died on Saturday in Accra, Ghana. He was 80.

Mr. Annan was the first African to head the United Nations, serving for two successive five-year terms beginning in 1997 — a decade of turmoil that challenged that sprawling body and redefined its place in a changing world.

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**NATIONAL 16-24**  
**Fact-Checking the President**  
 Fact-checking President Trump's comments on the Russian investigation, an analysis based on 758 quotations, misquoting or rate claims. PAGE 18

**"Crazy Rich" And Very Poor**  
 Asian-Americans have become the most economically divided racial or ethnic group in the United States, according to new data. PAGE 18

**States Take On Drug Prices**  
 Several states have introduced legislation to cap the prices of drugs, but an effort to cap the rising cost of prescription drugs. The pharmaceutical industry's pushback. PAGE 20

### Parishioners Didn't Suspect Him. Then They Scrolled to Page 631.

A small Catholic church in Pennsylvania reels after its former priest is named in a report on sexual abuse.



Holy Angels Parish in Pittsburgh. When asked about the allegations against the Rev. John David Crowley, top, a man credited as remembered how Father Crowley had baptized his children. Some confided that they had lost sleep over the news.

By ELIZABETH BISHOP  
**PITTSBURGH** — Everything fell out of the news after people in Holy Angels Parish in Pittsburgh started scrolling to page 631 of the Catholic priest in Pennsylvania accused of sexual abuse in Pittsburgh. The bishop of Pittsburgh at the time, Donald Wuest, was a cardinal and the secretary of Washington, gave Father Crowley the chance to voluntarily resign and quit active ministry or face removal.

Father Crowley chose resignation. The bishop of Holy Angels was long in the shadows of the Pennsylvania scandal that accused more than 1,000 priests over decades, and that bishops largely hid their crimes from the public, in the Pittsburgh diocese, which had almost a third of the nation's accused priests, Catholics in nearly every parish tried to figure out if the names they knew had ever been accused, or had known, or allegations they knew.

Some of the names on the list were not surprises, as some priests had faced public criminal proceedings and were removed from ministry. Other priests had been the subject of rumors, but many, like Father Crowley, had had their names removed publicly.

At the time, the bishop of Pittsburgh was the Vatican's youngest cardinal, and he was on their side as they were removed from ministry.



Rev. John David Crowley, top, a man credited as remembered how Father Crowley had baptized his children. Some confided that they had lost sleep over the news.

Continued on Page 12

**TOP TRUMP AIDE GIVES MUELLER COVETED DETAILS**  
**ASSISTANCE IS UNUSUAL**

White House Counsel's Strategy Evolves Into Survival Tactic

By MICHAEL S. SCHMIDT  
 AND MAGGIE HABIBMAN  
 WASHINGTON — The White House Counsel, Donald F. McGahn II, has cooperated extensively in the special counsel investigation, sharing detailed accounts about the president's staff and the extent of the inquiry into whether President Trump obstructed justice, including what investigators would not have learned of otherwise, according to a new account and follow-up. While these officials are often seen in the White House and called to hours over the past few months, Mr. McGahn II had the president's fury toward the investigation and the special counsel, which was led by Robert Mueller, to respond to it. The president had the investigators examining whether

### An E.R. That Treats Opioid Use as an Emergency



Dr. Andrew Herring giving the withdrawal drug buprenorphine to a homeless patient at Highland Hospital in Oakland, Calif.

By ABBY GOODNOUGH  
**OAKLAND, Calif.** — Every day, thousands of people addicted to opioids show up in hospital emergency rooms in withdrawal, agonizing a severe time being and writing on their face.

Dr. Andrew Herring, a physician at Highland Hospital in Oakland, Calif., said he has seen thousands of patients in withdrawal from opioids, many of whom are homeless. He said he has seen thousands of patients in withdrawal from opioids, many of whom are homeless.

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**THE WEST SAW A DEMOCRACY; TURKEY EMBRACED AN AUTOCRACY**

By PETER G. GOODMAN  
 In Western capitals a deep sigh. History's own paradoxical leader, Recep Tayyip Erdogan, had presided as a proponent of democracy for a region with no religious divide.

Turkey was a vibrant NATO ally, bridge between the Islamic Middle East and the West. Erdogan, who had led his country in the ranks of the military, was seen as a moderate and a reformer. He had led his country in the ranks of the military, was seen as a moderate and a reformer.

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### An E.R. That Treats Opioid Use as an Emergency

Usually, they're given medicines that help with vomiting or diarrhea and sent on their way, maybe with a few numbers to call about treatment.

When Rhonda Hauswirth arrived at the Highland Hospital E.R. here, retching and shaking violently after a day and a half without heroin, something very different happened. She was offered a dose of buprenorphine on the spot. One of three medications approved in the United States to treat opioid addiction, it works by easing withdrawal symptoms and cravings. The tablet dissolved under her tongue while she slumped in a plastic chair, her long red hair obscuring her ashen face.

Soon, the shakes stopped. "I could focus a little more. I could see straight," said Ms. Hauswirth, 40. "I'd never heard of anyone going to an emergency room to do that."

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**THE TREATMENT GAP**  
**Help on Demand**

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**SPORTS 25-31**  
**It's Not Just Rubik's Anymore**  
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**THE MAGAZINE**  
**Big Tech War on Privacy**  
 Missing personal data is now big business, which is why Facebook and others are working to keep lawmakers from protecting your information. PAGE 28

**INTERNATIONAL 34-44**  
**Cuban Oppose Take a Stand**  
 A controversy prevented the destruction of many of the historical buildings where they live in Havana. PAGE 31

**US BUSINESS**  
**Stores View Them as Thieves**  
 Shoppers' actions are driving away customers, but retailers are trying to figure out how to keep them. PAGE 31

**ARTS & LIFESTYLE**  
**Live From New York, Sell**  
 The world's most famous concert venue is set to be sold to a private owner. PAGE 31

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**SUNDAY STYLES**  
**First Lady of Mystery**  
 Melania Trump has directed her team to operate independently of the White House, but she is still seen as a mystery. PAGE 31

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# Why Focus on the ED?



**Because that's where the patients are!**



July 2016 – September 2017

30%  Visits for Opioid Overdose

MMWR, March 9, 2018

# EDs and Emergency Physicians can...

- Identify patients with opioid use disorder
- Initiate treatment
  - buprenorphine
  - overdose education & naloxone distribution
- Link to continued opioid agonist treatment & preventive services



**What is the Evidence?**

# 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.

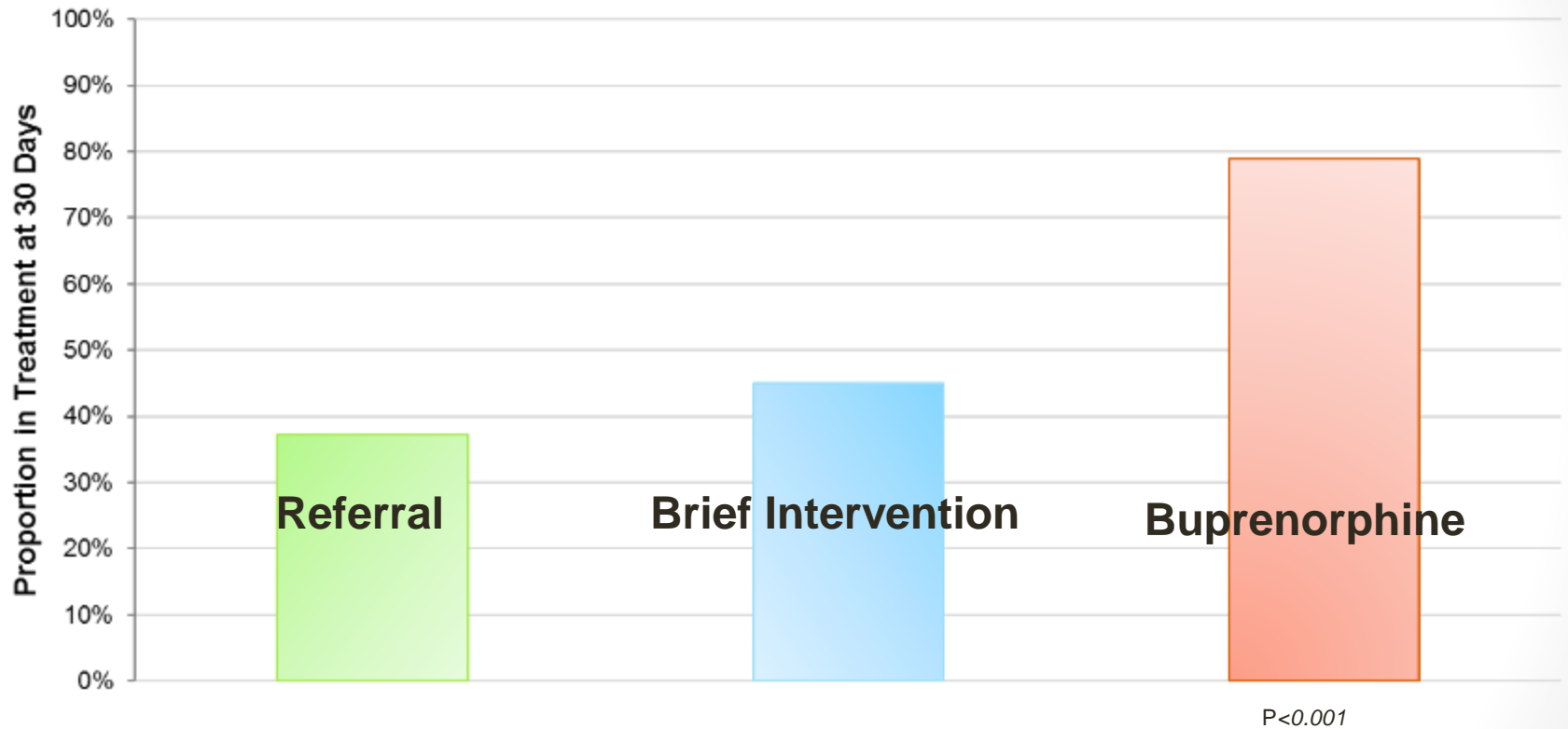
**INTERVENTIONS** After screening, 104 patients were randomized to the referral group, 111 to

+ JAMA Report Video and Author Video Interview at [jama.com](http://jama.com)

+ CME Quiz at [jamanetworkcme.com](http://jamanetworkcme.com)  
CME Questions p

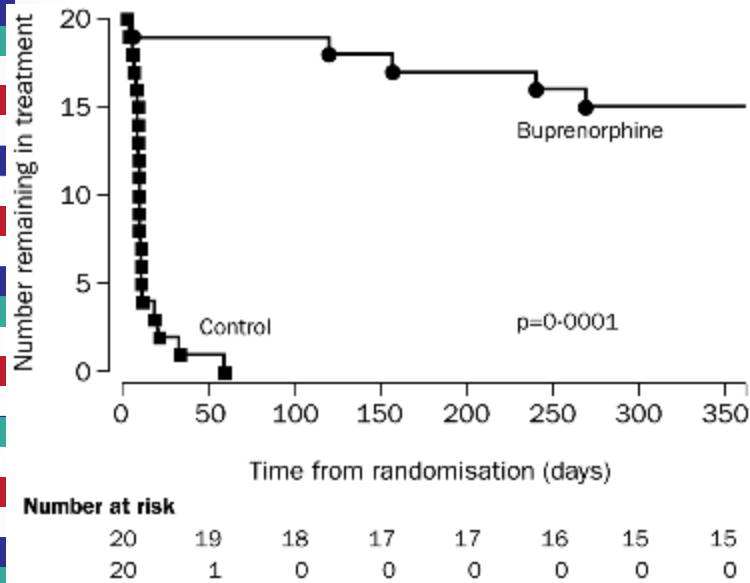


# MAT: 2x More Likely to be Engaged in Addiction Treatment at 30 Days



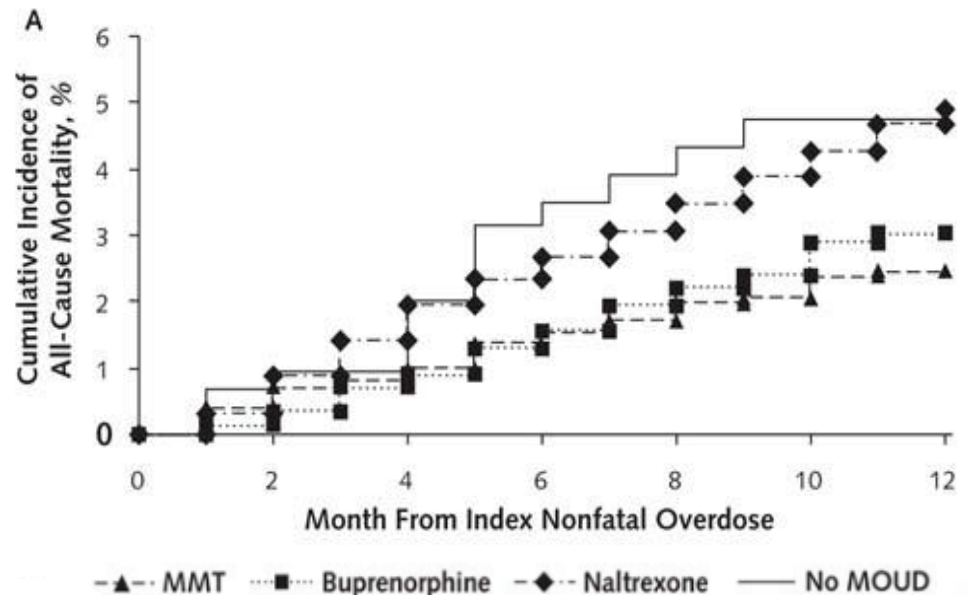


# Medication for Opioid Use Disorder



Kakko. *Lancet* 2003

Primary Exposure Classification: With Discontinuation\*



LaRoche. *Annals of IM* 2018

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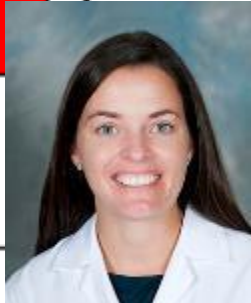
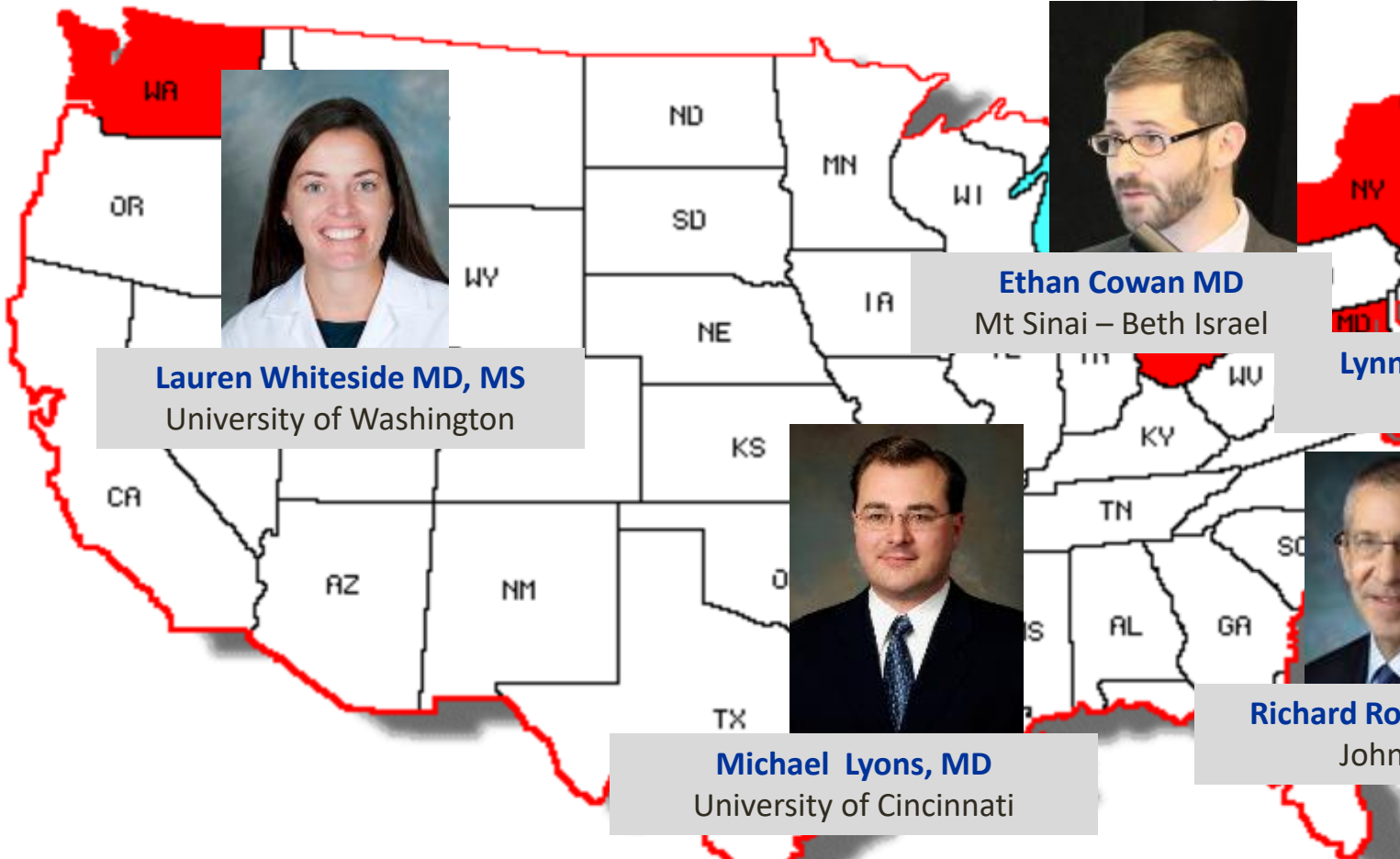
www.shannonburns.com

**The latest research shows that we really should do something with all this research**

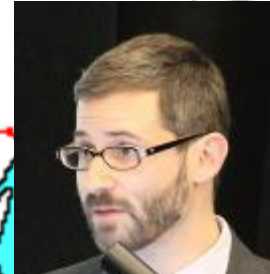


# NIDA Clinical Trials Network: Opioid Use Disorder in the ED Project ED Health (CTN-0069)

Design: Hybrid Type 3 Effectiveness-Implementation Study



**Lauren Whiteside MD, MS**  
University of Washington



**Ethan Cowan MD**  
Mt Sinai – Beth Israel



**Lynn Richardson MD**  
Mt Sinai



**Michael Lyons, MD**  
University of Cincinnati



**Richard Rothman MD, PhD**  
Johns Hopkins





# 0079 Clinical Trials Network: Initiating Extended Release Buprenorphine for OUD in Low Resourced, High Intensity EDs

**Ryan McCormack, MD**  
Lead Investigator

**Kate Hawk MD, MHS**  
Investigator

**Randy Knight MD**  
Investigator

AK  
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Clinical Trials Network



Clinical Trials Network

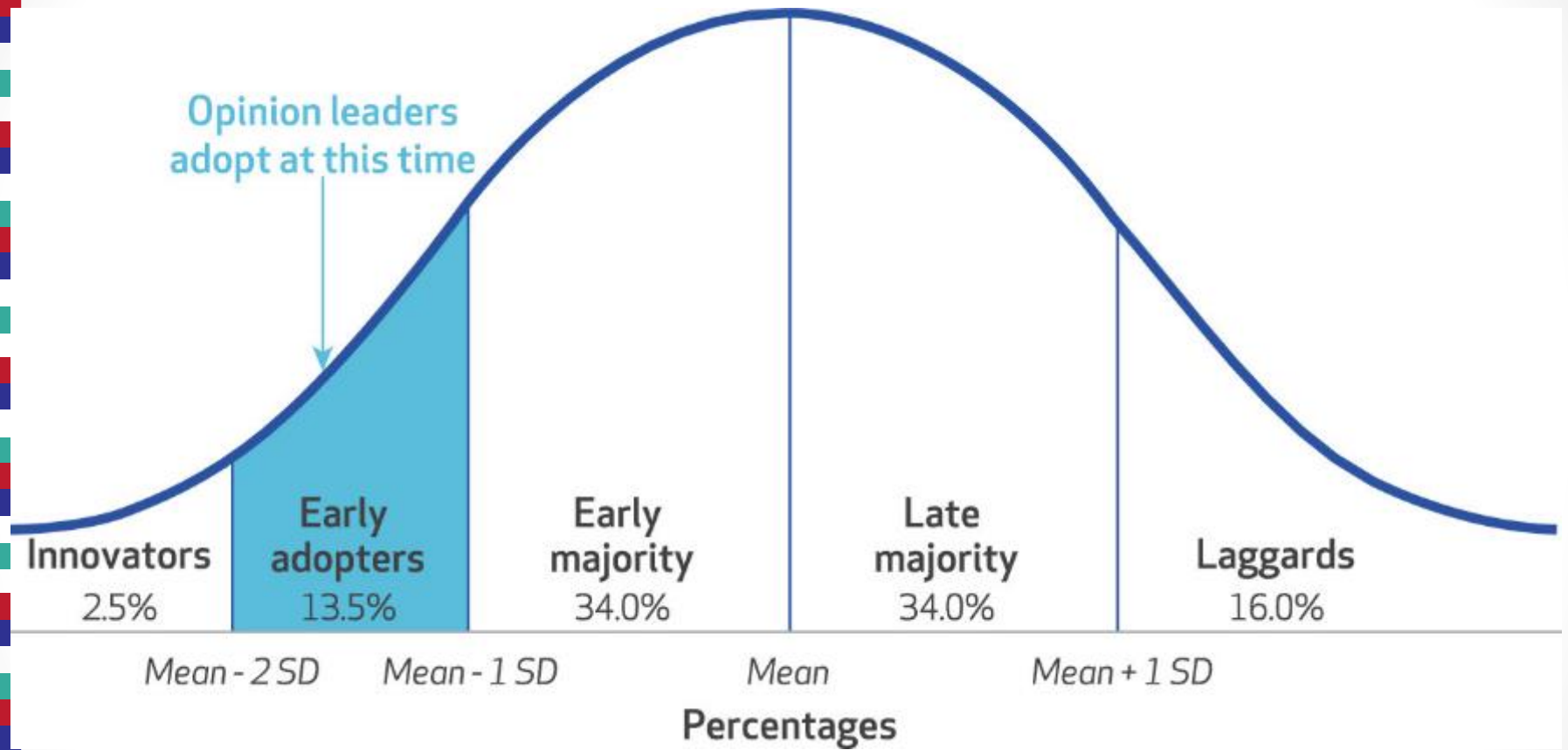
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**UG3 AT009851-01**

**UG3-UH3**



# Diffusion of Innovations



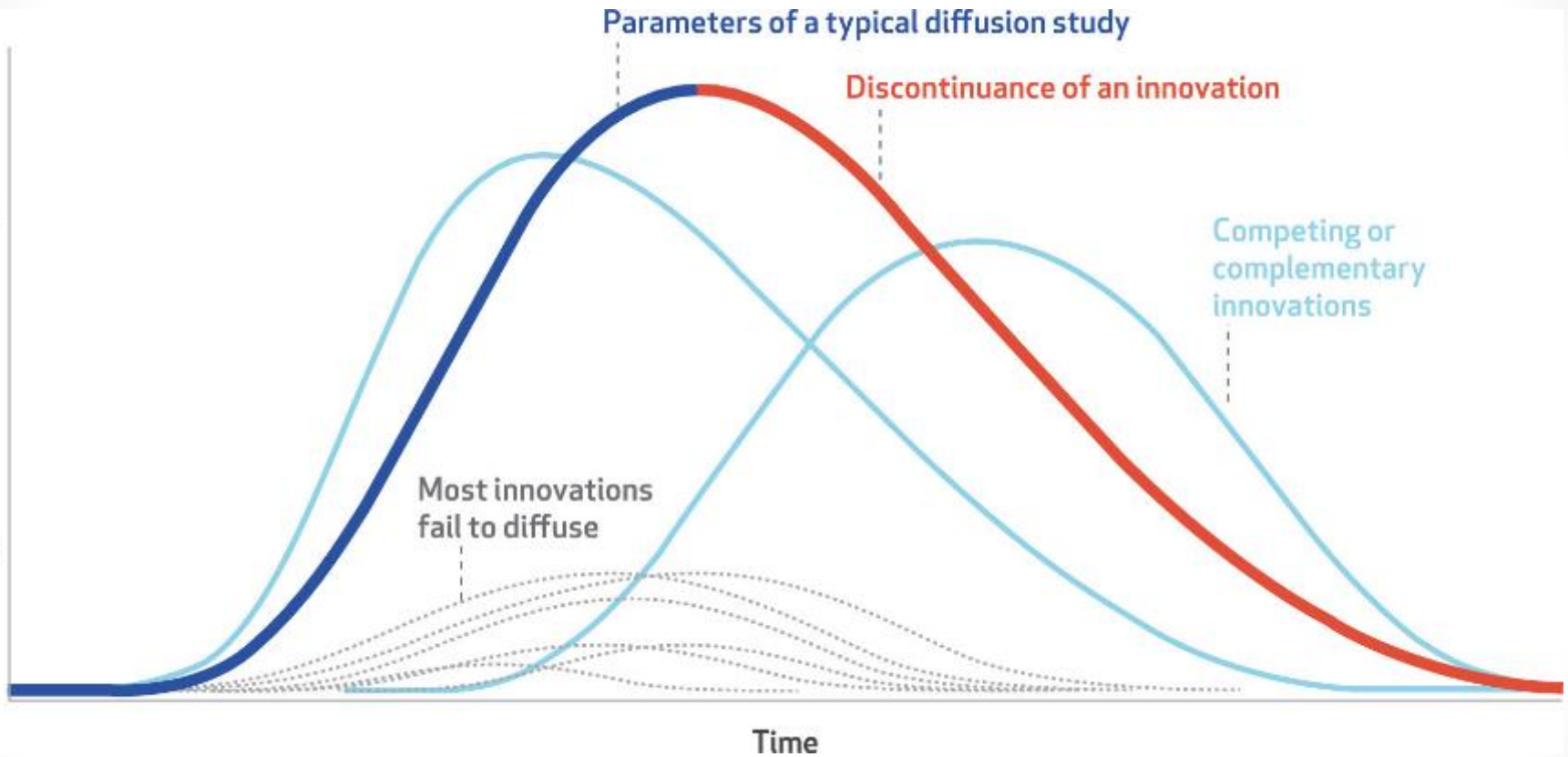
Rogers. *Diffusion of Innovations* 1962

Gladwell. *Tipping Point* 2000

Dearing & Cox. *Health Affairs* Feb 2018



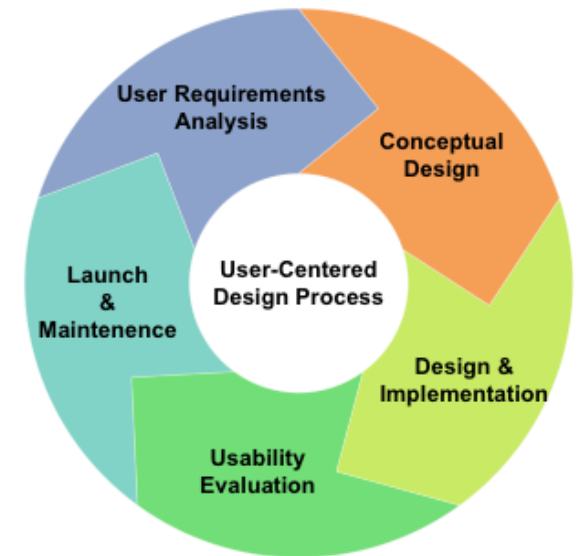
# Diffusion of Innovations



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- Gladwell. *Tipping Point* 2000
- Dearing & Cox. *Health Affairs* Feb 2018

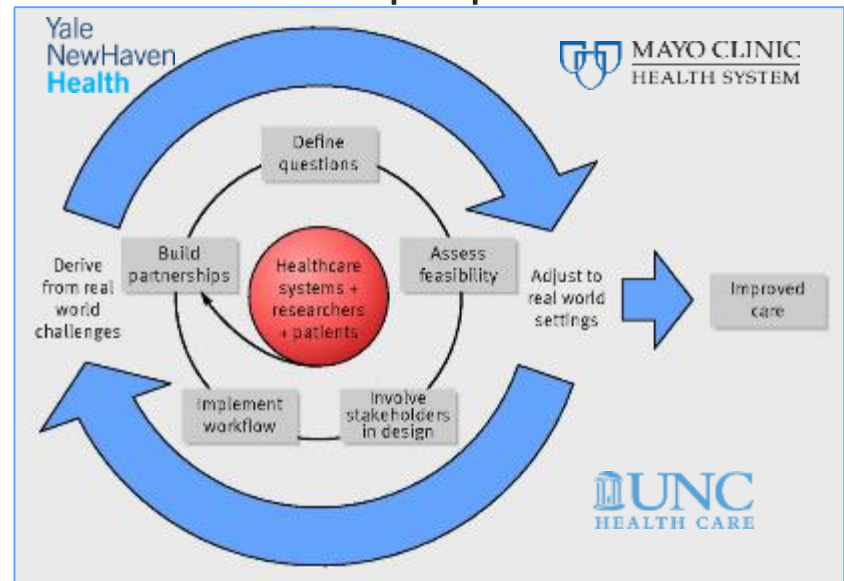
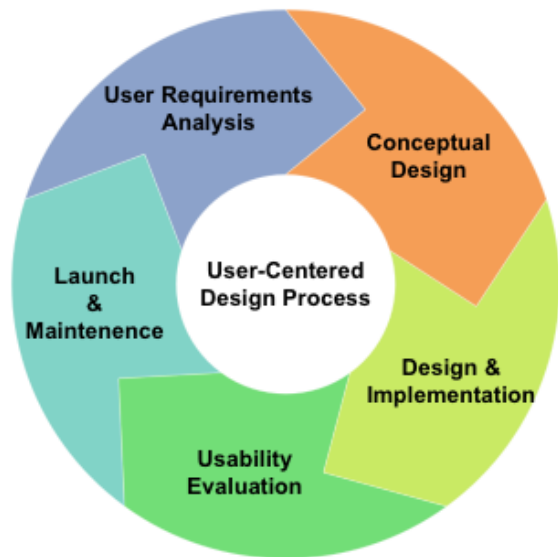
# Background: HIT

- Poor health IT (HIT) usability is major source of frustration with clinicians
- Electronic health record (EHR) usability is a fundamental barrier to implementation of evidence-based medicine
- IT should be designed to meet user needs
- User-centered design
  - streamline workflows
  - address barriers to adoption
  - embed ED-initiated BUP into routine ED care
  - to optimize adoption, dissemination, implementation, and scalability

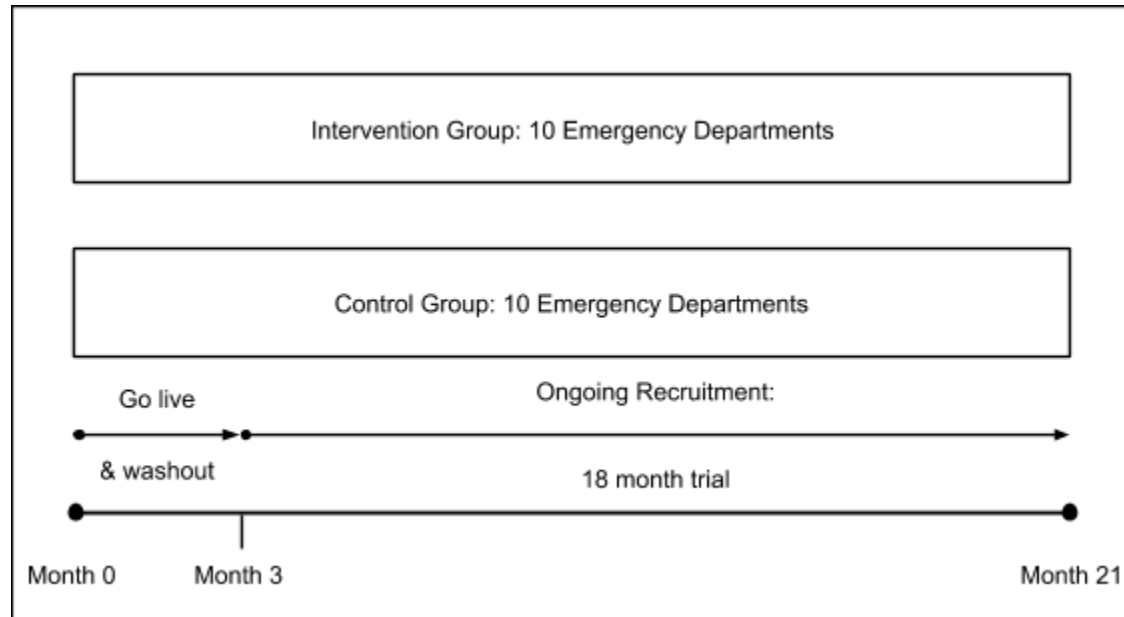


# Aims: UG3

- **UG3 Aim 1.** Develop a pragmatic, user-centered CDS for ED-initiated BUP and referral for MAT in ED patients with OUD which will automatically identify and facilitate management of potentially eligible patients.
- **UG3 Aim 2.** Establish the infrastructure for the proposed trial.







## UH3 Aims

1. Compare the effectiveness of user-centered CDS for BUP to usual care on outcomes in ED patients with OUD.
2. Disseminate the EMBED intervention nationally

# Teams and People

## MPI

- Ted Melnick, MD, MHS
- Gail D'Onofrio, MD, MS

## Design

- Matt Maleska
- Jessica Ray, PhD

## Technology

- Allen Hsiao, MD
- Yauheni Solad, MD, MHS
- Hyung Paek, MD, MSEE
- Cynthia Brandt, MD, MPH

## Data coordination

- Jim Dziura, PhD, MPH
- Lilly Katsovich, MBA
- Charles Lu

## Project Coordinator

- Shara Martel MPH, MS

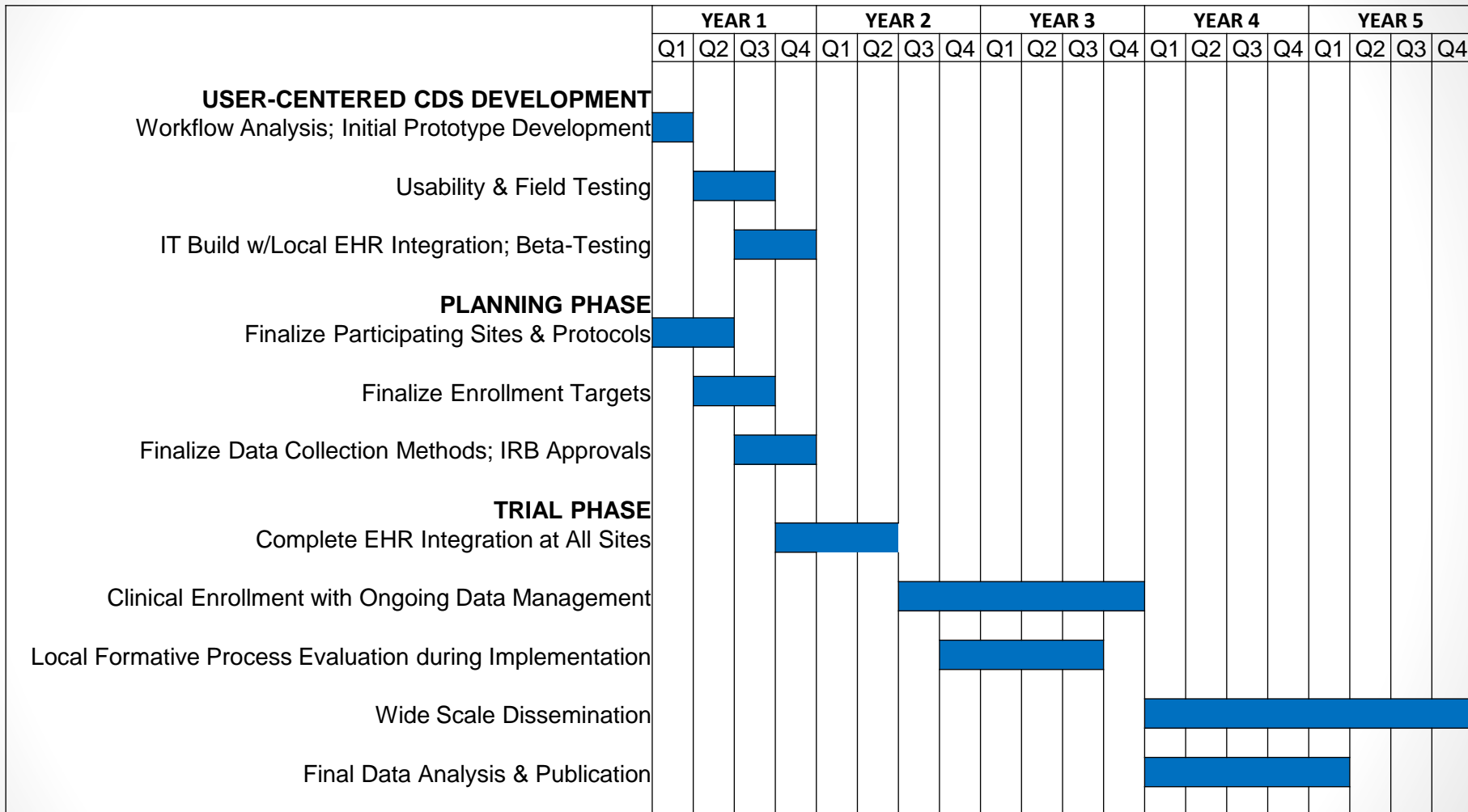
## External collaborators

- UNC
  - Tim Platts-Mills, MD, MSc
  - Mehul Patel, PhD
- Mayo
  - Molly Jeffery, PhD
- UAB
  - Erik Hess, MD, MSc
  - Jim Galbraith, MD
- Also: UC Davis
  - Josh Elder MD, MPH, MHS
- Colorado
  - Jason Hoppe, DO




Within each system

- Medical director
  - Clinical champions
  - IT leaders
  - MAT site contacts

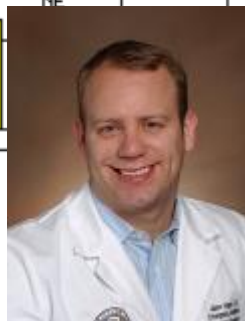
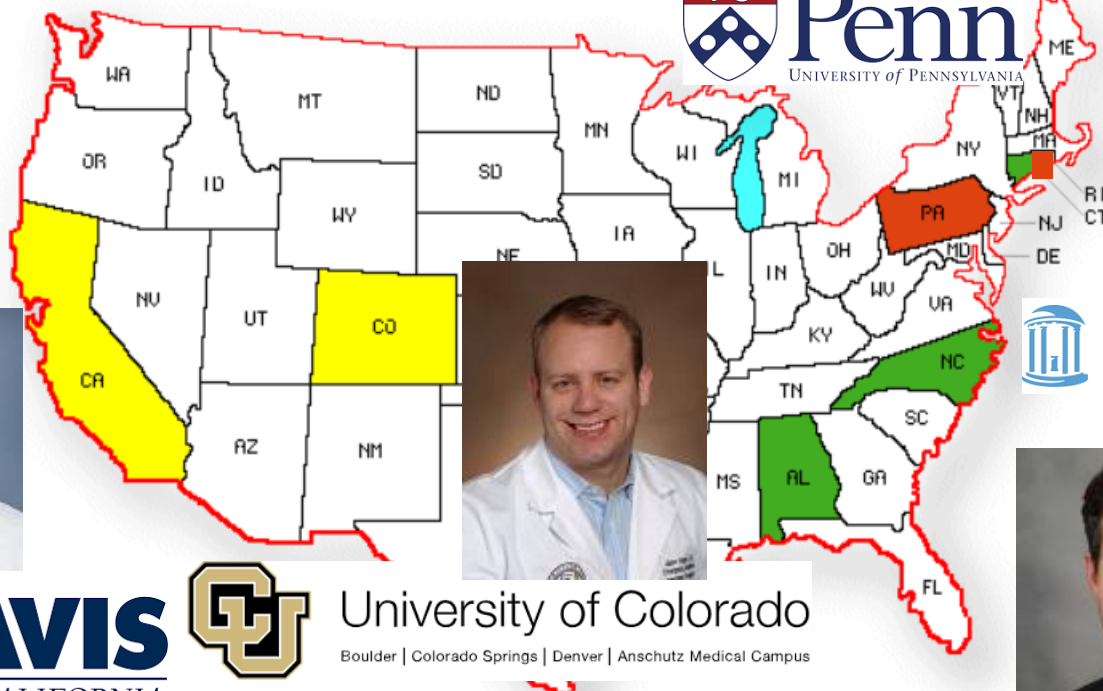
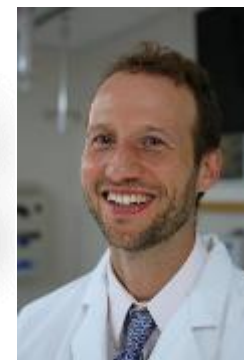
## EMBED TIMELINE



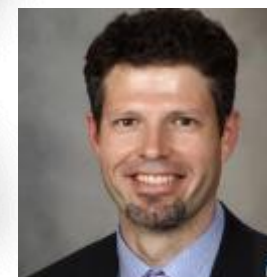
# Sites

-  pilot sites
-  confirmed trial sites
-  potential trial sites

# Yale



UNC  
SCHOOL OF MEDICINE



**UC DAVIS**  
UNIVERSITY OF CALIFORNIA



University of Colorado  
Boulder | Colorado Springs | Denver | Anschutz Medical Campus

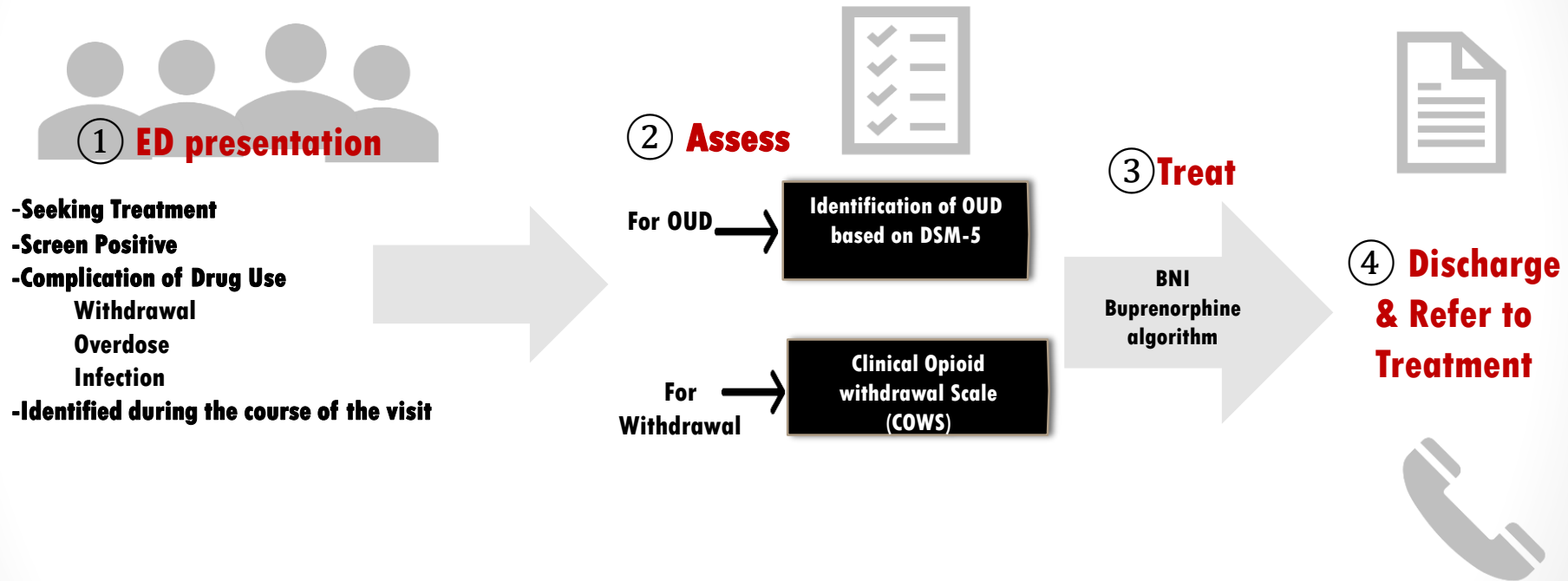
THE UNIVERSITY OF  
**ALABAMA**



# User-centered design progress

- Currently 25-30 minute workflow for an addiction counselor
  - Diagnostic criteria
  - Withdrawal assessment
  - Readiness for treatment
  - Treatment initiation
  - Referral (detailed form completed and faxed to referral center)
- Need to embed this in ED clinician busy, dynamic, interruptive workflow
- Goal to identify, treat, and refer in 2-5 minutes while
  - Minimize interruptions & additional cognitive load
  - Allow flexibility for initiation of tool, which parts to use, clinicians training for BUP use, novice-to-expert tool use
  - 30 mouse clicks down to as little as 1

# Buprenorphine Integration Pathway



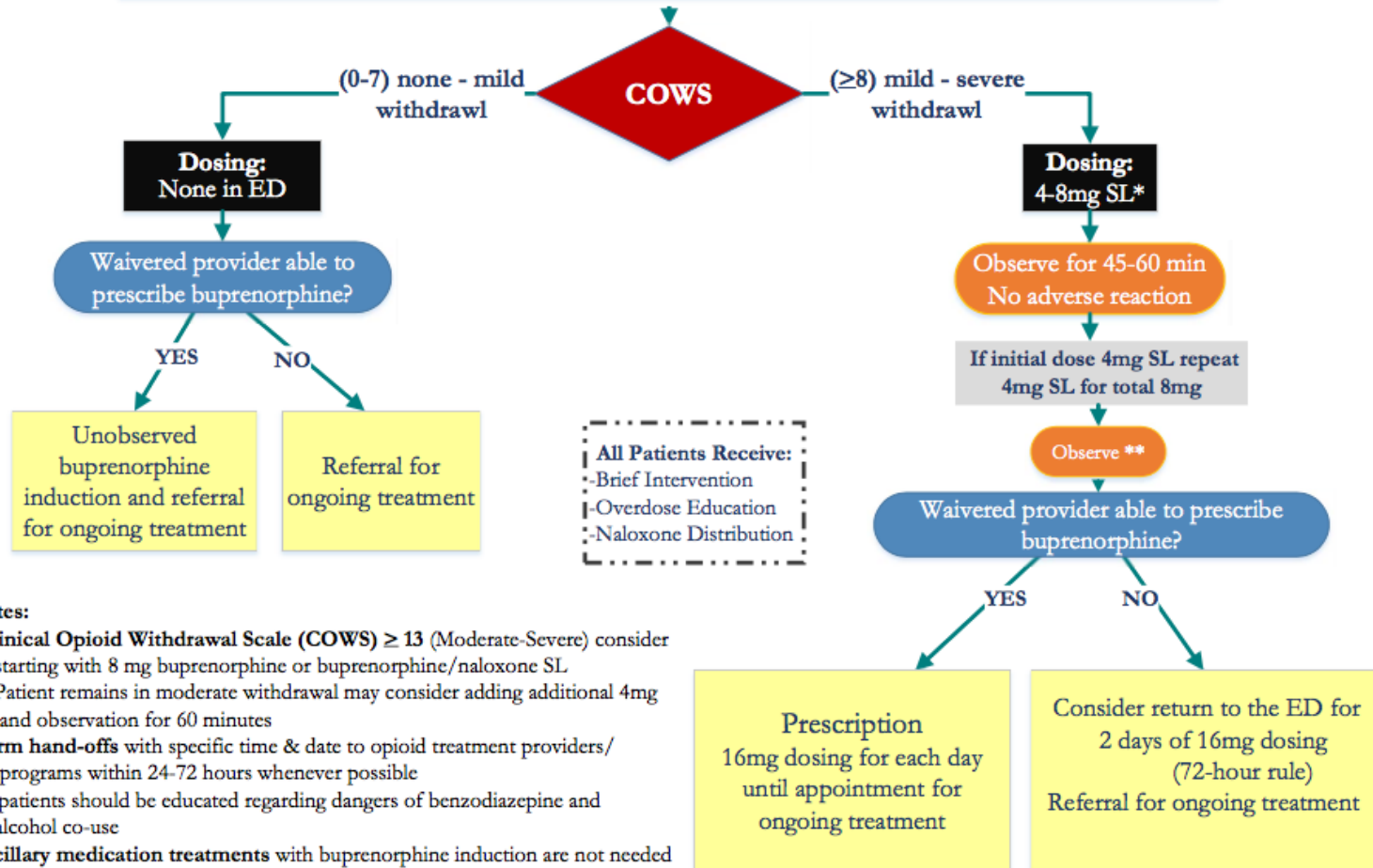
# ED-Initiated Buprenorphine

## Diagnosis of Moderate to Severe Opioid Use Disorder

Assess for opioid type and last use

Patients taking methadone may have withdrawal reactions to buprenorphine up to 72 hours after last use

Consider consultation before starting buprenorphine in these patients



**Notes:**

\*Clinical Opioid Withdrawal Scale (COWS)  $\geq 13$  (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 (BUP) Initiation

Do you have a waiver to prescribe Buprenorphine?

No  Yes

## Buprenorphine Treatment Options

TEXT 555-555-5555

WWW.WEBADDRESSHERE.COM

QR CODE

Select from one of the four treatment options below

	Care Pathway #1	Care Pathway #2	Care Pathway #3	Care Pathway #4	Decision Support
	<b>Exit / No BUP</b>	<b>Hold in ED</b>	<b>Start 4 mg BUP (2x)</b>	<b>Start 8 mg BUP</b>	Use these optional tools in any order to help you decide ↓
Does the patient have Opioid Use Disorder?	No  (<3 DSM Criteria)	Yes  (>= 3 DSM Criteria)	Yes  (>= 3 DSM Criteria)	Yes  (>= 3 DSM Criteria)	<a href="#">Diagnose OUD</a> using DSM tool
How severe is the patient's withdrawal?	None-to-Mild  < 8 DO NOT give if intoxicated	None-to-Mild  < 8 DO NOT give if intoxicated	Mild-to-Moderate  8 - 13	Moderate-to-Severe  > 13	<a href="#">Assess withdrawal</a> using COWS tool
Is the patient ready to start treatment?	 NO	 YES	 YES	 YES	<a href="#">Motivate Readiness</a> using interview tool
	<a href="#">Select #1</a>	<a href="#">Select #2</a>	<a href="#">Select #3</a>	<a href="#">Select #4</a>	



# DSM 5 - Criteria for Opioid Use Disorder (OUD)

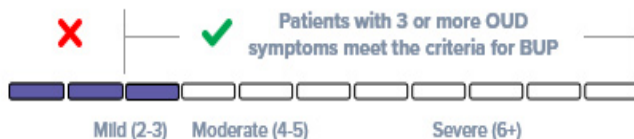
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Ask the patient the following questions about his/her use of opioids in the past 12 months to determine a diagnosis:

Select all that apply

- 1. Have you found that when you started using opioids you ended up taking more than you intended to?
- 2. Have you wanted to stop or cut down on using opioids?
- 3. Have you spent a lot of time getting or using opioids?
- 4. Have you had a strong desire or urge to use opioids?
- 5. Have you missed work or school or often arrived late because you were intoxicated, high, or recovering from the night before?
- 6. Has your use of opioids caused problems with other people such as with family members, friends, or people at work?
- 7. Have you had to give up or spend less time working, enjoying hobbies, or being with others because of your drug use?
- 8. Have you ever gotten high before doing something that requires coordination or concentration like driving, boating, climbing a ladder, or operating heavy machinery?
- 9. Have you continued to use even though you knew that opioids caused you problems like making you depressed, anxious, agitated or irritable?
- 10. Have you found you needed to use much more opioids to get the same effect that you did when you first started taking it?
- 11. When you reduced or stopped using opioids, did you have withdrawal symptoms or felt sick when you cut down or stopped using? (aches, shaking, fever, weakness, diarrhea, nausea, sweating, heart pounding, difficulty sleeping, or feel agitated, anxious, irritable, or depressed)?

03



YES - Meets Criteria

NO - Does Not Meet Criteria

Return to treatment options

Exit application

## Clinical Opiate Withdrawal Scale (COWS)

For each item, select the appropriate description of the patient's signs or symptoms (points per symptom)

					Score
1. Resting Pulse Rate	80 or below (0)	81 - 100 (1)	101 - 120 (2)	> 120 (4)	1
2. Restlessness	Able to sit still (0)	Some difficulty sitting still (1)	Frequent shifting of limbs (3)	Unable to sit still (5)	5
3. Anxiety or irritability	None (0)	Increasing amounts (1)	Obviously irritable/anxious (2)	Too difficult to participate (4)	2
4. Yawning	No yawning (0)	1 or 2 times/assessment (1)	3 or 4 times/assessment (2)	Several times/minute (4)	2
5. Pupil Size	Normal (0)	Possibly larger (1)	Moderately dilated (2)	Only rim of iris visible (5)	1
6. Runny nose or tearing	Not present (0)	Stiffness/moist eyes (1)	Nose running/tearing (2)	Constant running/ tears streaming (4)	1
7. Tremor	No tremor (0)	Felt - not observed (1)	Slight tremor observable (2)	Gross tremor/twitching (4)	4
8. Sweating	No report (0)	Subjective report (1)	Flushed / observable (2)	Beads of sweat (3)	3
9. Gooseflesh skin	Skin is smooth (0)	Piloerection/hairs standing (3)	Prominent piloerection (5)		3
10. Bone or joint pain	Not present (0)	Mild discomfort (1)	Severe aching (2)	Unable to sit due to pain (4)	2
11. GI upset	No symptoms (0)	Stomach cramps (1)	Nausea or loose stool (2)	Vomiting or diarrhea (5)	1

[Return to treatment options](#)

< 8    8 - 13    > 13

Moderate-to-Severe

25

# 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

4mg

Wait 45 minutes



### Step 2.

Still feel sick?  
Take next dose

4mg

Wait 6 hours



### Step 3.

Still uncomfortable?  
Take last dose

4mg

Stop



- 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

Most people feel better after two doses = 8mg

- 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

# Thank You

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Ted Melnick @Ted\_Melnick  
Gail D'Onofrio @DonofrioGail

## Websites

<https://drugabuse.gov/ed-buprenorphine>

<https://medicine.yale.edu/edbup/>