

# EMBED Update: Challenges and Solutions

*Ted Melnick MD, MHS*  
*Assistant Professor*  
*Informatics Fellowship Director*

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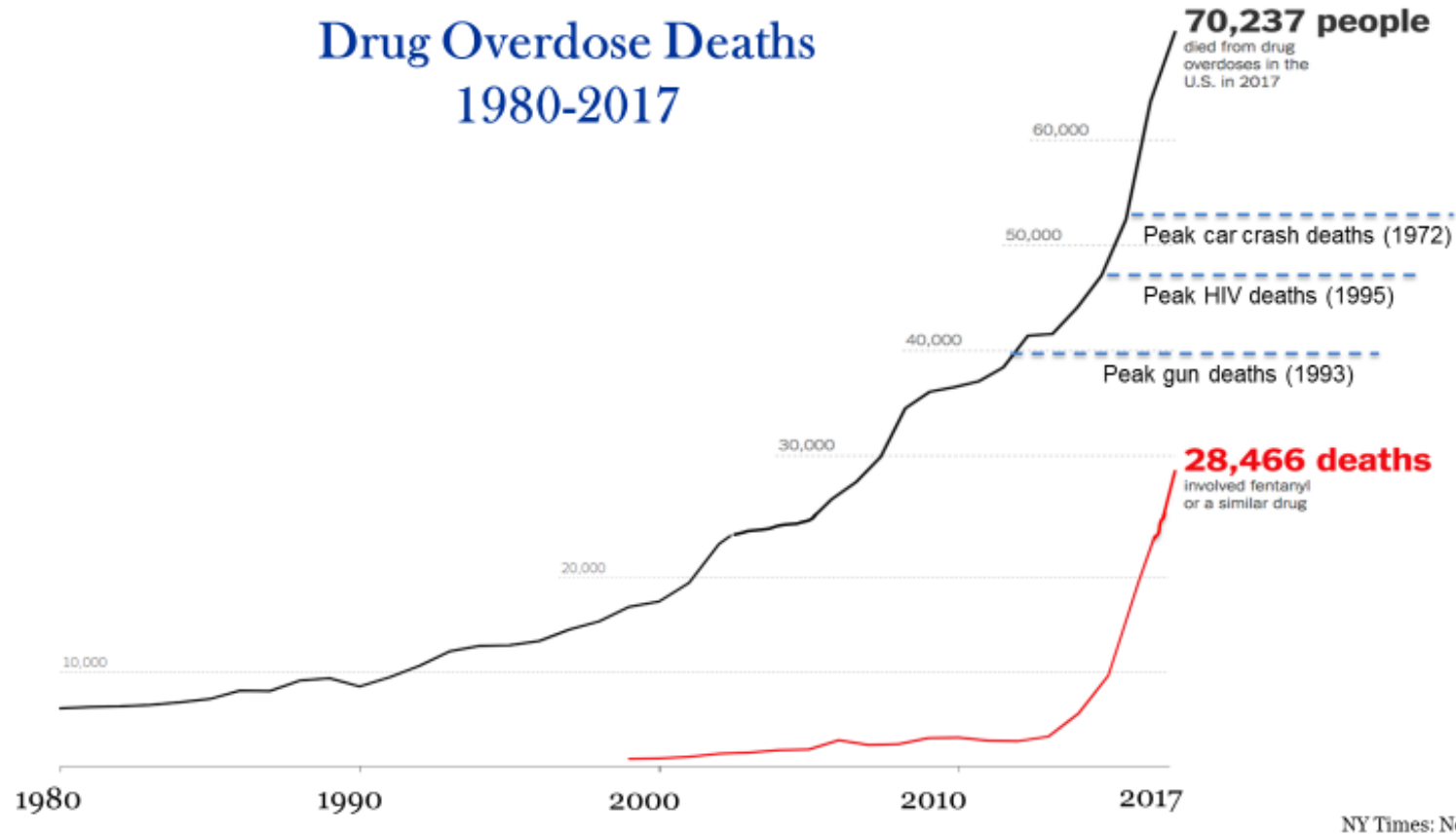
NIH Collaboratory Grand Rounds  
December 13, 2019



Yale SCHOOL OF MEDICINE



# Treatment of OUD in the ED: Is it Optional?



# 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

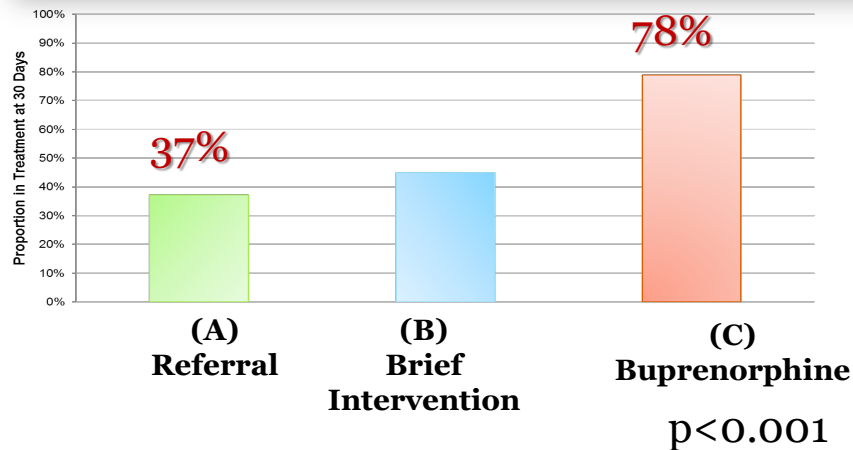
# What is the Evidence for ED-initiated BUP?

## 2015 RCT by D'Onofrio. et al. at Yale EM

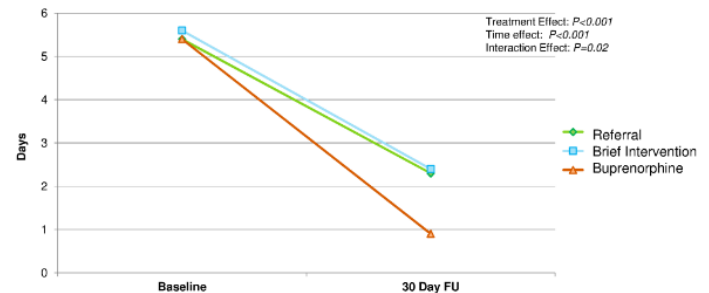
Original Investigation

Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence  
A Randomized Clinical Trial

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



### Past 7 Day illicit Opioid Use



Engagement in Treatment at 30 days

NIDA 5R01DA025991

# What is the Evidence for Inaction?

Annals of Internal Medicine

ORIGINAL RESEARCH

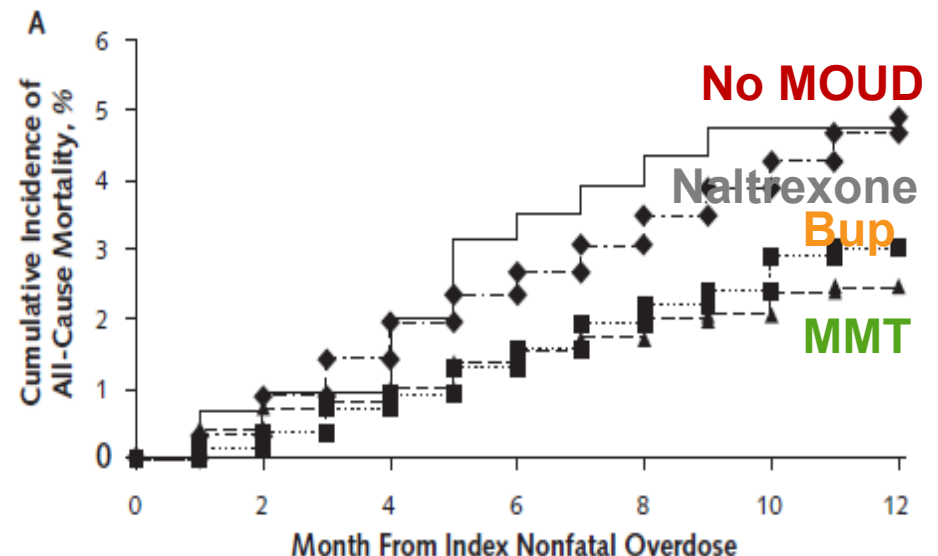
## Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality

### A Cohort Study

Marc R. Larochelle, MD, MPH; Dana Bernson, MPH; Thomas Land, PhD; Thomas J. Stopka, PhD, MHS; Na Wang, MA; Ziming Xuan, ScD, SM; Sarah M. Bagley, MD, MSc; Jane M. Liebschutz, MD, MPH; and Alexander Y. Walley, MD, MSc

- Larochelle, et al. (2018)
  - N=17,568, 12 months post non-fatal OD, between 2012-2014
  - 5% died within 1 year
  - < 30% received MOUD TX
  - significantly reduction in all-cause mortality with MOUD

Primary Exposure Classification: With Discontinuation\*



# Introducing EMBED

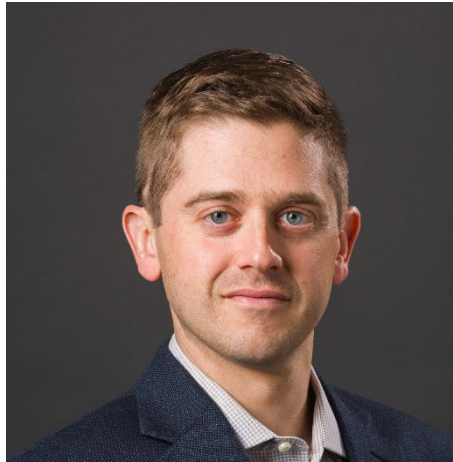
**EMBED:** Pragmatic trial of user-centered clinical decision support to implement **EM**ergency department-initiated **B**uprenorphin**E** for opioid use **D**isorder

ClinicalTrials.gov Identifier: NCT03658642



**Gail D'Onofrio,  
MD, MS**

Professor, Chair,  
Department of  
Emergency Medicine,  
YSM



**Edward Melnick, MD,  
MHS**

Assistant Professor, EM;  
Director, Clinical  
Informatics Fellowship,  
YSM



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



**National Institute  
on Drug Abuse**  
*Advancing Addiction Science*



**Yale University  
School of Medicine**

# Teams and People

## DATA COORDINATION TEAM (DCC, Yale)

- James Dziura, PhD, MPH
- Charles Lu
- Fangyong Li, MPH, MS
- Liliya Katsovich – PM
- Haseena Rajeevan, PhD
- Fan Li, MS, PhD
- David Chartash, PhD
- Molly Jefferey, PhD – Co-PI at Mayo Clinic

## IT TEAM (Yale)

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

## YNHH-Epic Analysts

- Nancy Rutski
- Cheryl Brophy
- Kristina Follo
- Michelle DeWitt

## DESIGN TEAM

- Mathew Maleska, MBA
- Jessica Ray, PhD

## LEADERSHIP/MANAGEMENT TEAM

- Ted Melnick, MD, MHS - PI
- Gail D'Onofrio, MD, MS – Co-PI
- Bidisha Nath – Project Manager

## GRANTS TEAM

- Theresa Odyniec- Budget, Finance
- Ann Criscuolo, Admin
- Shara Martel, Project Manager

## Summer Medical Students

- Wesley Holland, MS2, YSM
- Jodi Mao, MS3, EVMS
- Osama Ahmed, MS3, YSM

## SYSTEMS

### YALE-NEW HAVEN HEALTH SYSTEM

#### EHR Vendor: *Epic*

- **Pilot Study Site:** Yale New Haven Hospital, York St Campus
- **Trial Intervention Sites:**
  - St Raphael Campus;
  - Greenwich Hospital
- **Control Sites:**
  - Bridgeport Hospital
  - Lawrence + Memorial Hospital

### UNIVERSITY OF NORTH CAROLINA HEALTH SYSTEM

#### EHR Vendor: *Epic*

- **Intervention Sites:** Rex, Nash
- **Control Sites:** Main, Chatham, Johnston-Smithfield
- **PI:** Timothy Platts-Mills, MD, MSc
- **Co-PI:** Mehul Patel, MS, PhD
- **IT:** Edmund Finerty
- **Data:** Bill Korey Ross, Emily Pfaff

### UNIVERSITY OF COLORADO HEALTH SYSTEM

#### EHR Vendor: *Epic*

- **Intervention Sites:** UC Hospital AMC, Poudre Valley + Med Center of Rockies cluster
- **Control Sites:** Memorial Central
- **PI:** Jason Hoppe, MD
- **IT, Data -** Sean Michael, MD
- **Proj Coord** – Cheryl Napier

### UNIVERSITY OF ALABAMA, BIRMINGHAM HEALTH SYSTEM

#### EHR Vendor: *Cerner*

- **Intervention:** Gardendale
- **Control:** Main Campus, Highlands
- **Site PI:** Erik P. Hess, MD, MSc
- **IT, Data -** Carolyn Williams

### BAYSTATE HEALTH SYSTEM

#### EHR Vendor: *Cerner*

- **Intervention:** Main Campus- Baystate Springfield; Baystate Wing; Baystate Mary Lane
- **Control:** Baystate Franklin; Baystate Noble
- **Site PI:** William Soares MD
- **Data** – Haiping Li
- **IT - Tech Spring** Christian Lagier

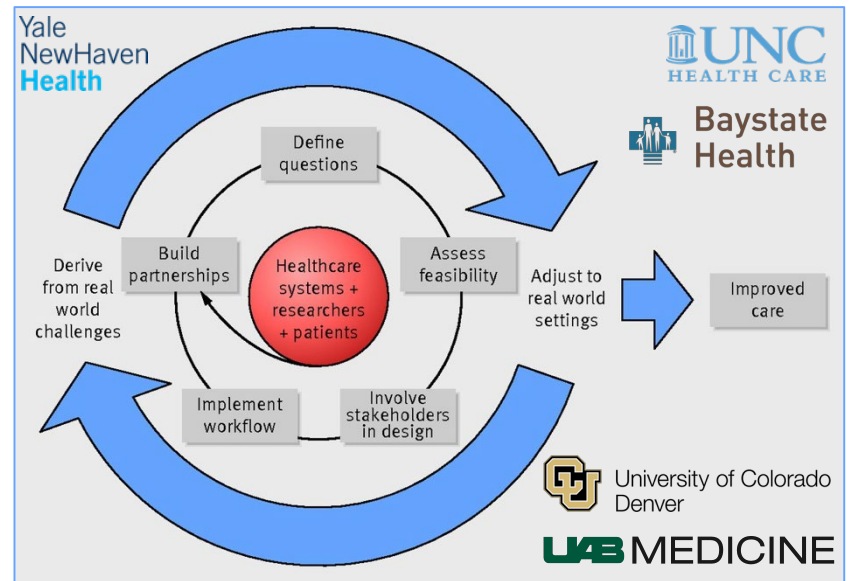
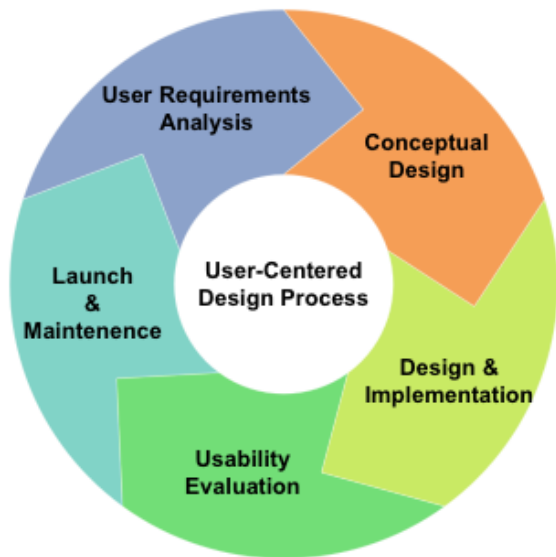
# Intervention & Outcomes

- **Setting:** 20 Emergency Departments (EDs) across 5 healthcare systems
- **Intervention:** The intervention consists of a user-friendly, integrated IT intervention to support:
  1. Evaluation for OUD
  2. Assessment of withdrawal severity
  3. Motivation of patient willingness to start treatment
  4. Initiating buprenorphine
  5. Documentation of the care process
  6. Referral for ongoing treatment
- **Primary Outcome:** Initiation of BUP in the ED (administered and/or prescribed)



# Background: UG3 Aims (Planning Phase)

- **UG3 Aim 1.** Develop a pragmatic, user-centered CDS for ED-initiated BUP and referral for MOUD 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.



# UG3 Phase: Challenges & Solutions

## BARRIERS

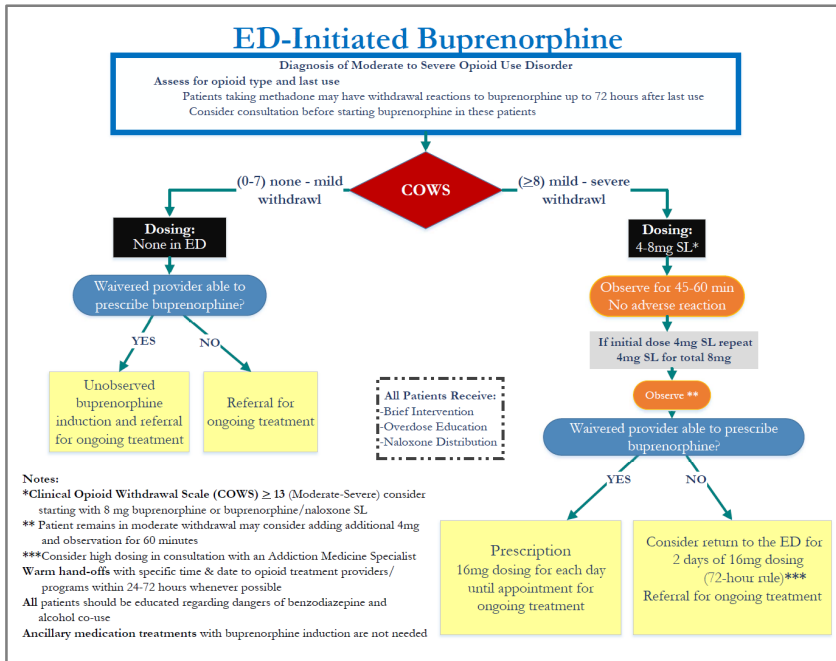
- Poor usability of HIT
- Complex protocol of BUP initiation
- Stigma, Unfamiliarity to BUP initiation protocol
- EHR limitation to identifying adult ED patients with OUD
- Limited capability of vendor provided CDS tool
- Lack of infrastructure for warm handoff from ED to community MOUD sites
- Growing Opioid crisis - need to find a timely solution

## SOLUTIONS

- Direct observation and interviews of residents and physicians → Identified current gaps and needs in HIT
- Developed user centered CDS tool
- Developed and validated a two-algorithm phenotype → Flags potential OUD cases
- EHR-integrated web based application
- Meetings with ED physicians and community stakeholders → Developed automated, flexible, electronic referral system
- Original plan of Step-wedge study design → Parallel group-randomized trial design

# User Centered Design: To simplify the process of initiating BUP in the ED

From a complicated algorithm ...



... to a simple, automated application

**Buprenorphine (BUP) Initiation**  
Do you have a waiver to prescribe Buprenorphine? No  Yes

**Buprenorphine Treatment Options** right

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)	Diagnose OUD using DSM tool
How severe is 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)	Assess Withdrawal using COWS tool
Is patient ready for treatment?	NO	YES	YES	YES	Motivate Readiness using interview tool
	Select #1	Select #2	Select #3	Select #4	

1

Clinicians continue in their current Epic workflow



2

Click the 'EMBED' button in the patient's chart to launch the app

The screenshot displays the Epic EMR interface for a patient named Edward M. The top navigation bar includes various tools like 'In Basket', 'ED Track Board', and 'ED Map'. The patient's demographic and clinical information is shown at the top, including MRN, gender, and various medical flags. The main content area is titled 'My Note' and shows 'ED Provider Notes' for a patient named Security, Resident, MD. A red circle highlights the 'EMBED' button in the left-hand navigation menu, which is also highlighted in red in the main content area. The 'EMBED' button is a blue rectangle with white text. The main content area also shows a list of procedures, including 'Nail Removal', and a physical exam section.

# 3

App offers care pathways & patient assessment tools with the flexibility to use just the parts you need

← → ▾
EMBED

### Buprenorphine (BUP) Initiation

Do you have a waiver to prescribe Buprenorphine?

No  Yes

#### Buprenorphine Treatment Options

[ED-initiated Buprenorphine Resources](#)

	Care Pathway #1	Care Pathway #2	Care Pathway #3	Care Pathway #4	
	<b>Exit/No BUP</b>	<b>Hold in ED</b>	<b>Start 4 mg BUP (2x)</b>	<b>Start 8 mg BUP</b>	<b>Decision Support</b>
Does the patient have Opioid Use Disorder?	<div style="background-color: #ff69b4; color: white; padding: 5px; display: inline-block; border: 1px solid black;">NO</div> <small>(&lt;4 DSM criteria)</small>	<div style="background-color: #90ee90; color: white; padding: 5px; display: inline-block; border: 1px solid black;">YES</div> <small>(≥4 DSM criteria)</small>	<div style="background-color: #90ee90; color: white; padding: 5px; display: inline-block; border: 1px solid black;">YES</div> <small>(≥4 DSM criteria)</small>	<div style="background-color: #90ee90; color: white; padding: 5px; display: inline-block; border: 1px solid black;">YES</div> <small>(≥4 DSM criteria)</small>	<p style="font-size: 0.8em; margin: 0;">Use these optional tools in any order to help you decide</p> <div style="text-align: center; margin: 5px 0;">↓</div> <div style="background-color: #4169e1; color: white; padding: 5px; display: inline-block; border: 1px solid black; margin: 0 auto; width: 80px;">Diagnose OUD</div> <small>using DSM tool</small>
How severe is patient's withdrawal?	<p style="margin: 0;">None-to-Mild</p> <div style="text-align: center; margin: 0;"> </div> <small>&lt; 8</small>	<p style="margin: 0;">None-to-Mild</p> <div style="text-align: center; margin: 0;"> </div> <small>&lt; 8</small>	<p style="margin: 0;">Mild-to-Moderate</p> <div style="text-align: center; margin: 0;"> </div> <small>8 - 13</small>	<p style="margin: 0;">Moderate-to-Severe</p> <div style="text-align: center; margin: 0;"> </div> <small>&gt; 13</small>	<div style="background-color: #4169e1; color: white; padding: 5px; display: inline-block; border: 1px solid black; margin: 0 auto; width: 80px;">Assess Withdrawal</div> <small>using COWS tool</small>
Is patient ready for treatment?	<div style="background-color: #ff69b4; color: white; padding: 5px; display: inline-block; border: 1px solid black;">NO</div>	<div style="background-color: #90ee90; color: white; padding: 5px; display: inline-block; border: 1px solid black;">YES</div>	<div style="background-color: #90ee90; color: white; padding: 5px; display: inline-block; border: 1px solid black;">YES</div>	<div style="background-color: #90ee90; color: white; padding: 5px; display: inline-block; border: 1px solid black;">YES</div>	<div style="background-color: #4169e1; color: white; padding: 5px; display: inline-block; border: 1px solid black; margin: 0 auto; width: 80px;">Motivate Readiness</div> <small>using interview tool</small>
	Select #1	Select #2	Select #3	Select #4	

*Don't give buprenorphine if patient is intoxicated or has taken methadone within 72 hours*

EMBED
Scoring Tools

Dispo
Customize

Review Visit
Triage

My Note
Results Review

Manage Orders
Chart Review

Snapshot

# 4

## Orders appear in an Epic 'Shopping Cart' that allows for easy de/selection

**Thank you for using the Buprenorphine (BUP) initiation pathway. The following actions will now be completed:**

### Start 8mg BUP

[Back](#) [Launch Care Pathway](#)

#### Note

I have used the EMBED Buprenorphine Initiation decision support app to assess this patient for opioid use disorder, opioid withdrawal, and readiness for treatment.

Using this app, I determined that this patient has:

1. moderate OR severe opioid use disorder,
2. a clinical opioid withdrawal scale of 8-13, and
3. has expressed readiness to begin treatment with buprenorphine

The patient will receive:

1. buprenorphine 4 mg in the ED today, be observed for 45-60 minutes, and given another 4 mg dose if they have no side effects,
2. prescriptions for buprenorphine 16 mg sublingual daily for 3 days and a prescription for naloxone nasal spray,
3. referral to treatment, and
4. education on opioid use disorder, naloxone use and this study

#### Orders (The following orders will be placed now for your signature)

- Buprenorphine-naloxone SL tablet 4 mg
- Administer 4 mg now. Observe patient for 45-60 minutes. If no adverse events, administer second dose

#### Prescriptions (The following prescriptions will be placed now for your signature)

- Naloxone Nasal Spray 4 mg
- Buprenorphine-naloxone SL tablet 16 mg x 3 days

#### AVS/Discharge Instructions

- Opioid Use Disorder
- Naloxone (nasal spray)
- Buprenorphine buccal film

#### Referral to treatment

- A referral for an addiction specialist appointment will automatically be made when you exit this window.

**Place New Orders**

- buprenorphine-naloxone (SUBOXONE) SL tablet ×
- Observe patient for 60 minutes post-dose ×
- Complete Clinical Opioid Withdrawal Scale (COWS) assessment ×
- nalOXONE (NARCAN) 4 mg/actuation NASAL spray ×
- buprenorphine-naloxone (SUBOXONE) SL tablet 8-2 mg ×

**File Flowsheet Data**

Documentation Pathway	6	×
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Accept

5

After signing the orders, you can continue to use Epic

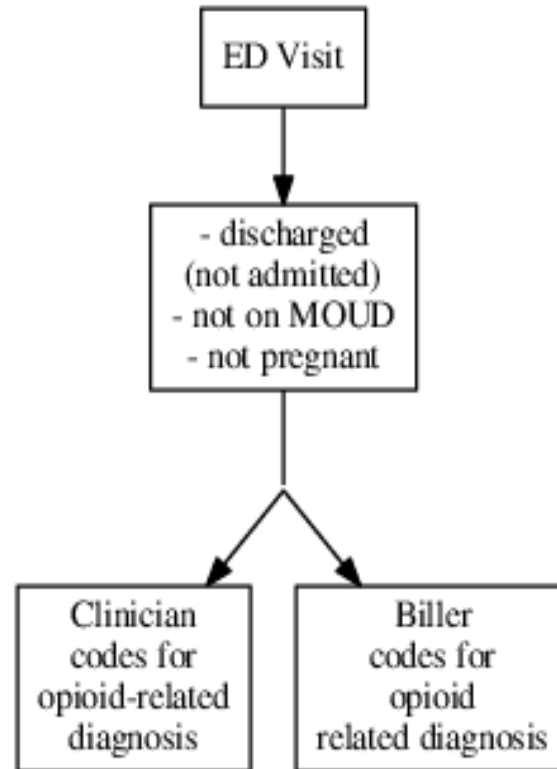




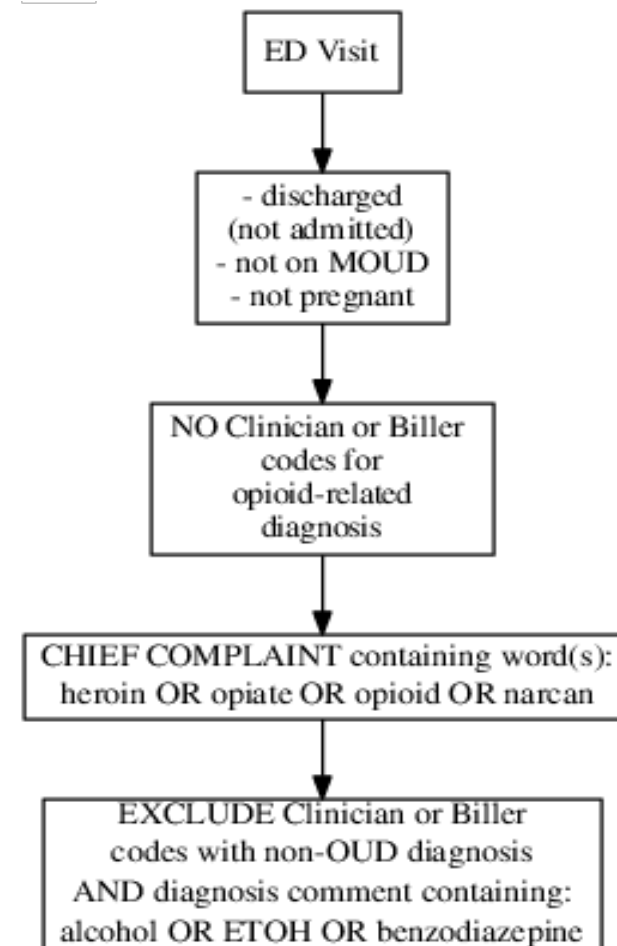
# EHR Phenotype – Derivation

- Identifies ED patients with OUD using
  - Diagnostic/billing codes (**Algorithm 1**)
  - EHR Based structured data elements (**Algorithm 2**)

## Algorithm 1



## Algorithm 2

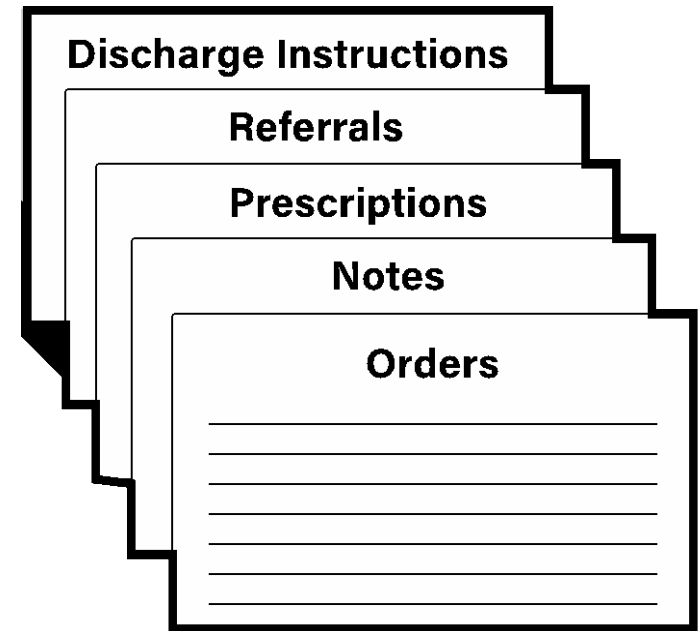
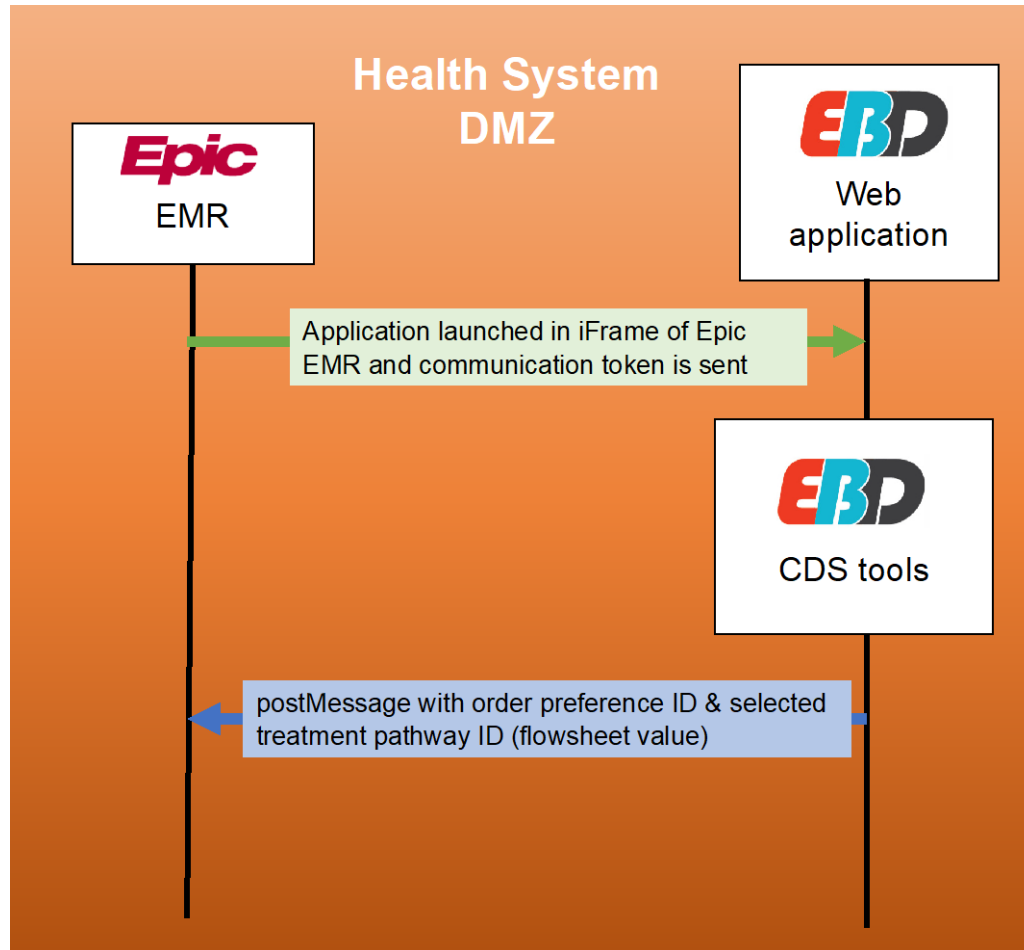


# EHR Phenotype –Validation

- **Validation** of EHR Phenotype - using physician chart review
  - High degree of validity across two healthcare systems

	Reviewers +	Reviewers -	Predictive Value (95% CI)
<b>Algorithm 1</b> (Internal Validation)			
Phenotype +	48	2	PPV 0.96 (0.863-0.995)
Phenotype -	1	49	NPV 0.98 (0.893-0.999)
<b>Algorithm 2</b> (Internal Validation)			
Phenotype +	20	5	PPV 0.8 (0.593-0.932)
Phenotype -	0	25	NPV 1.0 (0.863-1)
<b>Combined Phenotype</b> (Internal Validation)			
Phenotype +	53	3	PPV 0.95 (0.851-0.989)
Phenotype -	4	46	NPV 0.92

# EHR integration



*Populated in the EHR*

# Ethics / Regulatory

- Expert guidance from NIH Collaboratory core
- Protocol approved by Western IRB (**WIRB**)
- Waiver of informed consent under Common Rule 45 CFR 46.116
- Study Patients :
  - Deidentified
  - Not target of the intervention (minimal risk)
  - Do not interact with study directly, retrospective EHR data collection
- Control sites can still follow best practices
  - Patients can request MOUD
  - Physicians retain control over their practice

**A research study to help clinicians initiate Buprenorphine in the ED**

This hospital is taking part in a NIDA-funded implementation trial to increase the uptake of a computerized clinical decision support intervention to help clinicians treat Opioid Use Disorder (OUD).

**ED-initiated Buprenorphine**  
As patients with OUD often seek medical care in EDs, the ED visit provides an opportunity to access care when patients may be more motivated to start treatment. Buprenorphine/naloxone (BUP) is a treatment for OUD that decreases withdrawal, craving, and opioid use and that can be prescribed by appropriately trained physicians. Among OUD patients, ED-initiated BUP treatment with referral for ongoing medication for OUD doubles the rate of engagement in formal addiction treatment.

**How to start Buprenorphine in the ED for patients with a 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.

**COWS**

None - Mild Withdrawal (0-7 COWS) → Dosing: None in ED  
**For Waivered Providers:** Unobserved buprenorphine induction and referral for ongoing treatment  
**For Non-waivered Providers:** Referral for ongoing treatment

Mild - Severe Withdrawal (>= 8 COWS) → Dosing: 8mg SL\* → Observe for 45-60 min. No adverse reactions → If initial dose 4mg SL repeat 4mg SL for total 8mg → Observe\*\*  
**For Waivered Providers:** Prescription: 16mg dosing for each day until appointment for ongoing treatment  
**For Non-waivered Providers:** Consider return to the ED for 2 days of 16mg dosing (72 hour rule) Referral for ongoing treatment

All patients should be educated regarding dangers of benzodiazepine and alcohol co-use.  
Ancillary medication treatments with buprenorphine induction are not needed.

\*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

**Clinician participation in this study**  
This study evaluates how care is delivered to OUD patients in this ED. The study team will look at the treating clinicians' practice patterns. The privacy of your information is important, and we will only use secure ways to look at practice patterns. You will not be identified. Decisions not to participate or withdraw from the study at any time, or study results related to the provider if they do participate, will not affect their employment or standing at this hospital.

**Contact**  
If you would like more information on the EMBED trial or if you would like to opt out of the study, please call 203-737-2810.

EMBED: Pragmatic trial of user-centered clinical decision support to implement Emergency department initiated Buprenorphine for opioid use disorder; (IRB Protocol Number: #####)

disorder. The study team will not collect more data or do any extra tests, than they would for any other visit.

**Privacy**  
The privacy of this information is important, and we will not collect any identifying information about you. Specifically, we will not collect your name, medical record number, date of birth, address phone number, or any other private information from your visit that could be linked back to you.

**Questions**  
If you have any other questions about this research project, please call 203-737-2810 and a member of the study team will call you back.

EMBED: Pragmatic trial of user-centered clinical decision support to implement Emergency department initiated Buprenorphine for opioid use disorder; (IRB Protocol Number: #####)

# UH3 Aims

## EMBED TIMELINE

	YEAR 1				YEAR 2				YEAR 3				YEAR 4				YEAR 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>USER-CENTERED CDS DEVELOPMENT</b>																				
Workflow Analysis; Initial Prototype Development	█																			
Usability & Field Testing		█	█																	
IT Build w/Local EHR Integration; Beta-Testing			█	█																
<b>PLANNING PHASE</b>																				
Finalize Participating Sites & Protocols	█	█																		
Finalize Enrollment Targets		█	█																	
Finalize Data Collection Methods; IRB Approvals			█	█																
<b>TRIAL PHASE</b>																				
Complete EHR Integration at All Sites				█	█	█														
Clinical Enrollment with Ongoing Data Management							█	█	█	█	█	█								
Local Formative Process Evaluation during Implementation								█	█	█	█									
Wide Scale Dissemination													█	█	█	█	█	█	█	█
Final Data Analysis & Publication														█	█	█	█			

- **UH3 Aim 1.** Compare the effectiveness of user-centered CDS for BUP to usual care on outcomes in ED patients with OUD.
- **UH3 Aim 2.** Disseminate the EMBED intervention nationally.

# UH3 (Implementation Phase) – Progress so far..

- Finalize Master Data Dictionary, Codes
- Complete Data Validation
- Complete EHR Integration
- Check Site Readiness (Checklist)
- **Oct 31-Nov 14, 2019** - Trial Launched, Patient enrollment started
- First round of data collection – **Jan 15, 2020**

**SITE INITIATION CHECKLIST**

**A. DATA -**

1. Local SQL Query built
2. Sample data sent to Yale
3. Data meets validation requirements
  - a. Automated review
  - b. Face Validity review

**B. INTERVENTION:**

1. Intervention is live
2. Referral is live
3. Intervention has fidelity with goals to automate: 
  - i. Note writing
  - ii. Order entry
  - iii. Prescription writing
  - iv. Discharge notes
  - v. Referral
4. Training: local detailing is coordinated at intervention sites

**C. IRB COMPLIANCE**

1. Provider Notification:
2. Posters: 
  - i. Provider facing – posted in work station
  - ii. Patient Facing – posted in waiting room

# Publications related to EMBED Study

1. Ray JM, Ahmed OM, Solad Y, Maleska M, Martel S, Jeffery MM, Platts-Mills TF, Hess EP, D'Onofrio G, Melnick ER. Computerized Clinical Decision Support System for Emergency Department–Initiated Buprenorphine for Opioid Use Disorder: User-Centered Design. *Journal of Medical Internet Research Human Factors*. 2019;6(1):e13121.
2. Ahmed OM, Mao JA, Holt SR, Hawk K, D'Onofrio G, Martel S, Melnick ER. A scalable, automated warm handoff from the emergency department to T community sites offering continued medication for opioid use disorder: Lessons learned from the EMBED trial stakeholders. *Journal of Substance Abuse Treatment*. 2019;102:47-52.
3. Melnick ER, Jeffery M, Dziura JD, Mao JA, Hess EP, Platts-Mills TF, Solad Y, Paek H, Martel S, Patel MD, Bankowski L, Lu CC, Brandt C, D'Onofrio G. User-Centered Clinical Decision Support to Implement Emergency Department-Initiated Buprenorphine for Opioid Use Disorder: Protocol for the Pragmatic Group Randomized EMBED Trial. *BMJ Open*. 2019;9:e028488.
4. Chartash D, Paek H, Dziura JD, Ross BK, Noguee DP, Boccio E, Hines C, Schott AM, Jeffery MM, Patel MD, Platts-Mills TF, Ahmed O, Brandt C, Couturier K, Melnick ER. Identifying Opioid Use Disorder in the Emergency Department: Multi-System Electronic Health Record–Based Computable Phenotype Derivation and Validation Study. *JMIR Med Inform* 2019;7(4):e15794; URL: <https://medinform.jmir.org/2019/4/e15794>; DOI: 10.2196/15794; PMID: 31674913;
5. Edward R Melnick, Wesley C Holland, Osama M Ahmed, Anthony K Ma, Sean S Michael, Howard S Goldberg, Christian Lagier, Gail D'Onofrio, Tomek Stachowiak, Cynthia Brandt, Yauheni Solad, An integrated web application for decision support and automation of EHR workflow: a case study of current challenges to standards-based messaging and scalability from the EMBED trial, *JAMIA Open*, , 00z053, <https://doi.org/10.1093/jamiaopen/00z053>

# Thank you.

Questions?

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[@DonofrioGail](#)

