UG3 EMBED

Pragmatic trial of user-centered clinical decision support to implement Emergency department-initiated Buprenorphine for opioid use Disorder

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Discussion from New UG3 for NIH Collaboratory Steering Committee Meeting
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Overview

- Multicenter (across 3 healthcare systems), pragmatic, stepped wedge implementation trial to evaluate the effect of user-centered clinical decision support (CDS) for ED patients with opioid use disorder (OUD) upon rates of ED-initiated buprenorphine (BUP) and referral for ongoing medication for addiction treatment (MAT) in two phases:
  - UG3 planning phase (Year 1, pre-trial)
  - UH3 implementation phase (Years 2-5, trial)

- Background
- Aims
- Barriers
- User-centered design
- Data Sharing
Background: OUD

- Opioid use disorder (OUD): Dependence on prescription opioids and heroin
- Major public health problem: 3 million Americans have or have had OUD
- Less than 1 in 5 in treatment
- Devastating toll on Americans, their families, and their communities
- Deaths quintupled since 1999 (42,000 in 2016)
Background: MAT

- Medication for addiction treatment (MAT): effective in primary care
- Buprenorphine/naloxone (BUP), partial opioid agonist combined with an antagonist
  - Treatment for OUD that decreases withdrawal, craving, and opioid use
  - DATA 2000 Restrictions to prescribing
- Emergency department (ED)
  - may be only access to care for many opioid users (420,000 visits in 2011)
  - often at vulnerable time: overdose, withdrawal, seeking treatment, comorbid conditions
  - ED-initiated BUP with referral to MAT doubles rate of engagement in addiction treatment
  - Paradigm shift to chronic, relapsing condition

Background: HIT

- Poor health IT (HIT) usability is a 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.
Innovating Opioid Use Disorder treatment in the Emergency Department

**EMBED UG3 goals**

1. **Identify the right patients for BUP**
   - The opioid epidemic is increasing the number of OUD patients in the Emergency Department, resulting in greater resource, time, and care pressures on ED staff.

2. **Treat OUD patients with optimal systems and processes**
   - BUP + MAT is an effective but complicated treatment to initiate in the ED, but it is more effective than the current care for OUD in the ED. As opposed to methadone, BUP can help patients rebuild their lives.
   - There are limited number of MDs waivered in DATA 2000 (a requirement to prescribe BUP).
   - There are many processes that make prescribing and initiating BUP in the ED time and labor intensive.

3. **Refer patients to Medically Assisted Treatment**
   - In the ED, there is a lack of availability of referral for treatment and lack of integration of referral into care/workflow. As a result of these factors, there is less use of BUP + MAT, and patients risk missing referrals and treatments.

**Project EMBED: EMergency department initiated BuprenorfiE for opioid use Disorder**

This project intends to improve the way emergency departments identify, treat, and refer Opioid Use Disorder (OUD) patients. Buprenorphine/naloxone (BUP) treatment initiated in the ED has proven to be effective for OUD. However, there are a number of challenges to start BUP in the ED. The goal of this work is to develop a clinical decision support system that addresses the hardships of providing care in a busy emergency department while delivering integrated and impactful treatment for patients.
## UG3 Milestone Overview

<table>
<thead>
<tr>
<th>Q1: Apr-Jun</th>
<th>Q2: Jul-Sept</th>
<th>Q3: Oct-Dec</th>
<th>Q4: Jan-Mar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epic vs web application</td>
<td>Build functional prototype</td>
<td>CDS can fire in background</td>
<td>IT integrate at Yale, other sites ready</td>
</tr>
<tr>
<td>Wireframe</td>
<td>Finalize:</td>
<td>Collect sample data w/ ICC</td>
<td>MAT ready</td>
</tr>
<tr>
<td>Assemble advisory board</td>
<td>Sites</td>
<td>Report how MAT network assembled</td>
<td>Develop training materials</td>
</tr>
<tr>
<td>Finalize:</td>
<td>Protocol</td>
<td>BUP available at all ED sites</td>
<td>100 cases from each site for final power calc</td>
</tr>
<tr>
<td>- inclusion criteria</td>
<td>data coordination plans</td>
<td>Integrate CTN findings</td>
<td>MAT scheduling available</td>
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<tr>
<td>- baseline comparator</td>
<td></td>
<td>Obtain IRB approval</td>
<td>Governing document finalized</td>
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<tr>
<td>- outcome measures</td>
<td></td>
<td>Prepare randomization schedule</td>
<td>DSMB?</td>
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<tr>
<td>- healthcare systems</td>
<td></td>
<td></td>
<td>UH3 timeline</td>
</tr>
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<td></td>
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<td>UH3 budget</td>
</tr>
</tbody>
</table>
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

- External collaborators
  - UNC
    - Tim Platts-Mills, MD, MSc
    - Mehul Patel, PhD
  - Mayo
    - Molly Jeffery, PhD

- UAB
  - Erik Hess, MD, MSc
  - Jim Galbraith, MD

- Also: Cooper, UC Davis

- Each site within each system
  - Medical director
  - Clinical champions
  - IT leaders
  - MAT site contacts
Aims: UH3

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

- Long-term goal of wide-scale adoption of ED-initiated BUP and referral to MAT by leveraging and integrating substance use disorder, design, IT, and data coordination innovation, expertise, and experience.

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### UH3 STUDY DESIGN SCHEMATIC & TIMELINE

<table>
<thead>
<tr>
<th>MONTH</th>
<th>UH3 Year 1</th>
<th>UH3 Year 2</th>
<th>UH3 Year 3</th>
<th>UH3 Year 4</th>
</tr>
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<tbody>
<tr>
<td>DATE</td>
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<td>3/19</td>
<td>4/19</td>
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<td>11/22</td>
<td>12/22</td>
<td>1/23</td>
<td>2/23</td>
</tr>
</tbody>
</table>

- **Cluster 1:** Control | Imp | Post-imp Evaluation
- **Cluster 2:** Control | Imp | Post-imp Evaluation
- **Cluster 3:** Control | Imp | Post-imp Evaluation
- **Cluster 4:** Control | Imp | Post-imp Evaluation
- **All:** Ongoing data coordination & preparation for final analysis | Analysis

**KEY:** Control = BASELINE EVALUATION, Imp = IMPLEMENTATION
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
Diagnosis of Moderate to Severe Opioid Use Disorder

**Note:**

- Consider initiating buprenorphine in these patients.
- Physicians should try to avoid initiating buprenorphine up to 72 hours before initiating treatment to allow pharmacokinetic adjustment.
- Waivered providers are able to prescribe buprenorphine.

**Action:**

- If initial dose fails to achieve further treatment.
- Waivered providers are able to prescribe buprenorphine.
- If initial dose fails to achieve further treatment.
- Waivered providers are able to prescribe buprenorphine.

**Sequence:**

1. Consider initiating buprenorphine in these patients.
2. Physicians should try to avoid initiating buprenorphine up to 72 hours before initiating treatment to allow pharmacokinetic adjustment.
3. Waivered providers are able to prescribe buprenorphine.
4. If initial dose fails to achieve further treatment.
5. Waivered providers are able to prescribe buprenorphine.
6. If initial dose fails to achieve further treatment.
7. Waivered providers are able to prescribe buprenorphine.

**Steps:**

- Observation
- Observation
- Observation
- Observation

**Assessment:**

- COWS
- COWS
- COWS
- COWS

**Diagnosis:**

- Moderate to Severe Opioid Use Disorder
- Moderate to Severe Opioid Use Disorder
- Moderate to Severe Opioid Use Disorder
- Moderate to Severe Opioid Use Disorder
Embed: Initiation of Buprenorphine in the Emergency Department (People, Processes, Technologies, Content)

1. Patient Triage
2. Triage MD/RN
3. Bed
4. Evaluations, Treatment, Referral
   - PAC evaluation
   - RN evaluation
   - MD/Resident evaluation
   - Consultations
   - HPA / Project ASSERT
5. Attending MD ‘sign off’ + Prescription
6. Discharge
7. Post-ED Treatments
   - Referral to treatment center (fax, call, electronic order)
   - Referral back to ED (72 hours)
   - ‘Indirect’ referral (given contact info to treatment center)
   - No referral / no treatment

Identifies patients
1. Walks around ED
2. Checks patient panel (Epic)
3. Receives calls about specific patient

Connects with patient
1. Conducts BN for readiness for treatment
2. Assesses appropriateness for treatment
3. Determines if patient is in severe withdrawal

Referral, Admit, or Discharge with info
1. Prints ‘Interagency Referral’ information
2. Calls to make sure there is a bed
3. Faxes treatment center and follow-up

'Epic' Workflows within EHR

Ideal patient for BUP initiated treatment in the ED presents with OUD symptoms, is in severe withdrawal, and is ready for treatment.

Patients being in the right severity of withdrawal for treatment is the hardest part of the process.
User Interface Categories and Sequence

1. DSM 5 Opioid Use Disorder Checklist
   - A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two (2) of the following...
   - Select all that apply: Required to occur in the prior twelve months:
     - 1. Opioids are often taken in larger amounts or over a longer period of time than intended.
     - 2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
     - 3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
     - 4. Giving a strong desire to use opioids.
     - 5. Recurrent use resulting in failure to fulfill major role obligations at work, school, or home.
     - 6. Continued use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
     - 7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
     - 8. Recurrent use in situations in which it is physically hazardous.
     - 9. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.
   - 10. Tolerance, as defined by either of the following:
       - a) Increased need for increased amounts of opioids to achieve intoxication or desired effect
       - b) Markedly diminished effect with continued use of the same amount of the opioid
   - 11. Withdrawal, as manifested by either of the following:
       - a) Characteristic withdrawal syndrome
       - b) The same or a similar substance is taken to relieve or avoid withdrawal symptoms

   Total: 0
   Opioid Use Disorder Score: None (0-1), Milder (2-5), Moderate (6-15), Severe (16+)

2. COWS determines severity of withdrawal

3. Dosage and treatment guidance (patient education?)

4. SUPPLEMENT SPN Referral Form for Opioid Use Disorder
   - Patient demographics
   - History of opioid use
   - Referral details

Patient is flagged for possible OUD ('Best Practice Alert')
Does the patient have Opioid Use Disorder?

- Yes
- No
- Uncertain (launch DSM checklist)

### DSM 5 Opioid Use Disorder Checklist
Quantifies severity of symptoms

#### >3 - 6 Symptoms
Severe

Select all that apply

- [ ] 1. Have you found that when you started using (insert drug (X) here) you ended up taking more than you intended to?
- [ ] 2. Have you wanted to cut down using (X)?
- [ ] 3. Have you spent a lot of time getting or using (X)?
- [ ] 4. Have you had a strong desire or urge to use (X)?
- [ ] 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 (X) 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?
# Buprenorphine Initiation Process

Complete this checklist to expedite the initiation of buprenorphine treatment:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>UNCLEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️</td>
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<td>✔️</td>
</tr>
</tbody>
</table>

- **Does the patient have Opioid Use Disorder?** [DSM Criteria](#)
- **Is the patient in withdrawal?** [Clinical Opiate Withdrawal Scale](#)
- **Is the patient ready to start treatment?** [Motivational Interview](#)
- **Is buprenorphine dosing determined?** [Dosing Workflow](#)
- **Will the patient be referred to a treatment center?** [Referral Form](#)

[Start](#)
Buprenorphine Initiation Process

Welcome! The Buprenorphine initiation process will help you identify, treat, and refer patients with Opioid Use Disorder.

To begin treatment, the patient must be considered "YES" for the following criteria:

- Opioid Use Disorder
- Moderate-to-severe withdrawal
- Ready for treatment

Dosing and referral

Begin!
Welcome!

This Buprenorphine treatment initiation process will help you identify, treat, and refer patients with Opioid Use Disorder.

Dosing and patient referral will begin once the three criteria are met.

Or, use the decision support information to guide you through the process.

Select: 
>- to expedite dosing and referral
>- for information and decision support
## Buprenorphine (BUP) Initiation Treatment Options

**Are you credentialed to prescribe buprenorphine?**

<table>
<thead>
<tr>
<th>Provider Type</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EXIT</strong></td>
<td>with no BUP</td>
<td><strong>HOLD</strong></td>
<td><strong>START (4MG)</strong></td>
<td><strong>START (8MG)</strong></td>
</tr>
<tr>
<td>- not ready for treatment</td>
<td>- withdrawal is too mild</td>
<td>- entered looking for treatment</td>
<td>- entered ED by overdose</td>
<td></td>
</tr>
<tr>
<td>- incorrectly identified in EHR</td>
<td>- have returned for treatment</td>
<td></td>
<td>- clearly in severe withdrawal</td>
<td></td>
</tr>
</tbody>
</table>

### Opioid Use Disorder Diagnosis

<table>
<thead>
<tr>
<th>Clinical Opiate Withdrawal Scale</th>
<th>None-to-mild</th>
<th>Moderate-to-severe</th>
<th>Moderate-to-severe</th>
<th>Moderate-to-severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typical symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting pulse rate &lt;80</td>
<td>&lt; 8</td>
<td>&gt; 13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not restless, anxious, irritable</td>
<td>None-to-mild</td>
<td>Mild-to-moderate</td>
<td></td>
<td></td>
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<tr>
<td>No yawning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal pupil size</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>No runny nose</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>No tremors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No sweating or gooseflesh</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>No bone/joint pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>No GI upset</td>
<td></td>
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</tbody>
</table>

### Ready to Start Treatment

<table>
<thead>
<tr>
<th>In the ED treatment</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>- wait until withdrawal worsens, and then 4 mg SL/P dose</td>
<td>- 4mg SL/PO</td>
<td>- Observe for 45 min</td>
<td>- Observe for 45 min</td>
<td>- Observe for 45 min</td>
</tr>
<tr>
<td>- Ensure no side effects</td>
<td>- Repeat dose of 4mg SL/PO</td>
<td>- Ensure no side effects</td>
<td>- Ensure no side effects</td>
<td>- Ensure no side effects</td>
</tr>
<tr>
<td>Select treatment option</td>
<td>No BUP Refer for Treatment</td>
<td>Order BUP (4mg) in 60 min. Refer for treatment</td>
<td>Order BUP (4mg) Return to ED in 24 hrs. for 16 mg Refer for treatment</td>
<td>Order BUP (8mg) Return to ED in 24 hrs. for 16 mg Refer for treatment</td>
</tr>
</tbody>
</table>

All patients receive: Note populaed to chart, brief intervention, overdose education, naloxone prescription, no BUP prescription
<table>
<thead>
<tr>
<th>Treatment Options</th>
<th>Opioid Use Disorder</th>
<th>Withdrawal Status</th>
<th>Patient is ready</th>
<th>Treatment in ED</th>
<th>Select and Return to EHR</th>
</tr>
</thead>
</table>
| 1. **Start 8 mg BUP** | YES | (>13 Severe) | ✓ | - 8mg SL/PO  
- Observe for 45 min  
- Ensure no side effects | - Order BUP (8 mg)  
- Refer for treatment  
- Prescribe naloxone  
- Populate note & instructions  
- Return to EHR |
| 2. **Start 4 mg BUP (2x)** | YES | (8 to 13 Mild-to-Moderate) | ✓ | - 4mg SL/PO  
- Observe for 45 min  
- Ensure no side effects  
- Repeat dose of 4mg SL/PO  
- Observe for 60 min | - Order BUP (4 mg)  
- Refer for treatment  
- Prescribe naloxone  
- Populate note & instructions  
- Return to EHR |
| 3. **Hold in ED** | YES | (<8 Mild-to-Moderate) | ✓ | - Wait until withdrawal worsens  
- Then 4 mg SL/PO dose | - Wait 1 hour - Order BUP (4mg)  
- Refer for treatment  
- Prescribe naloxone  
- Populate note & instructions  
- Return to EHR |
| 4. **Exit / No BUP** | NO / MILD | (<8 None-to-Mild) | ✗ | - No | - Refer for treatment  
- Prescribe naloxone  
- Populate note & instructions  
- Return to EHR |
# Buprenorphine (BUP) Initiation

Are you credentialed to prescribe Buprenorphine?

<table>
<thead>
<tr>
<th>Treatment Options</th>
<th>Opioid Use Disorder</th>
<th>Withdrawal Status</th>
<th>Patient is ready</th>
<th>Treatment in ED</th>
<th>Select and Return to EHR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DSM</td>
<td>COWS</td>
<td>Interview</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. **Start 8 mg BUP**
   - Consider if... patient is in severe withdrawal
   - YES
   - (>13 Severe)
   - 8mg SL/PO
   - Observe for 45 min
   - Ensure no side effects
   - Order BUP (8 mg)
   - Rx: 8mg / 3 times daily
   - Refer for treatment

2. **Start 4 mg BUP (2x)**
   - Consider if... patient entered ED for treatment
   - YES
   - (8 to 13 Mild-to-Moderate)
   - 4mg SL/PO
   - Observe for 45 min
   - Ensure no side effects
   - Repeat dose of 4mg SL/PO
   - Observe for 60 min
   - Order BUP (4 mg)
   - Rx: 8mg / 3 times daily
   - Refer for treatment

3. **BUP Rx for Home**
   - Consider if... patient’s withdrawal is too mild
   - YES
   - (<8 Mild-to-Moderate)
   - Educate patient on home induction
   - BUP Home Induction
   - Rx: 8mg / 3 times daily
   - Refer for treatment

4. **Exit / No BUP**
   - Consider if... Patient is not ready for treatment
   - NO / MILD
   - (<8 None-to-Mild)
   - No
   - Refer for treatment
   - Prescribe naloxone
   - Populate note & instructions
   - Return to EHR
## Clinical Opiate Withdrawal Scale (COWS)

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Resting Pulse Rate</td>
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<td>1</td>
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<tr>
<td>2. Restlessness</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>3. Anxiety or irritability</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>4. Yawning</td>
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<td>0</td>
</tr>
<tr>
<td>5. Pupil Size</td>
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<td>0</td>
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<tr>
<td>6. Runny nose or tearing</td>
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<td>0</td>
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<tr>
<td>7. Tremor</td>
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<td>0</td>
</tr>
<tr>
<td>8. Sweating</td>
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<td>0</td>
</tr>
<tr>
<td>9. Gooseflesh skin</td>
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<td>0</td>
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<tr>
<td>10. Bone or joint pain</td>
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<td>0</td>
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<tr>
<td>11. GI upset</td>
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<td>0</td>
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</table>

Return to treatments
# Barriers Scorecard

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>X</td>
</tr>
<tr>
<td>Engagement of clinicians and health systems</td>
<td>X</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>X collection</td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>X consent</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>X</td>
</tr>
<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
<td>X</td>
</tr>
</tbody>
</table>

*Your best guess!  
1 = little difficulty  
5 = extreme difficulty
Date Sharing UG3

- What is your current data sharing plan and do you foresee any obstacles?
  - Follow NIH guidelines & HIPAA compliant
  - Mindful of rights and privacy of participants given vulnerability of OUD
- What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent, if applicable?
  - Pending external IRB review once sites finalized
  - Identifiers confidential, used only for data integrity, only shared with subject permission or as required by law
- What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?
  - Primary outcome: rate of BUP use in ED (clinician-level)
  - Secondary outcomes: related to success of referral to MAT
Thank you. Let’s discuss.

Questions & Answers?
Thoughts on need for DSMB?

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