UG3 EMBED

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

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Discussion from New UG3 for NIH Collaboratory Steering Committee Meeting

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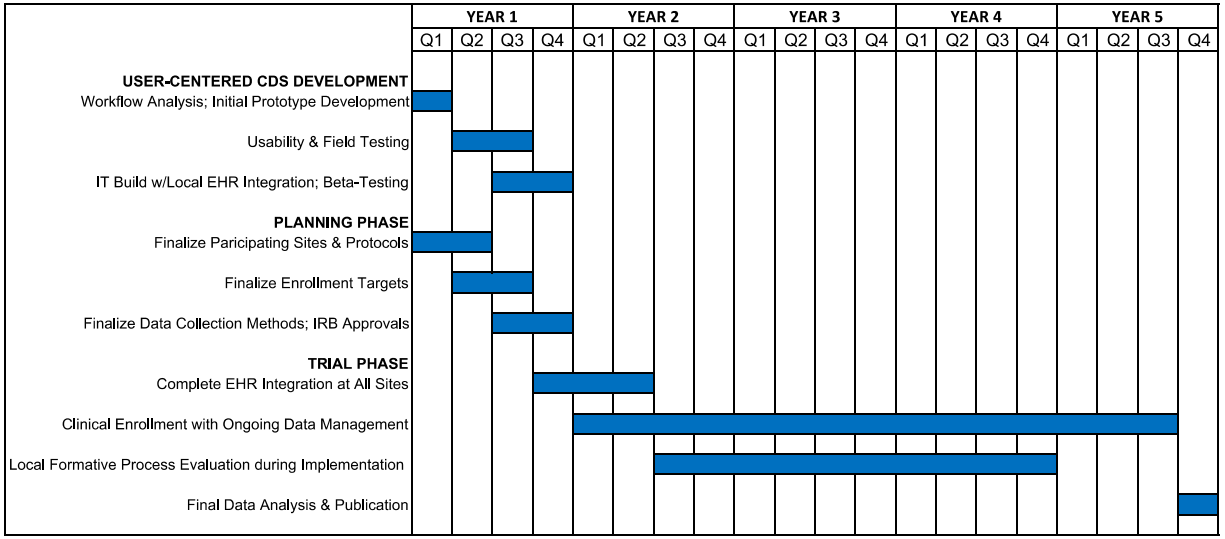
Yale SCHOOL OF MEDICINE

Overview

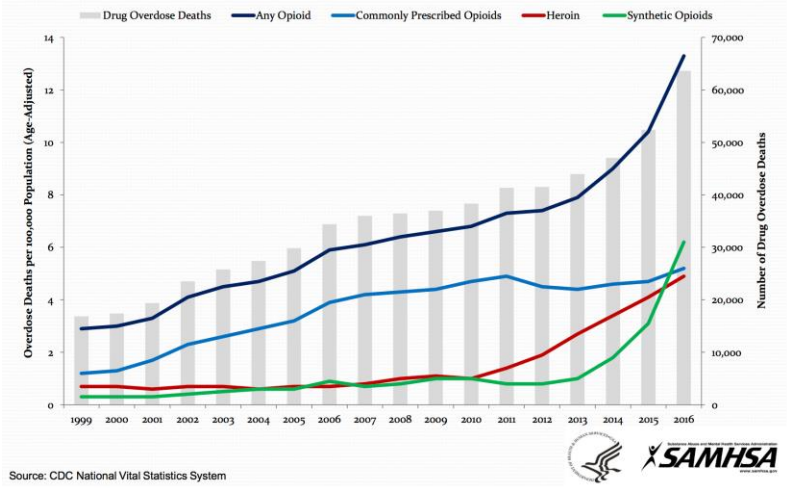
- Multicenter (across 3 healthcare systems), pragmatic, stepped wedge implementation trial to evaluate the effect of user-centered clinical decision support (CDS) for ED patients with opioid use disorder (OUD) upon rates of ED-initiated buprenorphine (BUP) and referral for ongoing medication for addiction 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



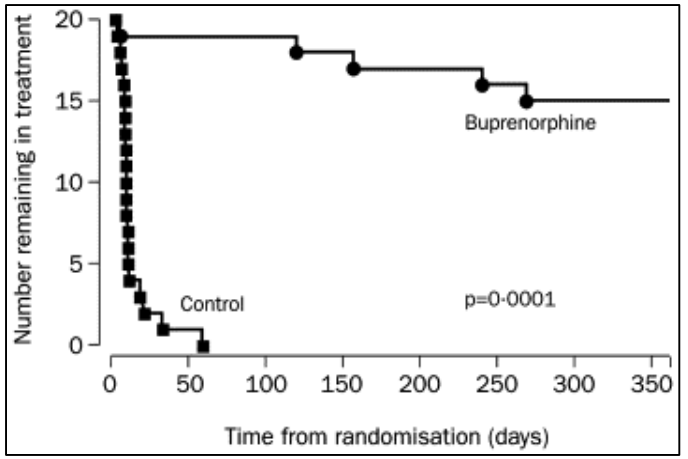
Background: OUD

- 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

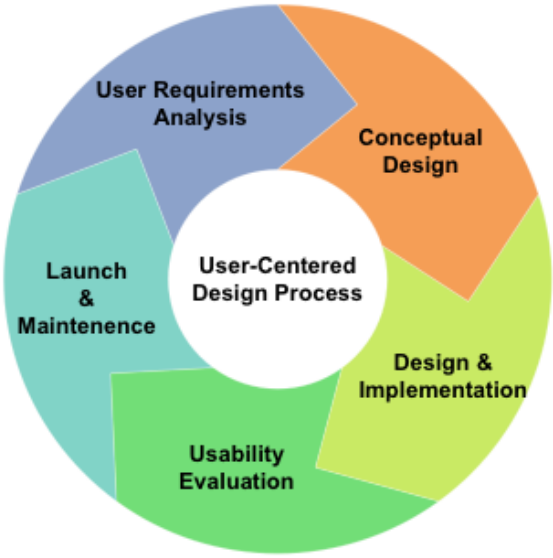
- Medication for addiction treatment (MAT): effective in primary care
- Buprenorphine/naloxone (BUP), partial opioid agonist combined with an antagonist
  - Treatment for OUD that decreases withdrawal, craving, and opioid use
  - DATA 2000 Restrictions to prescribing
- Emergency department (ED)
  - may 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



Kakko. Lancet 2003.

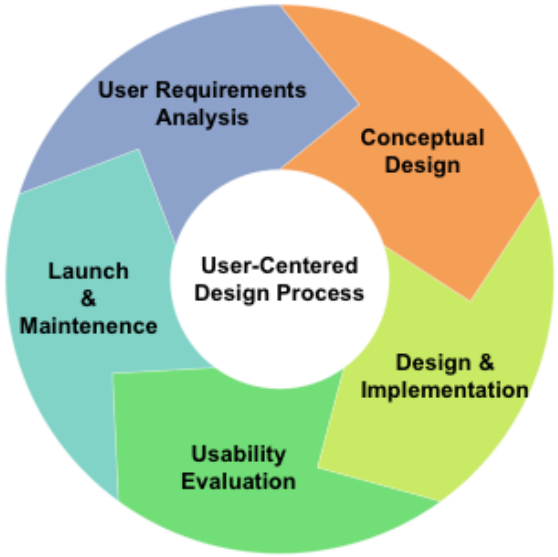
Background: HIT

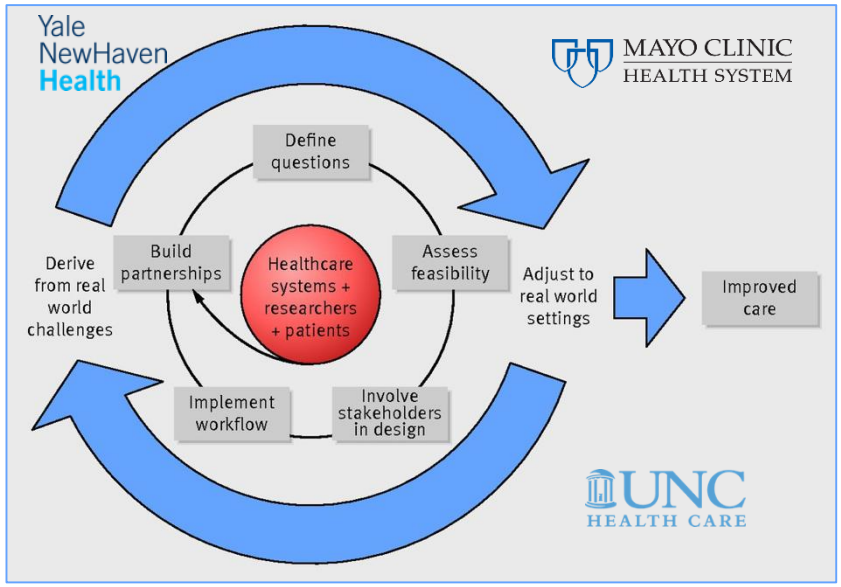
- Poor health IT (HIT) usability is major source of frustration with clinicians
- Electronic health record (EHR) usability is a fundamental barrier to implementation of evidence-based medicine
- IT should be designed to meet user needs
- User-centered design
  - streamline workflows
  - address barriers 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.





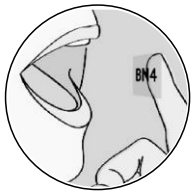
EMBED UG3 goals

Innovating Opioid Use Disorder treatment in the Emergency Department

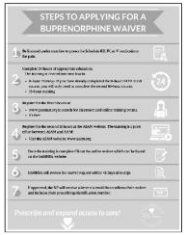
Identify
the right patients for BUP

① The opioid epidemic is increasing the number of OUD patients in the Emergency Department, resulting in greater resource, time, and care pressures on ED staf

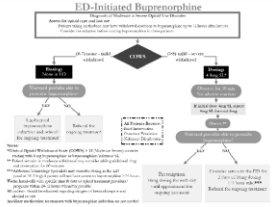
Treat
OUD patients with optimal systems and processes



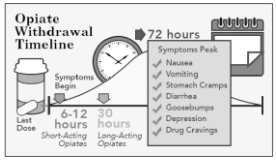
② BUP + MAT is an ef ective but complicated treatment to initiate in the ED, but it is more ef ective than the current care for OUD in the ED. As opposed to methadone, BUP can help patients rebuild their lives



③ There are a limitied number of MDs waivered in DATA 2000 (a requirement to prescribe BUP)

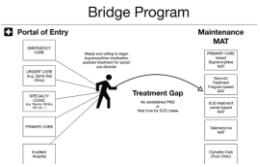


④ There are many processes that make prescribing and initiating BUP in the ED time and labor intensive



⑤
- DSM 5 OUD Checklist
- Clinical Opiate Withdrawl Scale
- BUP Referral Form for OUD
- Rx dosage amount and protocol

Refer
patients to Medically Assisted Treaatmnt



⑥ 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 treaments

Project EMBED: EMergency department initiated BuprenorphiE 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 ef ective 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

Q1: Apr-Jun	Q2: Jul-Sept	Q3: Oct-Dec	Q4: Jan-Mar

• Epic vs web application
• Wireframe
• Assemble advisory board
• Finalize:
  • inclusion criteria
  • baseline comparator
  • outcome measures
  • healthcare systems
	• Build functional prototype
	• Finalize:
	  • Sites
	  • Protocol
	  • data coord-ination plans
	• Identify:
	  • MAT sites
	  • Clinical champs
		• CDS can fire in background
		• Collect sample data w/ ICC
		• Report how MAT network assembled
		• BUP available at all ED sites
		• Integrate CTN findings
		• Obtain IRB approval
		• Prepare randomization schedule
			• IT integrate at Yale, other sites ready
			• MAT ready
			• Develop training materials
			• 100 cases from each site for final power calc
			• MAT scheduling available
			• Governing document finalized
			• DSMB?
			• UH3 timeline
			• UH3 budget

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

UH3 STUDY DESIGN SCHEMATIC & TIMELINE

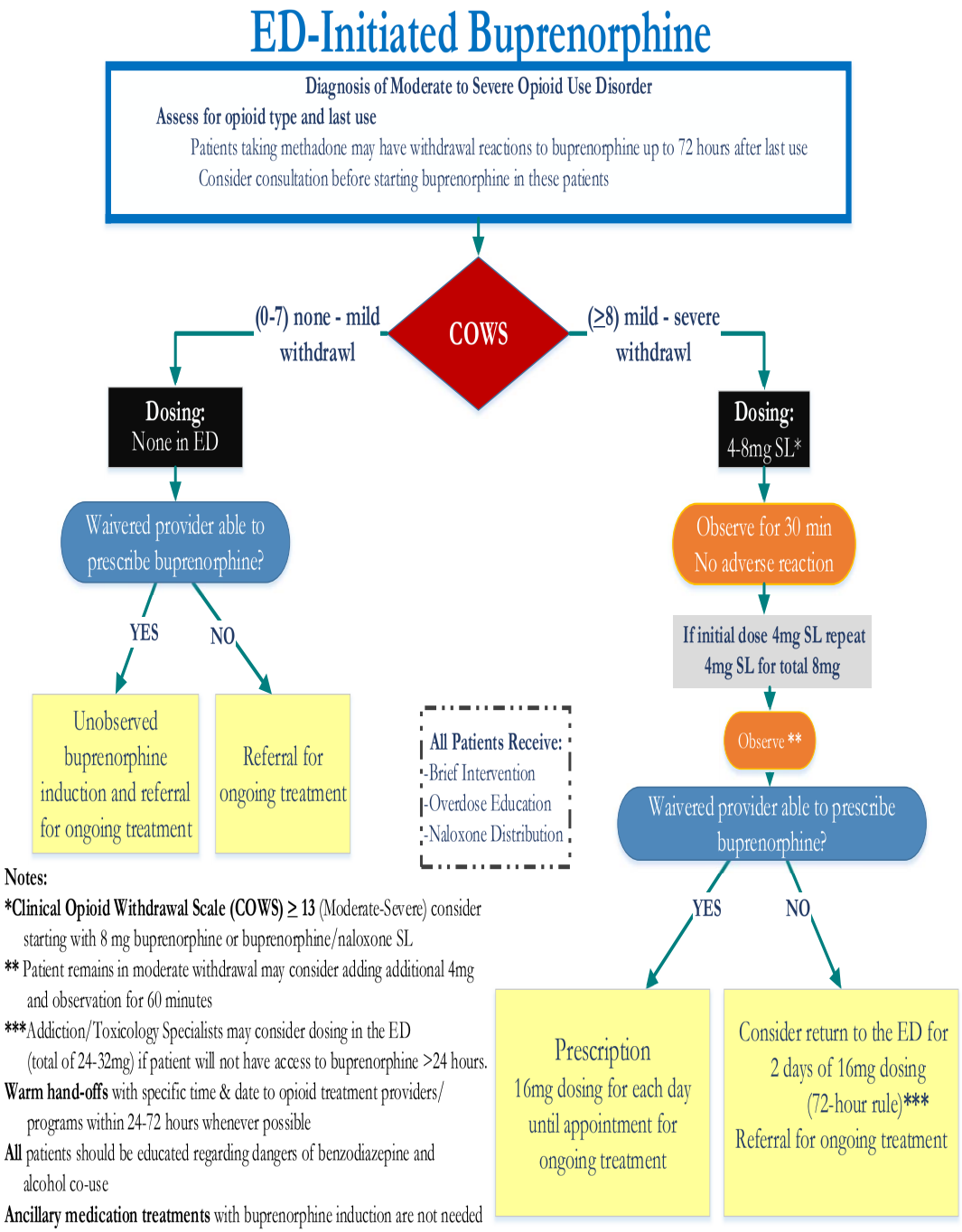
	UH3 Year 1												UH3 Year 2												UH3 Year 3												UH3 Year 4											
MONTH	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48
DATE	3/19	4/19	5/19	6/19	7/19	8/19	9/19	10/19	11/19	12/19	1/20	2/20	3/20	4/20	5/20	6/20	7/20	8/20	9/20	10/20	11/20	12/20	1/21	2/21	3/21	4/21	5/21	6/21	7/21	8/21	9/21	10/21	11/21	12/21	1/22	2/22	3/22	4/22	5/22	6/22	7/22	8/22	9/22	10/22	11/22	12/22	1/23	2/23
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

Treatment Algorithm



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

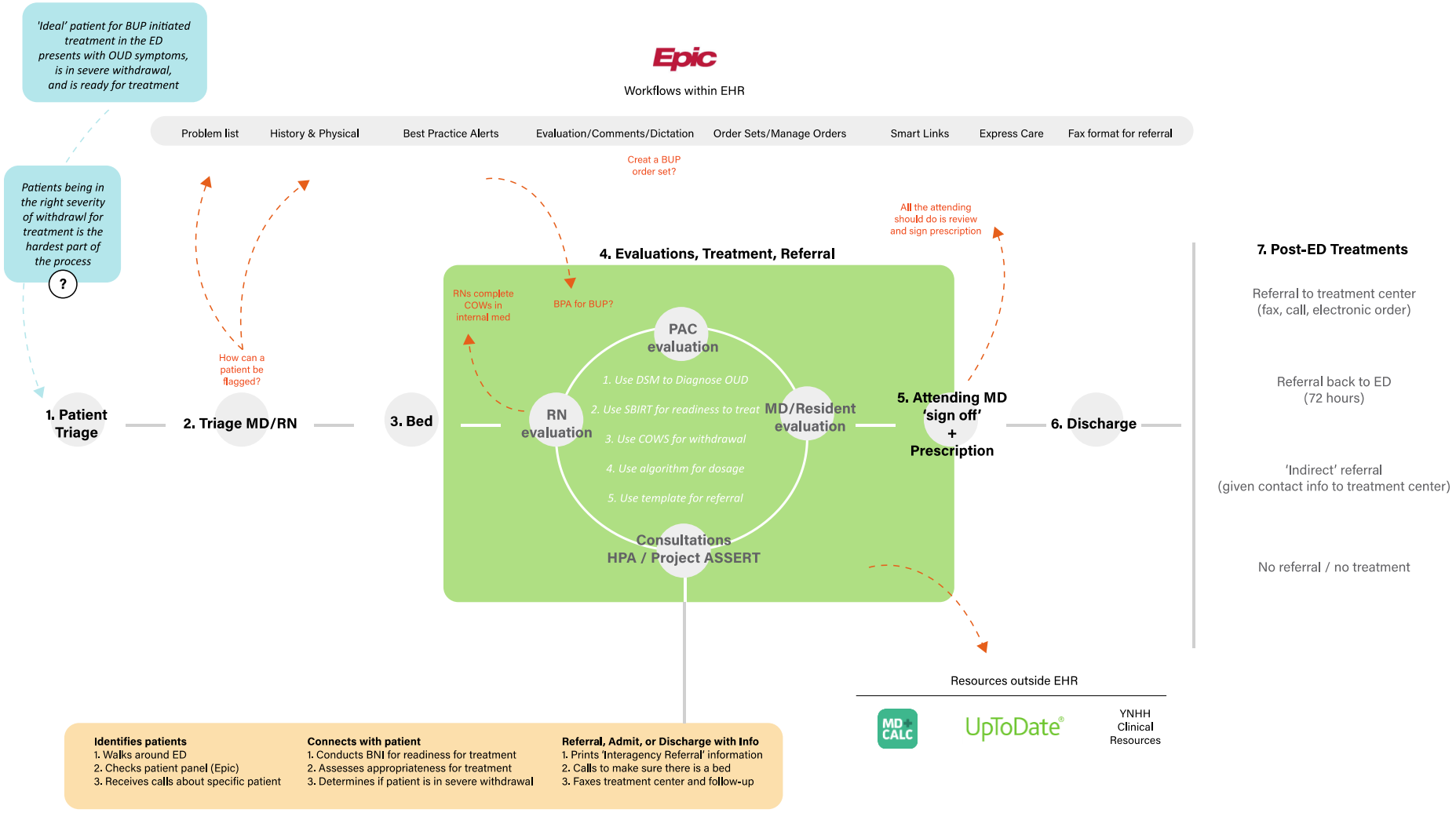
***Addiction/Toxicology Specialists may consider dosing in the ED (total of 24-32mg) if patient will not have access to buprenorphine >24 hours.

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

Embed: Initiation of Buprenorphine in the Emergency Department (People, Processes, Technologies, Content)



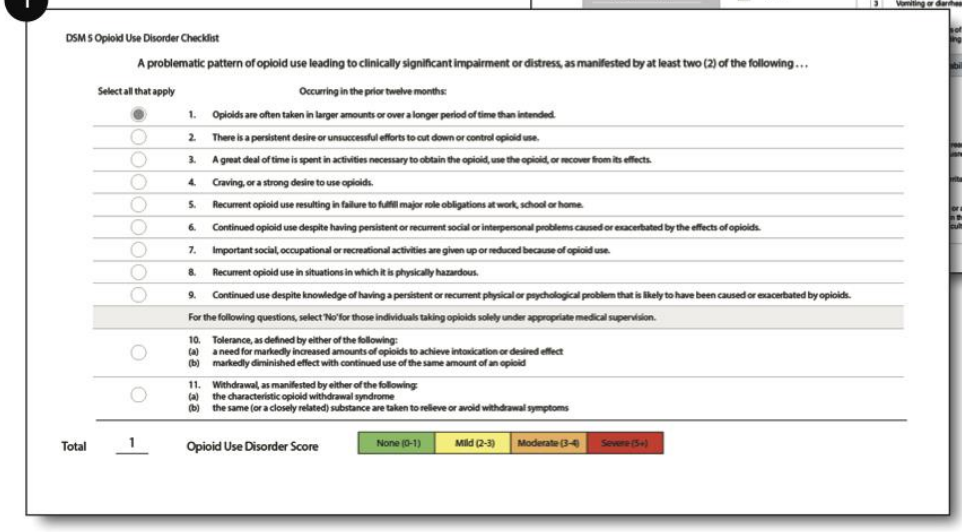
User Interface Categories and Sequence

0

Patient is flagged for possible OUD ('Best Practice Alert')

1

DSM Score provides severity of OUD



DSM 5 Opioid Use Disorder Checklist

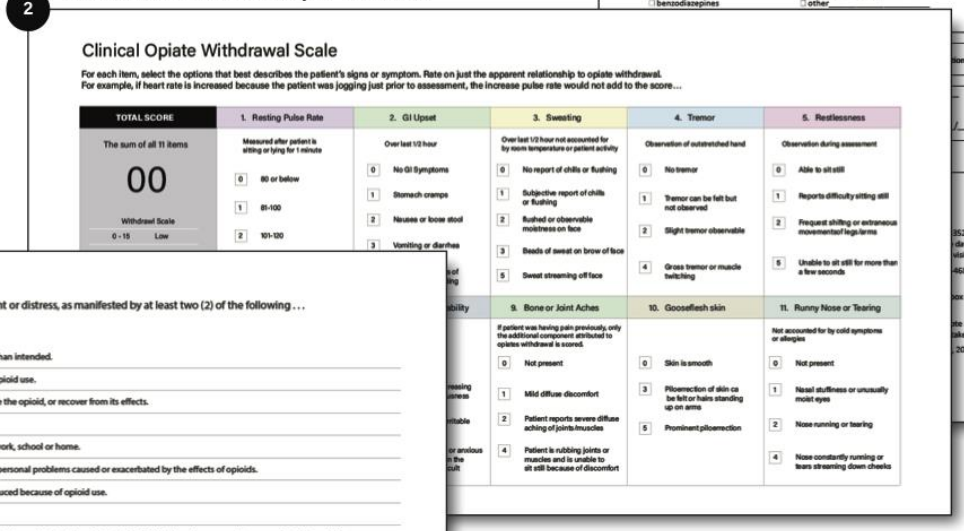
A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two (2) of the following . . .

Select all that apply		Occurring 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.	Craving, or a strong desire to use opioids.
○	5.	Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
○	6.	Continued opioid 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 opioid 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.
		For the following questions, select 'No' for those individuals taking opioids solely under appropriate medical supervision.
○	10.	Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid
○	11.	Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms

Total 1 Opioid Use Disorder Score — None (0-1) | Mild (2-3) | Moderate (3-4) | Severe (5+)

2

COWS determines severity of withdrawl



Clinical Opiate Withdrawal Scale

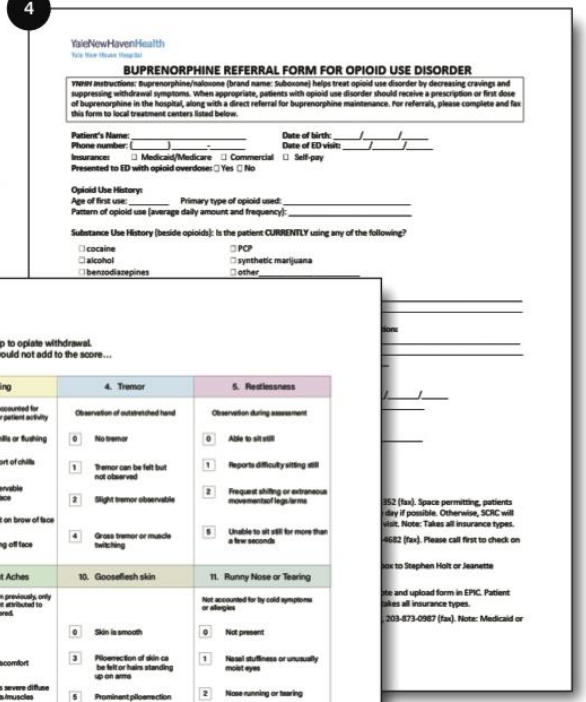
For each item, select the options that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal.
For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score…

TOTAL SCORE	1. Resting Pulse Rate	2. GI Upset	3. Sweating	4. Tremor	5. Restlessness
The sum of all 11 items 00 Withdrawal Scale 0 - 15 Low	Measured after patient is sitting or lying for 1 minute 0 80 or below 1 81-100 2 101-120	Over last 1/2 hour 0 No GI Symptoms 1 Stomach cramps 2 Nausea or loose stool 3 Vomiting or diarrhea	Over last 1/2 hour not accounted for by room temperature or patient activity 0 No report of chills or flushing 1 Subjective report of chills or flushing 2 Flushed or observable moistness on face 3 Beads of sweat on brow of face 5 Sweat streaming off face	Observation of outstretched hand 0 No tremor 1 Tremor can be felt but not observed 2 Slight tremor observable 4 Gross tremor or muscle twitching	Observation during assessment 0 Able to sit still 1 Reports difficulty sitting still 2 Frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds
	9. Bone or Joint Aches	10. Gooseflesh skin	11. Runny Nose or Tearing		
	If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored. 0 Not present 1 Mild diffuse discomfort 2 Patient reports severe diffuse aching of joints/muscles 4 Patient is rubbing joints or muscles and is unable to sit still because of discomfort	0 Skin is smooth 3 Piloerection of skin ca be felt or hairs standing up on arms 5 Prominent piloerection	Not accounted for by cold symptoms or allergies 0 Not present 1 Nasal stuffiness or unusually moist eyes 2 Nose running or tearing 4 Nose constantly running or tears streaming down cheeks		

3

Dosage and treatment guidance (patient education?)

4



YaleNewHavenHealth
Yale New Haven Hospital

BUPRENORPHINE REFERRAL FORM FOR OPIOID USE DISORDER

YNHH Instructions: Buprenorphine/naloxone (brand name: Suboxone) helps treat opioid use disorder by decreasing cravings and suppressing withdrawal symptoms. When appropriate, patients with opioid use disorder should receive a prescription or first dose of buprenorphine in the hospital, along with a direct referral for buprenorphine maintenance. For referrals, please complete and fax this form to local treatment centers listed below.

Patient's Name: _____ Date of birth: ____/____/____
Phone number: (____) ____-____ Date of ED visit: ____/____/____
Insurance: ☐ Medicaid/Medicare ☐ Commercial ☐ Self-pay
Presented to ED with opioid overdose: ☐ Yes ☐ No

Opioid Use History:
Age of first use: _____ Primary type of opioid used: _____
Pattern of opioid use (average daily amount and frequency): _____

Substance Use History (beside opioids): Is the patient CURRENTLY using any of the following?
☐ cocaine ☐ PCP
☐ alcohol ☐ synthetic marijuana
☐ benzodiazepines ☐ other_____

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 — Ask the patient the following questions:

- [x] 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

[X]

PLAN | DIAGNOSIS | WITHDRAWAL SCALE | READINESS FOR TREATMENT | DOSING | REFERRAL

Complete this checklist to expedite the initiation of buprenorphine treatment

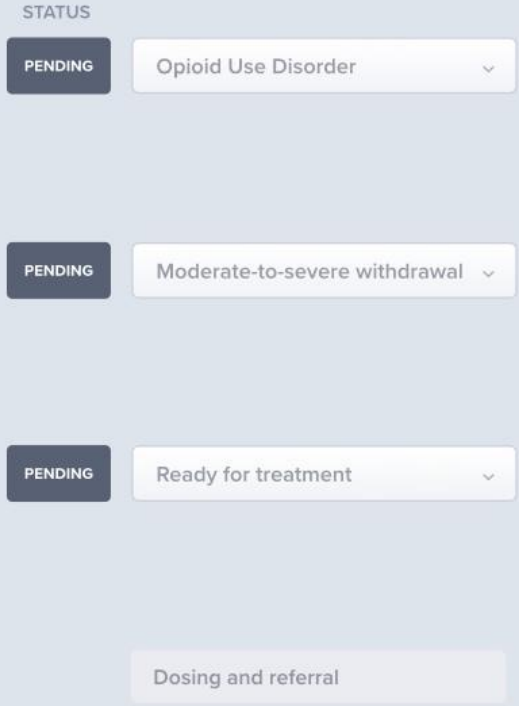
YES	NO	UNCLEAR	
☑	☐	☐	Does the patient have Opioid Use Disorder? DSM Criteria
☐	☐	☑	Is the patient in withdrawal? Clinical Opiate Withdrawal Scale
☐	☐	☑	Is the patient ready to start treatment? Motivational Interview
☐	☑	☐	Is buprenorphine dosing determined? Dosing Workflow
☐	☐	☑	Will the patient be referred to a treatment center? Referral Form

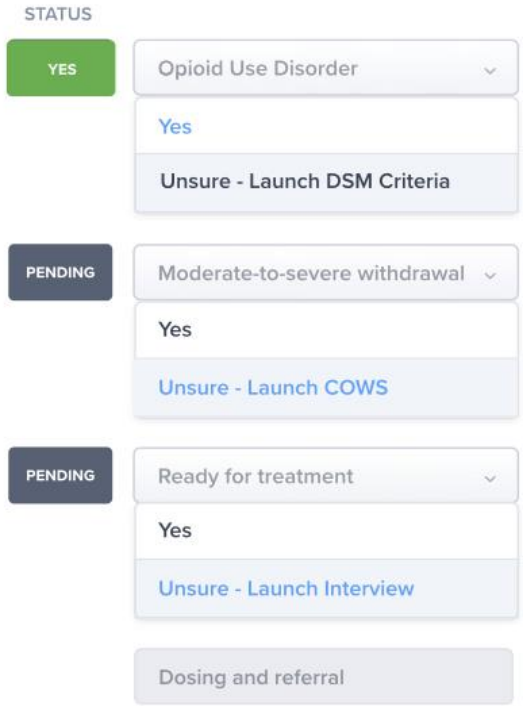
Start

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:





[X]

Buprenorphine Initiation Process

Buprenorphine can be adminstered in patients who meet the following criteria:

PATIENT MEETS CRITERIA

START DECISION SUPPORT

- [ ] **Opioid Use Disorder is moderate-to-severe**

(DSM 5 - Criteria for Opioid Use Disorder)

- [ ] **Withdrawal symptoms are moderate-to-severe**

(Clinical Opiate Withdrawal Scale)

- [ ] **Ready to start treatment**

(Motivational Interview Guide)

Dosing and Referral

[X]

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

EMAIL PRINT TEXT [X]

ARE YOU CREDENTIALED TO PRESCRIBE BUPRENORPHINE?

Waivered Provider | Not-waivered Provider

SELECT FROM ONE OF THE FOUR TREATMENT OPTIONS

	EXIT	HOLD	START (4MG)	START (8MG)
	with no BUP	In ED for BUP	4 mg BUP (2 doses) in the ED	8 mg BUP in the ED
Can be given when ...	- not ready for treatment - incorrectly identified in EHR	- withdrawal is too mild - have returned for treatment	- entered looking for treatment	- entered ED by overdose - clearly in severe withdrawal
Opioid Use Disorder diagnosis	None-to-mild	Moderate-to-severe	Moderate-to-severe	Moderate-to-severe
Clinical Opiate Withdrawal Scale	< 8 None-to-mild	< 8 None-to-mild	8 to 13 Mild-to-moderate	> 13 Severe
Typical symptoms	Resting pulse rate <80 Not restless, anxious, irritable No yawning Normal pupil size No runny nose No tremors No sweating or gooseflesh No bone/joint pain No GI upset	Resting pulse rate <80 Not restless, anxious, irritable No yawning Normal pupil size No runny nose No tremors No sweating or gooseflesh No bone/joint pain No GI upset	Resting pulse rate >81 - 100 Frequent shifting Increasingly irritable / anxious Yawing 1 - 4 x / assessment Pupils dilated Runny nose / tearing eyes Slight tremor Flushed or some sweating Piloerection Mild or severe bone/joint Cramps, nausea, loose stool	Resting pulse rate > 120 Unable to sit still Too irritable to participate Frequent yawning Pupils completely dilated Runny nose / tearing eyes Gross tremor / twitching Beads of sweat Prominent piloerection Can't sit due to bone/join pain Vomiting / diarrhea
Ready to start treatment	No	Yes	Yes	Yes
In the ED treatment	No	- wait until withdrawal worsens, and then 4 mg SL/P dose	- 4mg SL/PO - Observe for 45 min - Ensure no side effects - Repeat dose of 4mg SL/PO - Observe for 60 min	- 8mg SL/PO - Observe for 45 min - Ensure no side effects
Select treatment option	No BUP Refer for Treatment	Order BUP (4mg) in 60 min. Refer for treatment	Order BUP (4mg) Return to ED in 24 hrs. for 16 mg Refer for treatment	Order BUP (8mg) Return to ED in 24 hrs. for 16 mg Refer for treatment

All patients receive: Note popultaed to chart, brief intervention, overdose education, naloxone prescription, no BUP prescription

Buprenorphine (BUP) Initiation

TEXT "5555" FOR RESOURCES [X]

WWW.WEBADDRESSHERE.COM

Are you credentialed to prescribe Buprenorphine?

No ⬤ Yes

Select from one of the four treatment options

Treatment Options	Opioid Use Disorder	Withdrawal Status	Patient is ready	Treatment in ED	Select and Return to EHR
	ⓘ DSM	ⓘ COWS	ⓘ Interview		
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)** - Refer for treatment - Prescribe naloxone - Populate note & instructions - Return to EHR
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)** - Refer for treatment - Prescribe naloxone - Populate note & instructions - Return to EHR
3 Hold in ED Consider if ... patient's withdrawal is too mild	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 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

Buprenorphine (BUP) Initiation

TEXT "5555" FOR RESOURCES [X]

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Are you credentialed to prescribe Buprenorphine?

No  Yes

Select from one of the four treatment options

Treatment Options	Opioid Use Disorder	Withdrawal Status	Patient is ready	Treatment in ED	Select and Return to EHR
	DSM	COWS	Interview		
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

Buprenorphine (BUP) Initiation

TEXT "5555" FOR RESOURCES [X]

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)	0
3.	Anxiety or irritability	None (0)	Increasing amounts (1)	Obviously irritable / anxious (2)	Too difficult to participate (4)	0
4.	Yawning	No yawning (0)	1 or 2 times / asessment (1)	3 or 4 times / assessment (2)	Several times /minute (4)	0
5.	Pupil Size	Normal (0)	Possibly larger (1)	Moderately dilated (2)	Only rim of iris visible (5)	0
6.	Runny nose or tearing	Not present (0)	Stuffiness / moist eyes (1)	Nose running / tearing (2)	Constant running / tears streaming (4)	0
7.	Tremor	No tremor (0)	Felt - not observed (1)	Slight tremor observable (2)	Gross tremor / twitching (4)	0
8.	Sweating	No report (0)	Subjective report (1)	Flushed / observable (2)	Beads of sweat (3)	Streaming down face (4)	0
9.	Gooseflesh skin	Skin is smooth (0)	Piloerection / hairs standing (3)	Prominent piloerrection (5)			0
10.	Bone or joint pain	Not present (0)	Mild discomfort (1)	Severe aching (2)	Unable to sit due to pain (4)		0
11.	GI upset	No symptoms (0)	Stomach cramps (1)	Nausea or loose stool (2)	Vomiting or diarrhea (5)	Multiple episodes (5)	0

Return to treatments

01

Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and health systems		X			
Data collection and merging datasets		X collection		X merging	
Regulatory issues (IRBs and consent)		X consent		X IRB	
Stability of control intervention				X	
Implementing/delivering intervention across healthcare organizations		X			

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*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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