



# NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

## Pragmatic Trial of User-Centered Clinical Decision Support to Implement Emergency Department–Initiated Buprenorphine for Opioid Use Disorder (EMBED)

### Principal Investigators

Edward Melnick, MD, MHS;  
Gail D'Onofrio, MD, MS

### ClinicalTrials.gov Identifier

[NCT03658642](https://clinicaltrials.gov/ct2/show/study/NCT03658642)

### Sponsoring Institution

Yale University

### Collaborators

- University of North Carolina at Chapel Hill
- University of Alabama at Birmingham
- University of Colorado Denver
- UMass Chan Medical School-Baystate

### NIH Institutes Providing Oversight

- National Institute on Drug Abuse (NIDA)

### DATA AND RESOURCE SHARING

- [Data sharing checklist](#)
- Melnick ER, Nath B, Dziura JD, et al. User centered clinical decision support to implement initiation of buprenorphine for opioid use disorder in the emergency department: EMBED pragmatic cluster randomized controlled trial. *BMJ*. 2022 Jun 27;377:e069271. doi: 10.1136/bmj-2021-069271. [PMID: 35760423](https://pubmed.ncbi.nlm.nih.gov/35760423/).

## STUDY AT A GLANCE



### STUDY QUESTION AND SIGNIFICANCE

Patients with untreated opioid use disorder often seek medical care in emergency departments (EDs). ED-initiated buprenorphine doubles the rate of engagement in addiction treatment by these patients. However, the practice of initiating buprenorphine in the ED has not been implemented into ED care. One major challenge for implementing evidence-based medicine has been the poor usability of health information technology. User-centered design of health information technology interventions can improve the user experience and the uptake of evidence-based medical care.



### DESIGN AND SETTING

Pragmatic cluster randomized controlled trial with 599 attending emergency physicians caring for 5047 adult patients who presented with opioid use disorder in 18 ED clusters across 5 healthcare systems in 5 states between November 2019 and May 2021.



### INTERVENTION AND METHODS

The study seamlessly integrated a user-centered, physician-facing clinical decision support system into user workflows in the electronic health record (EHR) to support initiation of buprenorphine in the ED. The system was designed to help clinicians diagnose opioid use disorder, assess withdrawal severity, motivate patients to accept treatment, and complete EHR tasks by automating clinical and after-visit documentation, order entry, prescribing, and referral. The primary study outcome was the rate of buprenorphine administration or prescription in the ED among patients with opioid use disorder. Secondary implementation outcomes were measured using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework.



### FINDINGS

Assessment of 1,413,693 ED visits for study eligibility identified 5047 patients with opioid use disorder (2787 in the intervention arm, 2260 in the usual care arm) under the care of 599 attending physicians (340 in the intervention arm, 259 in the usual care arm) for analysis. Buprenorphine was initiated in 347 patients (12.5%) in the intervention arm and 271 patients (12.0%) in the usual care arm (odds ratio [OR] from adjusted generalized estimating equations, 1.22; 95% CI, 0.61-2.43;  $P = .58$ ). Buprenorphine was initiated at least once by 151 physicians (44.4%) in the intervention arm and 88 physicians (34.0%) in the usual care arm (OR, 1.83; 95% CI, 1.16-2.89;  $P = .01$ ).



### CONCLUSIONS AND RELEVANCE

Although user-centered clinical decision support did not increase patient-level rates of buprenorphine initiation in the ED, when used, EMBED was associated with high rates of initiation of buprenorphine. EMBED also increased the number of unique physicians who provided initiation of buprenorphine in the ED and prescribed naloxone. Clinical decision support that streamlines and automates electronic workflows can increase physician adoption of complex, unfamiliar evidence-based practices. More interventions are needed to examine other barriers to the treatment of addiction at the patient level in the ED for patients with opioid use disorder.

[rethinkingclinicaltrials.org](https://rethinkingclinicaltrials.org)

## GENERALIZABLE LESSONS

Challenge	Solution
Establishing the need for and obtaining a waiver of informed consent	The study team received guidance from the Ethics and Regulatory Core to navigate the process of obtaining a waiver of informed consent.
Change in study design from stepped-wedge to parallel cluster randomized trial	The Biostatistics and Study Design Core provided advice on making the study design change.
Error encountered in the data analysis after submission of the main outcome paper	Early and open communication with the journal editor enabled the study team to address the error in the analysis.

*“Take the Biostatistics and Study Design Core’s advice seriously—get it early and act on it early. Hold regular meetings with your project’s biostats/data team.”*

*— Dr. Ted Melnick*

*“EMBED offers a major opportunity to accelerate adoption by offering a simple, automated, rapid solution to initiating treatment and referral for people suffering from opioid use disorder. Additional prompts and interventions will be needed to increase more universal implementation into the routine care of ED patients with opioid use disorder.”*

*— Dr. Gail D’Onofrio*

*“We were really fortunate in terms of who was on our teams and the great people we had to work with. So, find good people to work with and then get out of their way and let them thrive and succeed.”*

*— Dr. Ted Melnick*

## ADDITIONAL RESOURCES

- Article: [A Scalable, Automated Warm Handoff From the Emergency Department to Community Sites Offering Continued Medication for Opioid Use Disorder: Lessons Learned From the EMBED Trial Stakeholders](#)
- Article: [Identifying Opioid Use Disorder in the Emergency Department: Multi-System Electronic Health Record–Based Computable Phenotype Derivation and Validation Study](#)
- Article: [Commentary: Right Truncation in Cluster Randomized Trials Can Attenuate the Power of a Marginal Analysis](#)
- Article: [Trends and Disparities in Access to Buprenorphine Treatment Following an Opioid-Related Emergency Department Visit Among an Insured Cohort, 2014-2020](#)
- Video Interview: [Update on the EMBED Demonstration Project](#)

Access the complete set of [EMBED resources](#).