

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, and Gail D’Onofrio, MD, MS

Sponsoring Institution

Yale University

Collaborators

- University of North Carolina-Chapel Hill
- University of Alabama-Birmingham
- University of Massachusetts-Baystate
- University of Colorado, Aurora

NIH Institute Providing Oversight

[National Institute on Drug Abuse \(NIDA\)](#)

Program Official

Sarah Duffy (NIDA)

Project Scientist

Shelley Su (NIDA)

ClinicalTrials.gov Identifier

[NCT03658642](#)

ABSTRACT

Opioid use disorder (OUD) is a major public health issue taking a devastating toll on Americans, their families, and their communities. Opioid overdose deaths have quadrupled in the United States since 1999. Buprenorphine/naloxone (BUP), a partial opioid agonist combined with an antagonist, is a well-established outpatient treatment for OUD that can only be prescribed by appropriately trained physicians. Patients with untreated OUD often seek medical care in emergency departments (EDs). ED-initiated BUP doubles the rate of engagement in addiction treatment of ED patients with OUD. However, the practice of initiating BUP in the ED has not been integrated into routine emergency care. One major challenge to implementation is poor usability of health information technology.

To address this gap, the EMBED study team developed and pilot-tested a user-centered clinical decision support system that provides ED clinicians with the necessary information and tools for diagnosis of OUD, assessment of withdrawal, and subsequent treatment algorithms, thus helping to automate a complex treatment algorithm into a simpler streamlined workflow for initiating BUP in the ED. After a successful pilot test at one site, EMBED is implementing this intervention in the UH3 phase in a pragmatic, group-randomized trial at 20 EDs across 5 healthcare systems with the aim of evaluating the effectiveness of this tool in facilitating a large-scale adoption of ED-initiated BUP treatment protocol for OUD patients in the ED.

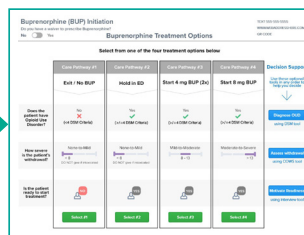
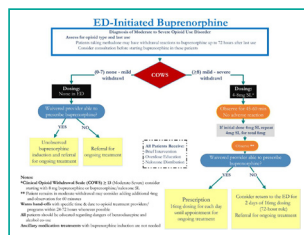


From a complex, multi-step process ...

... to a simple, automated application

A 25-30 min workflow for an addiction counselor, that includes

- Diagnostic criteria
- Withdrawal assessment
- Assessing patient readiness for treatment
- Treatment initiation
- Referral—includes detailed forms, fax, etc.



- Embedded within the EHR
- Diagnose, treat, and refer within 2-5 min of uninterrupted workflow,
 - Without exiting EHR
 - Supports clinicians unfamiliar with BUP regardless of waiver training

WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Stigma associated with OUD treatment and the perception of ED clinicians that BUP treatment protocol is unfamiliar, complicated, and burdensome for a crowded and chaotic ED environment has prevented incorporation of BUP treatment into routine ED care for OUD patients. Also, the current system for ED referral to community-based medication for OUD (MOUD) sites is complex and fragmented.	The study team developed a user-centered clinical decision support (CDS) system that automated a complex multifactor algorithm into a simpler workflow. The tool offers ED clinicians necessary information and tools for individual patient-level diagnosis of OUD, assessment of withdrawal severity, assessment of patient readiness for treatment, and motivation to initiate appropriate treatment algorithms. In addition to generating automatic patient-specific discharge notes, with prescriptions, the tool helps to generate an automatic referral to community-based MOUD sites for ongoing MOUD. Read more about EMBED's user-centered design process .
Limitation of ED documentation posed a barrier to identifying the pool of OUD patients for purposes of matching study inclusion criteria.	Using diagnostic codes and chief complaint-based structured data elements from the EHR, a 2-algorithm phenotype was developed, which is able to detect ED patients with OUD with high degrees of validity across 2 large healthcare systems.
Poor EHR usability is a barrier for incorporation of a complex workflow.	The EMBED intervention was implemented with the goal of optimizing its usability, EHR integration, automation of EHR workflow, and scalability across a variety of healthcare systems.
Vendor-provided CDS tools have limited capabilities for interface customization to develop intuitive, efficient user interfaces and workflow, which was a barrier to large scale system-level implementation.	The team created a centralized web application that can be integrated into EHR clinical workflow for the end-user. This adaptation was done only in the primary health system. Secondary health systems made local, pragmatic decisions on how the intervention was built in their system to allow for decision support for diagnosing OUD, assessing withdrawal, and automating documentation, orders, prescriptions, referral, and discharge instructions.
There was little streamlined infrastructure for scalable, automated warm handoff from the ED to community sites offering continued MOUD.	The team conducted meetings and surveys with ED physicians and other community stakeholders to identify needs and infrastructure requirements for an automated electronic workflow to initiate a flexible referral process, with on-demand and protected communication channels between EDs and community prescribers for MOUD to prevent dropouts from the referral cascade. Read more about lessons learned in the MOUD referral process .
Current federal regulations around BUP administration for OUD require physicians to have specialized time-consuming training to be able to prescribe BUP.	EMBED's CDS tool provides flexibility for both waived and non-waived ED clinicians to use this tool, while remaining in compliance with regulatory statutes around BUP administration.
Solutions to the opioid crisis are urgently needed.	Using a parallel group-randomized trial design with constrained randomization will better address the temporal trends of the opioid crisis. Read more in the published EMBED study protocol .

“With EMBED, we’re taking evidence-based research and implementing it to improve practice. EMBED is both a research and patient care project.”

SELECTED PUBLICATIONS & PRESENTATIONS

- June 2019: [Interview with EMBED PIs in Living Textbook](#)
- November 2018: [PCT Grand Rounds webinar](#)