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Clinical Decision Support For Emergency Department-Initiated Buprenorphine For Opioid Use Disorder

Wesley Holland

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Clinical Decision Support for Emergency Department-Initiated Buprenorphine for Opioid Use Disorder

A Thesis Submitted to the Yale University School of Medicine

in Partial Fulfillment of the Requirements for the Degree of Doctor of Medicine

by

Wesley C. Holland 2024
Adoption of emergency department (ED) initiation of buprenorphine (BUP) for opioid use disorder (OUD) into routine emergency care has been slow, partly due to clinicians’ unfamiliarity with this practice and perceptions that it is complicated and time-consuming. To address these barriers and guide emergency clinicians through the process of BUP initiation, we implemented a user-centered computerized clinical decision support system (CDS). This study was conducted to assess the feasibility of implementation and to evaluate the preliminary efficacy of the intervention to increase the rate of ED-initiated BUP.

An interrupted time series study was conducted in an urban, academic ED from April 2018 to February 2019 (preimplementation phase), March 2019 to August 2019 (implementation phase), and September 2019 to December 2019 (maintenance phase) to study the effect of the intervention on adult ED patients identified by a validated electronic health record (EHR)-based computable phenotype consisting of structured data consistent with potential cases of OUD who would benefit from BUP treatment. The intervention offers flexible CDS for identification of OUD, assessment of opioid
withdrawal, and motivation of readiness to start treatment and automates EHR activities related to ED initiation of BUP (including documentation, orders, prescribing, and referral). The primary outcome was the rate of ED-initiated BUP. Secondary outcomes were launch of the intervention, prescription for naloxone at ED discharge, and referral for ongoing addiction treatment.

Of the 141,041 unique patients presenting to the ED over the preimplementation and implementation phases (i.e., the phases used in primary analysis), 906 (574 preimplementation and 332 implementation) met OUD phenotype and inclusion criteria. The rate of BUP initiation increased from 3.5% (20/574) in the preimplementation phase to 6.6% (22/332) in the implementation phase (p = 0.03). After the temporal trend of the number of physicians with X-waiver training and other covariates were adjusted for, the relative risk of BUP initiation rate was 2.73 (95% confidence interval [CI] = 0.62 to 12.0, p = 0.18). Similarly, the number of unique attendings who initiated BUP increased modestly 7/53 (13.0%) to 13/57 (22.8%, p = 0.10) after offering just-in-time training during the implementation period. The rate of naloxone prescribed at discharge also increased (6.5% preimplementation and 11.5% implementation; p < 0.01). The intervention received a system usability scale score of 82.0 (95% CI = 76.7 to 87.2).

Implementation of user-centered CDS at a single ED was feasible, acceptable, and associated with increased rates of ED-initiated BUP and naloxone prescribing in patients with OUD and a doubling of the number of unique physicians adopting the practice. We then implemented this intervention across several health systems in a trial to assess its effectiveness, scalability, and generalizability.
ACKNOWLEDGEMENTS

Dr. Edward Melnick was the student’s mentor and thesis advisor. He mentored and guided the student in his research starting in the summer of 2019 to present (2024). The larger randomized controlled trial on which this thesis is based was led by Dr. Melnick and he contributed significantly to all of the research conducted by the student throughout his time as a Yale Medical Student. His time and efforts are greatly appreciated. The student was supported during the summer of 2019 during which much of this thesis work took place by the Yale First Year Summer Research Fellowship.

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INTRODUCTION

At the time this study was conducted, it was estimated that 2.1 million people nationally suffered from opioid use disorder (OUD), contributing to nearly 50,000 overdose deaths annually [SAMHSA, Scholl 2018]. There were 605,000 opioid-related emergency department (ED) visits in 2011 [SAMHSA, Drug Abuse Warning Network, 2011] and a 30% increase in opioid overdose-related visits between 2016 and 2017 [Vivolo-Kantor 2018]. The type of opioid involved was also changing, highlighted by an increase of 72.2% in death rate due to non-methadone synthetic opioids such as fentanyl between 2014 and 2015 [Rudd 2016]. Amidst the opioid epidemic, the ED has emerged as a major and increasingly utilized setting for OUD treatment. People with OUD not only seek emergency care in high-acuity situations like overdose and withdrawal, but also for comorbid or general health issues [D’Onofrio 2018]. Given the stigma associated with OUD, the ED may serve as the primary access to health care for this vulnerable patient population [D’Onofrio 2018, Olsen 2014]. Thus, the ED provides a unique opportunity to initiate appropriate treatment for OUD [Duber 2018, Doran 2018, Houry 2018]. This opportunity had already been realized to some extent, with a 2020 systematic review of opioid overdose interventions in the ED grouping ongoing interventions into four main categories: 1) providing a combination of take-home naloxone and overdose education, 2) psychosocial interventions such as motivational interviewing, 3) medication safety interventions to increase knowledge regarding overdose risk, and 4) buprenorphine/naloxone initiation in the ED [Chen 2020].
This last intervention, buprenorphine-naloxone treatment initiation in the ED, was the focus of this project. Buprenorphine/naloxone, henceforth referred to simply as buprenorphine (BUP), is a combination of the partial opioid agonist buprenorphine and the opioid antagonist naloxone (to discourage parenteral administration) that has shown promise as a maintenance therapy for OUD [Orman 2009]. Not only has BUP been shown to reduce mortality, but also has the potential to reduce withdrawal symptoms, craving, and future opioid use [Sullivan 2008], Larochelle 2018].

A 2014 meta-analysis that included 31 randomized controlled trials involving 5430 participants evaluated buprenorphine in comparison to both placebo and methadone as maintenance treatment for opioid use disorder in terms of treatment retention and reduction in illicit drug use, criminal activity, and mortality. Buprenorphine was found to be superior to placebo in treatment retention at doses greater than 2mg, with larger doses required to produce a significant effect for other outcome measures. Compared to methadone, buprenorphine administered at fixed medium and high doses were as effective as methadone in all outcome measures, including treatment retention and suppression of illicit drug use [Mattick 2014].

The effectiveness of BUP for the treatment of OUD extends to the ED setting, as demonstrated in a 2015 trial comparing engagement in addiction treatment at 30 days for three interventions: 1) screening plus a simple referral for treatment in the form of a handout with local services and contact information, 2) screening plus a brief intervention in the form of a 10-15 interview plus a facilitated treatment referral more directly linking patients to services while also accounting for service eligibility, patient insurance, and transportation, and 3) screening plus brief intervention plus treatment with BUP plus
scheduled primary care follow-up within 72 hour and then every two to four weeks.

Patients who received BUP in the ED were significantly more likely to be engaged in addition treatment at 30 days compared to those randomized to the simple referral group (78% vs. 37%) or the brief intervention plus facilitated referral group (78% vs. 45%). Similarly, patients who received BUP had significantly fewer days per week of illicit opioid use compared to both other groups (p<0.001) [D’Onofrio JAMA 2015].

Despite the high-quality evidence supporting BUP as an effective treatment for OUD and feasibility to initiate in the ED, adoption of BUP initiation into routine emergency care was slow to replace the existing standard of care which historically included symptomatic treatment for opioid withdrawal symptoms and referral for addiction treatment without addressing the underlying disorder [D’Onofrio 2018, Duber 2018, Houry 2018]. Furthermore, the rate of naloxone prescription upon ED discharge following nonfatal overdose remained low even as an evidence-based practice known to decrease mortality and risk of future overdose [Larochelle 2018, Samuels 2019]. Just as the ED is a unique setting to increase rates of BUP initiation, it is also an opportunity to implement other harm reduction strategies such as naloxone prescribing [Gunn 2018].

Numerous patient-side barriers currently limit the adoption of BUP initiation, including confusion and cultural stigma surrounding medication therapy for OUD and patient perceptions that such treatment is harmful, inferior to detoxification, and even incompatible with being truly “drug-free” [Schwartz 2008, Uebelacker 2016, Luty 2004]. The lack of adoption of ED initiation of BUP into routine emergency care has been attributed to emergency clinicians' lack of training in addiction treatment and
perception that BUP initiation is unfamiliar, complicated, and time-consuming [D’Onofrio 2018, Volkow 2014]. In fact, a 2019 survey of emergency physicians from two urban, academic EDs found that fewer than half of respondents felt prepared in several components of OUD emergency care. Only 39% of physicians self-rated themselves as prepared to determine the level of care needed by an OUD patient, while 29% felt prepared to connect OUD patients with outpatient treatment. Of all surveyed components, emergency physicians felt least prepared to actually initiate BUP, with only 27% self-reporting themselves as prepared [Lowenstein 2019].

One potential solution previously shown to provide effective guidance for drug therapy is clinical decision support (CDS), computerized systems that provide patient-specific guidance. A systematic review of sixty-five randomized controlled trials published in or prior to 2010 studied the effect of CDS on either process of care or patient-level outcomes for drug therapy management compared to standard care provided in the absence of CDS. Although CDS was associated with increased process of care performance in 64% of studies evaluating process of care, it was only associated with improved patient outcomes in 21% of trials investigating patient-level outcomes [Hemens 2011]. A second systematic review reported similar findings, in that CDS was associated with better clinician performance in 64% of studies that assessed the outcome of provider performance but only a 13% improvement in patient outcomes in the studies assessing patient-level measures. Additional conclusions of this review were that CDS systems which automatically assisted or prompted users (rather than user-activated decision support) and CDS interventions developed by the study authors were associated with improved performance on a provider level [Garg 2005].
Further evidence suggesting that CDS can lead to practice change stems from a 2005 systematic review of seventy studies which found that CDS significantly improved clinical practice in 68% of included trials evaluating this outcome. The review also identified four CDS features that were independent predictors of improved clinical practice: 1) automatic provision of decision support within physician workflow, 2) provide such support at the time and place decision making occurs, 3) provision of concrete and actionable recommendations, not assessments, and 4) computer generated. Of the included studies that evaluated a decision support system that possessed all four of these features, 94% were associated with significant improvements in clinical practice [Kawamoto 2005].

Incorporating many of the aforementioned features in an effort to simplify, address barriers to, and increase practice adoption of ED-initiated BUP as part of routine emergency care, our research team developed a user-centered CDS called EMBED (EMergency department-initiated BuprenorphinE for opioid use Disorder). The user-centered design of EMBED included five prototypes that were modified according to feedback from relevant stakeholders, including emergency medicine attending and resident physicians. Stakeholders were given the opportunity to share their needs in terms of workflow and information, which were incorporated into each subsequent design until a final, flexible and easy-to-use design was created which satisfied a range of users’ needs and experience levels with the process of initiating BUP [Ray2019]. To assess the feasibility of implementation and to evaluate the preliminary efficacy of the intervention to increase adoption of ED initiation of BUP, it was implemented in a single ED as the intervention in this interrupted time series study. The lessons learned from this pilot
study, particularly the qualitative feedback regarding intervention improvement, could be applied to the subsequent pragmatic group randomized trial involving 21 EDs across five health care systems [Melnick 2019].

STATEMENT OF PURPOSE

The primary hypothesis of this pilot study was that implementation of the EMBED CDS intervention would increase the rate of patients presenting to the ED with OUD who received BUP either in the ED and/or prescribed at discharge.

Secondary hypotheses of this study were: 1) implementation of EMBED would increase the number of emergency physicians who initiated BUP in the ED for a patient with OUD at least once during the study period, 2) rates of referral to follow-up for ongoing OUD treatment would increase, and 3) naloxone prescription rates at discharge for patients with OUD would increase.

In addition to testing the above hypotheses, the main aim of the EMBED pilot study was to evaluate the intervention’s potential efficacy to increase the practice of BUP initiation in the ED. Another aim was to obtain early feedback in the form of qualitative interviews that could be used to improve the intervention and guide its implementation (as well as its use by emergency physicians) in other EDs in the subsequent randomized trial.
METHODS

a) STUDENT CONTRIBUTIONS

The student contributed to the design of the pilot study in terms of delineating the date cutoff between the implementation phase and maintenance phase. The preimplementation phase began in April 2018 and ended in February 2019 when the EMBED CDS intervention became fully functional in March 2019. The student began summer research in June 2019 and was actively involved with the research team and the ongoing pilot study through August 2019, when the implementation phase ended and the maintenance phase began in September 2019. The student was solely responsible for the just-in-time training that occurred in the second half of the implementation phase. The student created the structure and template for the qualitative interviews with ED attendings to collect feedback on the intervention. He organized the qualitative data, identified salient themes, and shared the findings with the other members of the research team for the purpose of improving the intervention and streamlining its implementation at other sites during the multi-site randomized trial that was to follow. He was responsible for creating the qualitative feedback and RE-AIM framework tables that were submitted along with the final publication resulting from the pilot study. Additionally, he was primarily responsible for writing the bulk of the manuscript which was iteratively edited and revised with the help of the student’s thesis mentor, Dr. Edward Melnick. Although the student did not directly perform the quantitative data analysis, he was actively involved with the data team, meeting with them regularly and communicating with them as to what specific analyses were needed and desired for the manuscript.
The student’s thesis advisor, Dr. Edward Melnick, supervised the student throughout the research process and was always available for guidance and support. He was ultimately in charge of not only the pilot study, but the larger EMBED randomized trial which he lead. He assisted the student in study design and with deciding which measures to include in the qualitative interviews (e.g., system usability scale, Net Promoter Score). He regularly met with the student to discuss ongoing qualitative data collection and progress with manuscript writing along with associate research scientist Bidisha Nath, who worked closely with Dr. Melnick, the student, and the team during the pilot study and beyond. The data and statistics team consisted of Fangyong Li, Kaitlin Maciejewski, Hyung Paek, James Dziura, Haseena Rajeevan, and Charles Lu. Data and statistics team members were responsible for quantitative electronic healthcare record data extraction and performed the statistical analyses requested by the student and the rest of the research team. They met regularly with the student, Dr. Melnick, and other team members to discuss ongoing and desired analyses, troubleshoot and brainstorm solutions or explanations to encountered issues, and contributed to writing of the data analysis subsection of the methods section in the final publication. All authors, including Gail D’Onofrio and Liliya Katsovich reviewed the manuscript and offered edits, input, and feedback that were incorporated prior to submission for publication.

b) ETHICS STATEMENT

All research presented in this thesis was conducted ethically and responsibly, protecting subject anonymity and occurring within the bounds of institutional review board approval. Subjects neither experienced nor were exposed to any potential harm.
c) HUMAN SUBJECTS RESEARCH

This pilot study and associated protocol was approved by our institutional review board (Protocol 2000022749). Modifications to the study protocol, such as the addition of qualitative interviews and just-in-time training, were submitted and subsequently approved. A waiver for patient informed consent was obtained because data were retrospectively collected, did not involve patient interaction, and did not involve any identifiable patient information. Demographic data for attending emergency physicians at the study site eligible for inclusion were not collected in order to avoid the disruptive burden of the consent process on routine emergency care. Ultimately, an honest broker removed all patient and physician identifiers from electronic health record (EHR) data so that no identifying information was shared with the research team. Qualitative interviews preserved physician anonymity by only recording interviewed physicians’ names in a single, secure location, and not sharing that data with any other members of the research team, including those involved in data analysis. Attending physicians reporting that they had or had not used the intervention was not used in any way that could affect quantitative analysis.

d) LABORATORY ANIMALS

No laboratory animals were involved with the research presented in this thesis, only human subjects.
e) METHODS DESCRIPTION

Study Design and Setting:

A single-site time series study evaluating the preliminary efficacy of the EMBED intervention was conducted during April 2018 to December 2019 in an urban, academic Level I trauma center ED with 103,000 annual patient visits. The time series was divided into three phases for analysis: 1) preimplementation phase (April 2018–February 2019), 2) implementation phase (March 2019–August 2019), and 3) maintenance phase (September 2019–December 2019). The phased rollout of the CDS intervention began with a soft go-live in mid-January 2019. Users were then made aware of the CDS’s availability when full functionality was achieved in early March 2019. Provider feedback on the CDS was collected in the implementation phase to assist with planning the subsequent trial. The study protocol was reviewed and approved by our institutional review board (Protocol 2000022749).

Subjects:

Eligible patients were adult ED patients meeting the criteria of a computable phenotype derived from EHR data that was developed to capture ED patients likely to have OUD and not actively on medication for OUD (MOUD, i.e., methadone, BUP, or naltrexone) [Chartash 2019]. The phenotype is comprised of two algorithms: one based on clinician and billing codes (Algorithm 1) and the other based on structured EHR data of the chief complaint (Algorithm 2). Additionally, the phenotype excludes patients who are admitted to the hospital or pregnant. In this way, the phenotype was designed to
maximize specificity in identification of patients eligible for BUP initiation. Development, internal validation, and external validation of the phenotype occurred across two large health care systems containing 13 EDs. The phenotype has an externally validated positive predictive value of 0.95 and a negative predictive value of 0.92 [Chartash 2019]. A waiver of informed consent was obtained given that data were only collected retrospectively and did not involve patient interaction or identifiable information. Regarding clinician subject inclusion criteria, attending ED physicians practicing at the intervention site who cared for the phenotype-positive patients were eligible for inclusion. Given the additional burden of the consent process and to ensure the validity of the intervention's efficacy on changing routine care, clinician demographic information was not collected [Melnick 2019, Suffoletto 2018]. Therefore, all patient and physician identifiers were removed from EHR data by an honest broker and not shared with the investigative team. As a result of this deidentification process, it was not possible to match physician study data to our faculty roster to determine which physicians had an X-waiver to prescribe BUP. Therefore, a separate emergency medicine faculty roster was used to determine the proportion of physicians with an X-waiver (Figure 1).
Figure 1. Unadjusted patient and physician outcomes in the preimplementation, implementation, and maintenance periods. BUP=buprenorphine


Intervention:

The study intervention included an integrated Web application for decision support and automation of EHR workflow that streamlines the practice of initiating BUP in the ED (Figure 2). Full details of the intervention's design and IT integration have been previously reported [Ray 2019, Ahmed 2019, Melnick 2019 case study]. Briefly, the intervention is launched at the clinician's discretion for patients who they suspect may have OUD by clicking the “EMBED” button on the navigation bar of a patient's chart.
(the phenotype did not flag or alert clinicians of OUD cases). This opens a Web application within the EHR that offers three optional decision support tools to inform clinicians' selection of the appropriate care pathway through the diagnosis of OUD, assessment of withdrawal severity, and motivation of patient readiness to start treatment for OUD. The clinician can choose to use all, some, or none of these tools. Once the care pathway is selected, the Web application automates a series of EHR activities specific to that pathway including appropriate orders, prescriptions, documentation, discharge instructions, and referral to a community provider of MOUD.

Figure 2. Screenshot of EMBED with care pathways welcome screen within EHR workflow. EHR=electronic health record; BUP=buprenorphine

Early audits in the implementation period identified low intervention use despite targeted e-mail communication and group lectures. To enhance use, midway through the implementation period, 5-minute one-on-one tutorials were performed by the student to provide just-in-time training as an additional academic detailing component of the intervention. Compared to CDS alone, academic detailing combined with CDS has been shown to increase use when introducing a new CDS guiding medication therapy [Roberts 2010]. Used in both industry and medicine and usually occurring in a real-time work setting, just-in-time training is an approach that involves presenting relevant information for immediate application. [Chueh 1997, Jones 2001]. The just-in-time training that occurred during the later part of the implementation phase in this pilot study involved approaching attending physicians actively working on shift and first briefly explaining the EMBED intervention and probing their familiarity with the CDS. Whether familiar or not, the student offered to walk them through the CDS application using an example patient suspected of suffering from OUD and possibly benefiting from BUP. Physicians were shown where to find the CDS tool, how to launch the application, and provided an overview of the layout of the interface, including the tools and decision support offered (e.g., OUD diagnosis, COWS, motivational interview), including how each was optional. Next, the physicians were shown the process automation (e.g., order entry, discharge prescriptions, referral, etc) and how it could streamline their workflow without actually launching a specific care pathway that would result in a real patient receiving BUP or other treatment. Thus, no BUP initiation occurred during the just-in-time training itself.

Following this brief one-on-one training, physicians were asked to participate in a short qualitative interview to gather feedback. The semi-structured interview consisted of
three open-ended questions, System Usability Score (SUS), and Net Promoter Score (NPS). The three open-ended questions were designed to elicit feedback regarding improvements to the CDS intervention itself and changes or ways that could potentially increase its use during patient care. The SUS is a 10-item usability assessment that is widely used and considered the industry standard for rapid assessment of health IT usability; a score of >70 is considered “acceptable” [Brooke 2013, Johnson 2011].

NPS is a single-item measure of how likely an individual would be to recommend a product, company, or service to a friend or colleague [Reichheld 2003]. A convenience sample of attending physicians was used to for this just-in-time training paired with semi-structured interviews and physicians were compensated with a $10 Starbucks gift card for their participation. A formal qualitative analysis was not performed, but feedback on the CDS obtained through these interviews was synthesized and categorized according to common, recurring themes (Table 5).

Outcomes:

The primary outcome of this study was BUP initiation rate in the ED, defined as whether or not an eligible patient was administered BUP in the ED and/or prescribed BUP on discharge from the ED. Secondary outcomes to evaluate preliminary efficacy of the intervention's implementation included the attending physician adoption rate of the practice of ED initiation of BUP at least once in the study phase as well as the following patient-level rates in the cascade of care for treatment among eligible patients [Ahmed 2019, Kerkerian 2018]:

1) launch of the intervention, 2) referral to follow-up for
ongoing MOUD treatment as documented in the EHR, and 3) prescription for naloxone at ED discharge.

The RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework was also used to evaluate the success of the intervention [Glasgow 1999, Glasgow 2003, LeBlanc 2012]. The reach of the intervention—the proportion of the target population that participated in the intervention—was the proportion of unique attendings who ever launched the intervention. Effectiveness was assessed based on the rate of BUP initiation in the ED during the implementation period (the primary outcome). Adoption was based on the proportion of unique attendings who initiated BUP, and Implementation—the extent to which the intervention is implemented as intended—was the proportion of phenotype-positive patients for whom the intervention was launched. Maintenance was the rate of BUP initiation in the ED after training ended (September–December 2019).

f) STATISTICAL METHODS

Quantitative outcome data from the three study periods were extracted from the study site's EHR database using structured query language (SQL). The SQL query included all data elements specified in the master data dictionary created for the subsequent trial.

Patient characteristics were summarized as means and standard deviations (SDs) or frequencies and percentages as appropriate for the preimplementation and implementation periods. For patients with multiple visits, only the first visit was used to analyze patient-level outcomes. However, analysis of physician-level outcomes (i.e., BUP
initiation, launching the intervention) included multiple visits made by a single patient. T-tests and chi-square or Fisher's exact tests were used to make unadjusted comparisons of demographics, primary outcome rates of BUP initiation and secondary patient outcomes between periods. McNemar's test was used to compare the number of unique attendings who initiated BUP who were present during both the preimplementation and the implementation phases, while the generalized estimating equation method was used as a supportive analysis of all attendings (i.e., including those not present in both time periods). Following unadjusted analysis, a multivariate logistic regression model was used to adjust for age, race, sex, the number of waivered physicians, naloxone prescription within the past 24 months, and OUD diagnosis on problems list. To further contrast BUP initiation between study phases while “detrending” the time effect, Poisson regression was utilized for the interrupted time series adjusted analyses. For this analysis, an offset was used for the monthly volume of patients presenting to the ED with OUD. Relative risk and 95% confidence interval (CI) are reported, with values above 1 corresponding to greater relative rates of ED BUP initiation. Physician X-waiver status was used as a covariate in this analysis. All analyses were performed using SAS 9.4. Statistical significance was set as p < 0.05, two-sided.
RESULTS

Subject Characteristics:

Of the 141,014 total ED visits during the two study phases used for analysis of main outcomes, 906 (574 preimplementation and 332 implementation) met inclusion criteria for analysis. Of these 906 OUD phenotype–positive visits, 98 patients in total (11%) had more than one ED visit, including a maximum of four visits (of which four patients had). Across these two phases, patients had a mean age of 39.9 years, 31.2% were female, 71.7% were white, and 73.4% had Medicaid insurance (Table 1).

Table 1. Subject Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Preimplementation (n = 574)</th>
<th>Implementation (n = 332)</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td>40.2 (±12.6)</td>
<td>39.4 (±12.1)</td>
<td>0.34</td>
</tr>
<tr>
<td>Sex, n (% female)</td>
<td>172 (30.0)</td>
<td>111 (33.4)</td>
<td>0.28</td>
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<tr>
<td>Race</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Black or African American</td>
<td>90 (15.7)</td>
<td>43 (13.0)</td>
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</tr>
<tr>
<td>White or Caucasian</td>
<td>425 (74.0)</td>
<td>225 (67.8)</td>
<td></td>
</tr>
<tr>
<td>Characteristic</td>
<td>Preimplementation $(n = 574)$</td>
<td>Implementation $(n = 332)$</td>
<td>p-value</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-------------------------------</td>
<td>-----------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Asian, American Indian, or Alaska</td>
<td>2 (0.3)</td>
<td>6 (1.8)</td>
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<tr>
<td>Other</td>
<td>57 (9.9)</td>
<td>58 (17.5)</td>
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</tr>
<tr>
<td>Ethnicity</td>
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<tr>
<td>Hispanic or Latino</td>
<td>91 (15.9)</td>
<td>65 (19.6)</td>
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<tr>
<td>Non-Hispanic</td>
<td>481 (83.8)</td>
<td>264 (79.5)</td>
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<tr>
<td>Other</td>
<td>2 (0.4)</td>
<td>3 (0.9)</td>
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<td>Insurance information</td>
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<td>0.56</td>
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<td>BCBS or commercial</td>
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<td>22 (6.6)</td>
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<td>Managed care</td>
<td>35 (6.1)</td>
<td>15 (4.5)</td>
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<td>Medicaid</td>
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<td>Medicare</td>
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<td>35 (10.5)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>26 (4.5)</td>
<td>21 (6.3)</td>
<td></td>
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<tr>
<td>Characteristic</td>
<td>Preimplementation $(n = 574)$</td>
<td>Implementation $(n = 332)$</td>
<td>p-value</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>-------------------------------</td>
<td>----------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Phenotype</td>
<td></td>
<td></td>
<td>0.57</td>
</tr>
<tr>
<td>Algorithm 1</td>
<td>368 (64.1)</td>
<td>219 (66.0)</td>
<td></td>
</tr>
<tr>
<td>Algorithm 2</td>
<td>206 (35.9)</td>
<td>113 (34.0)</td>
<td></td>
</tr>
<tr>
<td>Naloxone prescribed during encounter as inpatient medication</td>
<td>24 (4.2)</td>
<td>17 (5.1)</td>
<td>0.51</td>
</tr>
<tr>
<td>Prescribed naloxone within past 24 months</td>
<td>30 (5.2)</td>
<td>27 (8.1)</td>
<td>0.08</td>
</tr>
<tr>
<td>OUD diagnosis on problems list at time of encounter</td>
<td>105 (18.3)</td>
<td>83 (25.0)</td>
<td>0.02</td>
</tr>
<tr>
<td>Urine drug screen</td>
<td>88 (15.3)</td>
<td>56 (16.9)</td>
<td>0.54</td>
</tr>
<tr>
<td>Positive for opioids</td>
<td>52 (59.1)</td>
<td>26 (46.4)</td>
<td>0.14</td>
</tr>
<tr>
<td>Positive for oxycodone</td>
<td>9 (10.2)</td>
<td>7 (12.5)</td>
<td>0.67</td>
</tr>
</tbody>
</table>

Data are reported as mean (±SD) or n (%). BCBS = Blue Cross Blue Shield

Primary Outcome:

The rate of BUP initiation (i.e., BUP administered in the ED and/or prescribed on discharge) was 3.5% (20/574) in the preimplementation phase and 6.6% (22/332) in the implementation phase (p = 0.03; Table 2, Figure 1). Compared to the beginning of the implementation period, the rate of BUP initiation was higher after just-in-time training was offered as an additional component of the intervention (7.9% vs. 4.9%, p = 0.28). After adjusting for age, race, sex, number of waivered physicians, naloxone prescription within the past 24 months, and OUD diagnosis on problems list, the odds of ED-initiated BUP was 1.83 in the implementation phase compared to preimplementation (95% CI = 1.03 to 3.25). BUP initiation relative risk adjusting for the same covariates as well as the time trend with Poisson regression were 2.73 (95% CI = 0.62 to 11.99, p = 0.18) for implementation versus preimplementation phase. Of note, the significant difference between BUP initiation rates in the implementation and preimplementation phase persisted with adjustment for time trend, age, race, sex, naloxone prescription within the past 24 months, and OUD diagnosis on problems list and was only lost after adjusting for X-waiver status over time.
Table 2. Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Preimplementation</th>
<th>Implementation</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 574</td>
<td>n = 332</td>
<td></td>
</tr>
<tr>
<td>Primary outcome</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUP administered in ED or prescribed on discharge</td>
<td>20 (3.5)</td>
<td>22 (6.6)</td>
<td>0.03</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription for naloxone at ED discharge</td>
<td>37 (6.5)</td>
<td>38 (11.5)</td>
<td>0.009</td>
</tr>
<tr>
<td>Receipt of discharge instruction on opioid use, overdose education,</td>
<td>218 (38.0)</td>
<td>115 (34.6)</td>
<td>0.32</td>
</tr>
<tr>
<td>naloxone education, and BUP education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral for ongoing MOUD</td>
<td>97 (16.9)</td>
<td>60 (18.1)</td>
<td>0.65</td>
</tr>
<tr>
<td>Number of unique attendings present in both phases who initiated BUP</td>
<td>14/58 (24.1)</td>
<td>16/58 (27.6)</td>
<td>0.65A</td>
</tr>
<tr>
<td>Outcome</td>
<td>Preimplementation</td>
<td>Implementation</td>
<td>p-value</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------</td>
<td>----------------</td>
<td>---------</td>
</tr>
<tr>
<td>Rate of physician intervention launched per 100 phenotype-positive patients</td>
<td>7.3 (4.8–9.8)</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

Data are reported as n (%) or mean (95% CI).

^ McNemar's test.


Secondary Outcomes:

More subjects received a prescription for naloxone at discharge from the ED in the implementation period (37/574, 6.5% vs. 38/332, 11.5%, p < 0.01, Table 2). The rate of referral for ongoing MOUD treatment was 16.9% (97/574) preimplementation and 18.1% (60/332) in the implementation phase (p = 0.65).

The number of unique attendings who were present in both study phases (inclusive of all physician participants, not just faculty on the roster used to determine X-waiver status) who initiated BUP did not change significantly from 14/58 (24.1%) in the preimplementation phase to 16/58 (27.6%) in the implementation phase (p = 0.65). After just-in-time training was added for the second half of the implementation phase, the number of unique attendings who initiated BUP increased from 7/53 (13.0%) to 13/57
(22.8%, p = 0.10; Table 3). The addition of just-in-time training was also associated with an increase in the proportion of unique attendings who launched the intervention in the implementation period (7/53, 13.0% vs. 15/57, 25.9%; p = 0.07).

Table 3. Effect of Training on Physician Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Before Training</th>
<th>After Training</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique attendings who initiated BUP</td>
<td>7 (13.0)</td>
<td>13 (22.8)</td>
<td>0.10</td>
</tr>
<tr>
<td>Unique attendings who launched CDS intervention</td>
<td>7 (13.0)</td>
<td>15 (25.9)</td>
<td>0.07</td>
</tr>
</tbody>
</table>


Evaluation of the intervention's implementation using the RE-AIM framework (Table 4) shows that it reached roughly 28% (19/68) of the target population (unique ED attending physicians who launched the intervention at least once), resulting in 32.3% of attendings adopting the practice of ED initiation of BUP. The rate of BUP initiation in the ED after training ended in the maintenance phase was 5.5% and associated with a decline in BUP initiation rates over time as displayed in Figure 1 (adjusted time trend of BUP
initiation relative risk of 1.19 (95% CI = 0.03 to 56.3; p = 0.93)) for implementation versus maintenance phase.

Table 4. RE-AIM Table

<table>
<thead>
<tr>
<th>Type of Outcome</th>
<th>Specific Outcome</th>
<th>Value (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>Unique attendings who launched the intervention at least once in the implementation phase.</td>
<td>19/68 (27.9%)</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Rate of BUP initiation in the ED (Implementation: Mar–Aug 2019).</td>
<td>22/332 (6.6%)</td>
</tr>
<tr>
<td>Adoption</td>
<td>Unique attendings who initiated BUP in the implementation phase.</td>
<td>16/68 (32.3%)</td>
</tr>
<tr>
<td>Implementation</td>
<td>Phenotype-positive patients for whom the intervention was launched in the implementation phase.</td>
<td>28/332 (8.4%)</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Rate of BUP initiation in the ED after training ended (Sep–Dec 2019).</td>
<td>11/208 (5.5%)</td>
</tr>
</tbody>
</table>

Qualitative Interview Feedback:

As shown in Table 5, categorization of qualitative feedback according to common themes revealed that the CDS decision support tools could be improved by tracking and displaying calculated scores (DSM-5, COWS, etc.), on the main screen for easy reference and automatically highlighting the best care pathway based on these scores. Additional suggestions included making the decision support tools more visible and clarifying that they are optional and not required to launch a care pathway. Regarding EHR workflow, a common area of feedback was to increase clarity of what happens when a care pathway is launched. Other interview feedback focused on the need to decrease confusion of the referral process, particularly details of the referral timeline, coordination with external providers, required next steps, and how to explain this process to patients. Additional miscellaneous suggestions include clarification of which features are available to providers without an X-waiver, increasing awareness of availability, continuation of one-on-one training to promote use, and addition of a feature alerting providers to possible OUD patients likely to benefit from BUP.

Of those interviewed, 23 responded to the System Usability Scale (SUS) and Net Promoter Score (NPS) questionnaire items. The mean SUS score was 82.0 (95% CI 76.7-87.2) and the NPS was +61, a score consistent with more respondents indicating they were promoters than detractors of the intervention.
Table 5. Qualitative Interview Feedback

<table>
<thead>
<tr>
<th>Topic</th>
<th>Barrier</th>
<th>Provider feedback for addressing barrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision</td>
<td>Calculated scores not displayed on main screen</td>
<td>-Application should display calculated score on main screen for reference</td>
</tr>
<tr>
<td>Support</td>
<td>Best care pathway not indicated</td>
<td>-Systematic narrowing of remaining care pathways based on decision support tool calculations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Best care pathway for patient should be highlighted</td>
</tr>
</tbody>
</table>
| Decision Support | Design and interface | - Increase visibility of decision support column and tools  
-Make it clear that steps flow in vertical (not horizontal) direction  
-Simplify/shorten text of COWS assessment  
-Clarify that decision support tools are optional and not required to launch a pathway  
-Decision support tool for readiness motivation should include a message/note stating that there is nothing to click |
<p>| Automated EHR Workflow | Uncertainty of what happens when a care pathway is launched | - Application should display a summary of automated orders sent and actions taken following each launch of a care pathway |</p>
<table>
<thead>
<tr>
<th>Referral Process</th>
<th>Referral process timeline unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-Application should specify or approximate date of referral visit</td>
</tr>
<tr>
<td></td>
<td>-Application should provide information on what happens next</td>
</tr>
<tr>
<td></td>
<td>-Applications should display length of time between discharge and referral visit so BUP can be prescribed for home if necessary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unclear how to explain referral process to patients</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-Application should provide instructions to give patient explaining referral process and next steps (e.g. does the referral center contact the patient following discharge?)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>X-Waiver</th>
<th>Confusion of which CDS features are available to unwaivered clinicians and how to proceed without a waiver</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-Application should provide a list of waived ED clinicians currently working who can sign a BUP prescription on behalf of an unwaivered clinician</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unfamiliarity</th>
<th>Unawareness of intervention availability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-Change CDS icon name from “EMBED” to something more obvious like “Buprenorphine”</td>
</tr>
<tr>
<td>Unfamiliarity</td>
<td>Lack of clinician understanding on how to use CDS</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Other</td>
<td>Mobility of computers is limited</td>
</tr>
<tr>
<td></td>
<td>CDS does not automatically identify patients with OUD</td>
</tr>
</tbody>
</table>


**DISCUSSION**

In this interrupted time series evaluating the preliminary efficacy of the EMBED intervention at a single site, implementation of a user-centered CDS with a brief, just-in-time training was associated with close to a doubling in the BUP initiation rate in the ED for patients with OUD and receiving a prescription for naloxone at discharge. The increased rate of BUP initiation remained significant after adjustment for all covariates other than physician X-waiver status over time. Given the ED's significant role in caring
for patients affected by the opioid epidemic, these results suggest that a user-centered, well-integrated CDS like EMBED may be an important component of an efficacious multi-faceted approach to increase adoption of an effective treatment for OUD.

Creation of a CDS with these capabilities was the result of the research team’s choice to employ a user-centered design process which involved identifying users' needs and incorporating their feedback in each phase of iterative prototype development [Ray 2019]. The value of user feedback and collaboration also motivated changes to the intervention. After it was discovered that intervention usage during the first half of the implementation phase was relatively low, one-on-one tutorials and qualitative data collection were added to the intervention to enhance its use and performance. The decision to incorporate training as part of the intervention turned out to be one of the study's strengths. Although not statistically significant, increased rates of the primary outcome with one-on-one training component suggests that this feature of the intervention is necessary to increase user recognition of its presence and value. The training component also leverages the science of “diffusion of innovations,” as a way to promote intervention adoption via communication and sharing by local champions and among colleagues within a social system [Dearing 2018]. To generate a tipping point for adoption through visibility and diffusion, this training feature was to be encouraged as an intervention component in the following randomized controlled trial to facilitate implementation at study sites. Despite the increase in BUP initiation associated with training, the sustainability of its effect is questionable. Data collected in the maintenance phase showed a decrease in the rate of BUP initiation over the months following the conclusion of the training period (Figure 1). Examining the sustainability of such training
as a long-term solution versus a transient benefit as well as its impact on intervention scalability could be an area of future work.

Although 93% of emergency medicine faculty had an X-waiver by the end of the preimplementation phase, the proportion of unique attendings who had adopted the practice of ED initiation of BUP was low (19.2%). In the implementation phase, the proportion of X-waivered physicians increased slightly to 97%. However, during the implementation phase, we observed a close to a doubling in the proportion of unique attendings who had adopted the practice of ED initiation of BUP (19.2% vs. 32.3%, p = 0.53). Although this increase was not statistically significant, it seems more clinically significant and suggestive that the barrier of X-waivered physicians actually adopting the practice of ED-initiated BUP may require a user-centered CDS with just-in-time training (rather than simply increasing X-waiver training). Similarly, although not statistically significant, the proportion of unique attendings who initiated BUP after we began just-in-time training nearly doubled. Taking all of these findings together, we now hypothesize that all three (X-waiver training, user-centered CDS, and just-in-time training) may have been necessary and complementary to increase adoption of ED-initiated BUP (at that time, when X-waiver was required).

As this was a pilot study for a larger randomized trial that is now complete, the results can be compared. In brief, the EMBED trial was a cluster-randomized pragmatic trial evaluating the effectiveness of a CDS (very similar to or slightly modified from the one used for the pilot study due to the different EHRs used by different study sites, etc) to increase the rate of BUP initiation for patients with OUD in the ED as well as to increase emergency physician adoption of the practice of ED-initiated BUP. It was conducted from
November 2019 to May 2021, beginning at the time the maintenance phase of the pilot study was underway. Compared to the relatively small sample size of the pilot study, the EMBED trial included 5047 eligible patients with OUD and 599 attending physicians across 21 EDs in five states randomized to either the intervention (CDS) or usual care arm according to cluster. The main findings of the EMBED trial generally parallel those of its pilot study. The EMBED CDS intervention did not significantly increase rates of BUP initiation at the patient-level compared to usual care (12.5% vs. 12.0%, p=0.58). However, similar to what was found in the pilot study, the EMBED intervention was associated with a significant increase in adoption of ED BUP initiation as a practice by emergency physicians, defined as physicians who initiated BUP for a patient with OUD at least once. While 34.0% of physicians initiated BUP at least once in the usual care arm, 44.4% initiated BUP at least once in the EMBED intervention arm (p=0.01) [Melnick 2022]. Although thought to be clinically significant, the increase in practice adoption of ED-initiated BUP did not reach statistical significance in the pilot study due to sample size limitations. With a substantially larger sample size and greater power of the EMBED trial, this increase in adoption rate was able to reach statistical significance.

Since the publication of results from the pilot study, a systematic review and meta-analysis in 2020 that included 122 trials, 30 of which reported clinical endpoints (analogous to patient-level BUP initiation in the case of EMBED), found that CDS systems only increased target measures by a median of 0.3%, with an interquartile range of -0.7 to 1.9%. Based on this and other analyses presented in the paper, the authors concluded that the majority of CDS interventions have a quite small effect on patient outcomes [Persell 2020]. This goes back to our earlier conclusion that a CDS
intervention such as EMBED may only be one component of a more comprehensive intervention that is required to increase patient receipt of BUP in the ED.

Shortly after this interrupted time series was published, a mixed-methods study of 268 providers, including attending physicians, resident physicians, and advanced practice clinicians, concluded that a minority (20.9%) felt highly ready to initiate BUP in the ED. The major barriers to ED-initiated BUP were the paucity of training and experience, linking patients to ongoing care for OUD, and limited time and/or resources in the setting of a busy ED [Hawk 2020]. Specific features of the EMBED CDS intervention are available address each of these barriers: the CDS can assist physicians feeling unprepared to initiate BUP by guiding them through OUD diagnosis, assessing withdrawal, and BUP dose selection; help clinicians with setting up a referral for ongoing OUD treatment; automating many of these processes as well as things such as order sets and discharge summaries to reduce the effort and time required to initiate BUP in a busy clinical setting [Ray 2019].

In light of the results of both the multi-site EMBED trial and the associated pilot study, it is clear that a CDS intervention alone may be inadequate to significantly improve patient outcomes in terms of ED BUP initiation for OUD and that there are likely additional barriers not (or incompletely) addressed by the intervention. Geographic constraints have been found to play a role in the ability of patients with OUD being able to follow-up with an outpatient BUP treatment facility even when they are started on BUP in the ED; for example, in the state of Michigan, only half (66/131) of the EDs are located within 10 miles of such a facility [Dora-Laskey 2022]. The challenge of
accessing continuing BUP treatment is only further exacerbated by those who rely on public transportation [Drake 2020].

Barriers to BUP initiation may also be impacted by patient race and ethnicity, as can be seen in the secondary analysis of the EMBED trial data examining racial and ethnic disparities in ED-initiated BUP. This analysis found that Black patients with OUD were less likely to receive BUP than White patients, although this difference lost statistical significance when adjusted for discharge diagnosis. Fewer Black patients were diagnosed with opioid withdrawal as a discharge diagnosis, which in itself may represent a systemic bias based on race that an objective computerized CDS would be thought to decrease [Holland 2023].

One barrier to adoption of ED-initiated BUP into routine emergency care that has been eliminated since the publication of the interrupted time series is that of the X-waiver training previously required to prescribe buprenorphine and other treatments for OUD. On December 23, 2022, the spending bill passed by Congress and President Biden for the fiscal year 2023 included the Mainstreaming Addiction Treatment Act, which did away with the X-waiver training requirement and quantitative prescription limits [Knopf 2022]. Given the recency of this policy change, its full effects on ED BUP prescribing remain to be adequately characterized. However, policy change in itself is unlikely to remarkably increase BUP initiation in the ED. A survey-based study published in July 2023 analyzing trends and barriers to BUP prescribing across a variety of clinical settings and types of X-waiver training found that the most common reason for not prescribing BUP since obtaining a waiver was simply lack of patient demand [Jones 2023].
CHALLENGES & LIMITATIONS

As mentioned previously, there are many barriers to adoption of ED initiation of BUP into routine emergency care. For example, the EMBED intervention did not address negative attitudes toward addiction, the inconvenience of obtaining an X-waiver to prescribe BUP (which is no longer required), the limited number of providers with an X-waiver, systemic or structural inequities (e.g., racial and ethnic disparities in BUP treatment), and access and availability to MOUD in the community (including geographic constraints). This study was also conducted in a single ED with a high rate of X-waivered physicians compared to nonacademic or rural EDs. Because physicians without an X-waiver were limited in their ability to prescribe BUP for home induction, this could have had an impact on the primary outcome of rates of ED BUP initiation. Another weakness of the study's design is that it was neither randomized nor controlled, so causality between the intervention and outcomes could not be established. Given the urgency of the opioid crisis, additional temporal trends could have occurred that were not adjusted and remained as confounders. The increase in X-waivered physicians, although identified and adjusted during analysis, is an example of one trend which alone could have impacted study results if overlooked. Finally, in an effort to avoid unintended consequences from a hard-stop alert that triggered the CDS, not all attending physicians utilized the intervention during the implementation phase [Powers]. As mentioned in the introduction, such automaticity was one of the key features of successful CDS interventions [Garg 2005, Kawamoto 2005]. Although the phenotype identified potentially eligible patients, the less interruptive nature of the intervention also meant that we did not collect data on actual presence or absence of OUD, withdrawal severity, and
readiness for treatment. Therefore, the full potential and effect of the intervention on various outcomes may be underestimated or inaccurate. Future research could explore alternative approaches to triggering the intervention in a nonobstructive manner and whether lack of a hard-stop alert represents another barrier to physician adoption.

**DISSEMINATION**

The findings of this interrupted time series study were published in the journal *Academic Emergency Medicine* in April 2020 [Holland 2020]. The associated abstract was selected for a “lightning oral” presentation at the 2020 Society for Academic Emergency Medicine National Meeting in Denver, Colorado. However, this meeting was ultimately cancelled due to COVID-19 and the presentation was instead recorded and posted online and is available virtually [Holland 2020 presentation].

As mentioned previously, a secondary analysis of EMBED trial data exploring racial and ethnic disparities in ED BUP initiation was also led by the student. Preliminary study findings were presented as a plenary presentation at the 2022 Society for Academic Emergency Medicine National Meeting in New Orleans, Louisiana by the student [Holland 2023 Presentation]. The final analysis and findings were published in the journal *Academic Emergency Medicine* in January 2023 [Holland 2023].

To assist in dissemination efforts of EMBED after conclusion of the randomized controlled trial, a qualitative research study aimed at identifying determinants of adoption, implementation, and maintenance of EMBED was published in 2023. These determinants were based on 28 interviews with emergency physicians, most of whom
were familiar with and/or had used EMBED, and included: 1) organizational culture and commitment, 2) clinician training and support, 3) the ability to connect patients to ongoing treatment, and 4) the ability to tailor implementation to each ED [Simpson 2023]. The student was a co-author on this publication.
REFERENCES


