EMBED Update: Challenges and Solutions

Ted Melnick MD, MHS  
Assistant Professor  
Informatics Fellowship Director

Gail D’Onofrio, MD, MS  
Professor  
Chair & Physician-in-Chief

NIH Collaboratory Grand Rounds  
December 13, 2019
Treatment of OUD in the ED: Is it Optional?
Why focus on the ED?

Because that’s where the patients are!

July 2016 – September 2017

30% Visits for Opioid Overdose

MMWR, March 9, 2018
What is the Evidence for ED-initiated BUP?

2015 RCT by D'Onofrio. et al. at Yale EM

Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence
A Randomized Clinical Trial

JAMA 2015;313(16):1636-1644

Engagement in Treatment at 30 days

<table>
<thead>
<tr>
<th>(A) Referral</th>
<th>(B) Brief Intervention</th>
<th>(C) Buprenorphine</th>
</tr>
</thead>
<tbody>
<tr>
<td>37%</td>
<td>78%</td>
<td>p&lt;0.001</td>
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NIDA 5R01DA025991
What is the Evidence for Inaction?

Larochelle, et al. (2018)

- N=17,568, 12 months post non-fatal OD, between 2012-2014
- 5% died within 1 year
- < 30% received MOUD TX
- significantly reduction in all-cause mortality with MOUD
Introducing EMBED

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

ClinicalTrials.gov Identifier: NCT03658642

Gail D’Onofrio, MD, MS
Professor, Chair, Department of Emergency Medicine, YSM

Edward Melnick, MD, MHS
Assistant Professor, EM; Director, Clinical Informatics Fellowship, YSM

NIH National Institute on Drug Abuse Advancing Addiction Science

Yale University School of Medicine
Teams and People

**DATA COORDINATION TEAM (DCC, Yale)**
- James Dziura, PhD, MPH
- Charles Lu
- Fangyong Li, MPH, MS
- Liliya Katsoyvich – PM
- Haseena Rajeevan, PhD
- Fan Li, MS, PhD
- David Chartash, PhD
- Molly Jefferey, PhD – Co-PI at Mayo Clinic

**LEADERSHIP/MANAGEMENT TEAM**
- Ted Melnick, MD, MHS - PI
- Gail D’Onofrio, MD, MS – Co-PI
- Bidisha Nath – Project Manager

**GRANTS TEAM**
- Theresa Ody niec- Budget, Finance
- Ann Criscuolo, Admin
- Shara Martel, Project Manager

**IT TEAM (Yale)**
- Cynthia Brandt, MD, MPH
- Allen Hsiao, MD – CMIO
- Yauheni Solad, MD, MHS
- Hyung Paek, MD
- **YNHH-Epic Analysts**
  - Nancy Rutski
  - Cheryl Brophy
  - Kristina Follo
  - Michelle DeWitt

**Summer Medical Students**
- Wesley Holland, MS2, YSM
- Jodi Mao, MS3, EVMS
- Osama Ahmed, MS3, YSM

**SYSTEMS**

**YALE-NEW HAVEN HEALTH SYSTEM**
* EHR Vendor: Epic
  - **Pilot Study Site:** Yale New Haven Hospital, York St Campus
  - **Trial Intervention Sites:**
    - St Raphael Campus;
    - Greenwich Hospital
  - **Control Sites:**
    - Bridgeport Hospital
    - Lawrence + Memorial Hospital

**Univereity of North Carolina Health System**
* EHR Vendor: Epic
  - **Intervention Sites:** Rex, Nash
  - **Control Sites:** Main, Chatham, Johnston-Smithfield
  - **PI:** Timothy Platts-Mills, MD, MSc
  - **Co-PI:** Mehul Patel, MS, PhD
  - **IT:** Edmund Finerty
  - **Data:** Bill Korey Ross, Emily Pfaff

**University of Alabama, Birmingham Health System**
* EHR Vendor: Cerner
  - **Intervention:** Gardendale
  - **Control:** Main Campus, Highlands
  - **Site PI:** Erik P. Hess, MD, MSc
  - **IT, Data:** Carolyn Williams

**University of Colorado Health System**
* EHR Vendor: Epic
  - **Intervention Sites:** UC Hospital AMC, Poudre Valley + Med Center of Rockies cluster
  - **Control Sites:** Memorial Central
  - **PI:** Jason Hoppe, MD
  - **IT, Data:** Sean Michael, MD
  - **Proj Coord:** Cheryl Napier

**Baystate Health System**
* EHR Vendor: Cerner
  - **Intervention:** Main Campus- Baystate Springfield; Baystate Wing; Baystate Mary Lane
  - **Control:** Baystate Franklin; Baystate Noble
  - **Site PI:** William Soares MD
  - **IT, Data:** Haiping Li
  - **IT - Tech Spring:** Christian Lagier
Intervention & Outcomes

- **Setting**: 20 Emergency Departments (EDs) across 5 healthcare systems

- **Intervention**: The intervention consists of a user-friendly, integrated IT intervention to support:
  1. Evaluation for OUD
  2. Assessment of withdrawal severity
  3. Motivation of patient willingness to start treatment
  4. Initiating buprenorphine
  5. Documentation of the care process
  6. Referral for ongoing treatment

- **Primary Outcome**: Initiation of BUP in the ED (administered and/or prescribed)
Background: UG3 Aims (Planning Phase)

- **UG3 Aim 1.** Develop a pragmatic, user-centered CDS for ED-initiated BUP and referral for MOUD 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.
UG3 Phase: Challenges & Solutions

BARRIERS

- Poor usability of HIT
- Complex protocol of BUP initiation

- Stigma, Unfamiliarity to BUP initiation protocol

- EHR limitation to identifying adult ED patients with OUD

- Limited capability of vendor provided CDS tool

- Lack of infrastructure for warm handoff from ED to community MOUD sites

- Growing Opioid crisis - need to find a timely solution

SOLUTIONS

- Direct observation and interviews of residents and physicians → Identified current gaps and needs in HIT

- Developed user centered CDS tool

- Developed and validated a two-algorithm phenotype → Flags potential OUD cases

- EHR-integrated web based application

- Meetings with ED physicians and community stakeholders → Developed automated, flexible, electronic referral system

- Original plan of Step-wedge study design → Parallel group-randomized trial design
User Centered Design:
To simplify the process of initiating BUP in the ED

From a complicated algorithm ... . . . to a simple, automated application
Clinicians continue in their current Epic workflow
2. Click the ‘EMBED’ button in the patient’s chart to launch the app.
App offers care pathways & patient assessment tools with the flexibility to use just the parts you need

Buprenorphine (BUP) Initiation
Do you have a waiver to prescribe Buprenorphine?

Decision Support
Use these optional tools in any order to help you decide

Don’t give buprenorphine if patient is intoxicated or has taken methadone within 72 hours.
Orders appear in an Epic ‘Shopping Cart’ that allows for easy de/selection.
After signing the orders, you can continue to use Epic.
EHR Phenotype – Derivation

- Identifies ED patients with OUD using
  
  A. Diagnostic/billing codes (Algorithm 1)
  
  B. EHR Based structured data elements (Algorithm 2)
EHR Phenotype – Validation

- **Validation** of EHR Phenotype - using physician chart review
  - High degree of validity across two healthcare systems

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<th>Reviewers -</th>
<th>Predictive Value (95% CI)</th>
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<td>PPV 0.96 (0.863-0.995)</td>
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<td>NPV 0.98 (0.893-0.999)</td>
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<td>PPV 0.8 (0.593-0.932)</td>
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<td>Phenotype -</td>
<td>0</td>
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EHR integration

Health System DMZ

- Epic EMR
- Web application
- CDS tools

Application launched in iFrame of Epic EMR and communication token is sent

postMessage with order preference ID & selected treatment pathway ID (flowsheet value)

Discharge Instructions
Referrals
Prescriptions
Notes
Orders

Populated in the EHR
Ethics / Regulatory

- Expert guidance from NIH Collaboratory core
- Protocol approved by Western IRB (WIRB)
- Waiver of informed consent under Common Rule 45 CFR 46.116
- Study Patients:
  - Deidentified
  - Not target of the intervention (minimal risk)
  - Do not interact with study directly, retrospective EHR data collection
- Control sites can still follow best practices
  - Patients can request MOUD
  - Physicians retain control over their practice
**UH3 Aims**

- **UH3 Aim 1.** Compare the effectiveness of user-centered CDS for BUP to usual care on outcomes in ED patients with OUD.
- **UH3 Aim 2.** Disseminate the EMBED intervention nationally.

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**EMBED TIMELINE**

<table>
<thead>
<tr>
<th>USER-CENTERED CDS DEVELOPMENT</th>
<th>YEAR 1</th>
<th>YEAR 2</th>
<th>YEAR 3</th>
<th>YEAR 4</th>
<th>YEAR 5</th>
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<tr>
<td>Workflow Analysis; Initial Prototype Development</td>
<td>Q1</td>
<td>Q2</td>
<td>Q3</td>
<td>Q4</td>
<td>Q1</td>
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<td>Usability &amp; Field Testing</td>
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<td>IT Build w/Local EHR Integration; Beta-Testing</td>
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<th>PLANNING PHASE</th>
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<tr>
<td>Finalize Participating Sites &amp; Protocols</td>
<td>Q1</td>
<td>Q2</td>
<td>Q3</td>
<td>Q4</td>
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<td>Finalize Enrollment Targets</td>
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<tr>
<td>Finalize Data Collection Methods; IRB Approvals</td>
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<td>Complete EHR Integration at All Sites</td>
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<td>Clinical Enrollment with Ongoing Data Management</td>
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<td>Local Formative Process Evaluation during Implementation</td>
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<td>Wide Scale Dissemination</td>
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<td>Final Data Analysis &amp; Publication</td>
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UH3 (Implementation Phase) – Progress so far..

- Finalize Master Data Dictionary, Codes
- Complete Data Validation
- Complete EHR Integration
- Check Site Readiness (Checklist)
- **Oct 31-Nov 14, 2019** - Trial Launched, Patient enrollment started
- First round of data collection – **Jan 15, 2020**

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**SITE INITIATION CHECKLIST**

**A. DATA**
1. Local SQL Query built ✔
2. Sample data sent to Yale ✔
3. Data meets validation requirements
   a. Automated review ✔
   b. Face Validity review ✔

**B. INTERVENTION:**
1. Intervention is live ✔
2. Referral is live ✔
3. Intervention has fidelity with goals to automate: ✔
   i. Note writing
   ii. Order entry
   iii. Prescription writing
   iv. Discharge notes
   v. Referral
4. Training: local detailing is coordinated at intervention sites ✔

**C. IRB COMPLIANCE**
1. Provider Notification: ✔
2. Posters: ✔
   i. Provider facing – posted in work station
   ii. Patient Facing – posted in waiting room
Publications related to EMBED Study


Thank you.
Questions?

Edward.Melnick@yale.edu
@Ted_Melnick

Gail.Donofrio@yale.edu
@DonofrioGail