NIH Collaboratory Rethinking Clinical Trials®
Health Care Systems Research Collaboratory

Closeout Data and Resource Sharing Checklist

Data and Resource Sharing Checklist

All NIH Collaboratory Projects will be expected to complete this checklist at closeout. The information provided in the checklist will be published in the Living Textbook on each Demonstration Project's page and on a Data and Resource Sharing page.

Data and Resource Sharing Checklist		
1. Study information		
Trial name and acronym: EMBED (Emergency Department–Initiated Buprenorphine for Opioid Use Disorder)		
Checklist completed by: Bidisha Nath, MBBS, MPH		
Date: July 14, 2022		
Link to ClinicalTrials.gov registration: NCT03658642		
Link to study website:		
2. Resource location		
Item	**Provide hyperlink or indicate if item will be stored in the KR**	**If item will not be shared, please provide a brief explanation for the omission**
Publications		
Link to protocol paper	https://bmjopen.bmj.com/content/bmjopen/9/5/e028488.full.pdf	
Link to main outcome paper	https://www.bmj.com/content/bmj/377/bmj-2021-069271.full.pdf	
Link to other study-related publications	Link to NIH Living Textbook page listing all publications: https://rethinkingclinicaltrials.org/demonstration-projects/ug3-project-pragmatic-trial-of-user-centered-clinical-decision-support-	

	to-implement-emergency-department-initiated-buprenorphine-for-opioid-use-disorder-embed/	
Study tools		
Final version of the protocol, including summary of changes	**Link to final version of EMBED Protocol:** **Summary of Protocol changes requested –** **1. 4/19/20 – Amendment to collect additional data related to COVID.** With onset of COVID-19 pandemic in Mar 2020, we requested this amendment so that, leveraging the EMBED Trial data collection infrastructure, we could evaluate the impact of COVID-19 pandemic on utilization of ED services by the OUD patients (EMBED Trial's target population) and other population in general. Under this amendment we requested change in Phenotype SQL codes such that it will no longer exclude admitted patients and patients already on MOUD to collect a more comprehensive sample of ED patients with OUD. However, this change was done to conduct a secondary analysis to evaluate impact of COVID. The phenotype remained unchanged for the trial itself. **Articles coming out of COVID Study:** a) Emergency Department Visits for Nonfatal Opioid Overdose During the COVID-19 Pandemic Across Six US Health Care Systems b) Trends in Emergency Department Visits and Hospital Admissions in Health Care Systems in 5 States in the First Months of the COVID-19 Pandemic in the US **2. 6/16/20 – Amendment to allow change in PI at two EMBED health systems UAB and UNC.** Dr Erik Hess, MD (Site PI for UAB) left UAB to join Vanderbilt University (erik.hess@vumc.org). Dr Lauren Walters, MD is the new Site PI for UAB. **Change in PI for UNC:** Dr Tim Platts-Mill, MD (Site PI for UNC) left UNC. Dr Martin Casey took over his position and because the new Site PI for UNC. No other change was made to the protocol. **3. 12/4/20 – Amendment to collect additional Physician Level data for EMBED Trial.** In this amendment we requested WIRB approval for *collecting additional deidentified demographic data (specifically gender and age) for ED physicians at the EMBED Trial study sites*. The remainder of the EMBED Trial protocol remains unchanged. **Background for requesting additional demographic data for physicians:** In discussion	

	with the study Independent Study Monitor, Dr. Marek Chawarski, PhD, the addition of physician demographic data related to physician participants was suggested to strengthen the analysis and findings related to use of the intervention. Originally we had approval for a waiver of informed consent for collecting deidentified data on individual physician's behavior of prescribing or administering Buprenorphine in the Emergency Department for patients with Opioid Use Disorder with or without using the trial intervention ie, the EMBED CDS to facilitate Buprenorphine initiation in the ED. Given that the additional data collected was deidentified, it did not pose any additional risk to change the waiver status.	
Consent documents or consent process	Waiver of consent was obtained for this study. Hence no consent.	
Computable phenotypes for outcome measures	The outcome measures for EMBED Trial were not obtained from a computable phenotype per se, and can be found listed on the trial manuscript.	
Computable phenotypes for the inclusion/exclusion criteria	https://medinform.jmir.org/2019/4/e15794/ The above is the link to our phenotype article which has all the details about the phenotypes for inclusion/exclusion criteria.	
Code for generating variables in the analytic dataset from standard sources	EMBED SAS code	
Datasets and documentation		
Annotated data collection forms	EMBED Data Submission Specs	
Link to public use dataset	We have uploaded our final dataset and data dictionary to ICPSR (Inter-university Consortium for Political and Social Research) via NAHDAP (National Addiction & HIV Data Archive Program). It is currently in queue and has not become public yet. We will share the link when available.	
Data dictionary (proc contents) for public use dataset	EMBED Data Dictionary	
Other resources		