

Plan Overview

A Data Management Plan created using DMPTool

Title: Data-Driven Approaches for Opioid Use Disorder Treatment, Recovery, and Overdose Prevention in Rural Communities via Mobile Health Clinics and Peer Support Services

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Project abstract:

Over 100,000 lives were lost due to drug overdose in the past year, of which 80% involved opioids. Despite the effectiveness of medications for opioid use disorder (MOUD) at reducing opioid misuse and risk of overdose, only 10% of people in need receive treatment. Moreover, treatment retention is low (30-50%) with half of patients experiencing an opioid use recurrence. Peer support specialists (PSSs), who are individuals with direct experience with and successful recovery from Substance Use Disorder, can offer social support and directly address treatment and recovery barriers for individuals with Opioid Use Disorder (OUD). Our systematic review showed that OUD patients receiving a PSS intervention were more likely to initiate MOUD, but evidence of effectiveness for MOUD retention or opioid use remain inconclusive. Low treatment initiation and retention rates for OUD are especially concerning for rural populations and underserved communities, who rarely have access to clinicians who can prescribe MOUD and experience substantial barriers to care, including limited social support, lack of insurance, homelessness, transportation issues, and stigma. Given that these populations are also at an elevated risk of opioid overdose due to many of these same factors, interventions to increase OUD treatment, retention, and overdose prevention in rural and medically underserved communities are urgently needed. Mobile health clinics (MHC) are an effective and versatile tool for timely delivery of interventions, including those for OUD treatment, to medically underserved and at-risk communities. However, effective intervention delivery for

OUD treatment initiation, retention, and overdose prevention have not been explored in MHC settings. **The goal of our proposal is to increase MOUD treatment initiation, treatment retention, and prevent overdose deaths in medically underserved communities (via MHC)** through development, testing, delivery, and evaluation of an innovative 1) PSS intervention to increase MOUD initiation and retention rates in rural and underserved populations and 2) modeling framework to prioritize at-risk communities for MHC delivery (based on overdose deaths prevented). Research has shown that such modeling frameworks can drastically increase the efficiency of resource allocation efforts for other diseases. The PSS intervention and modeling framework will be developed in the R61 phase (R61 Aims 1 and 2) and implemented in the R33 phase to systematically deliver MHCs with PSS services to the highest priority communities (identified via modeling) in South Carolina (SC) in order to increase MOUD treatment initiation, retention, and overdose prevention. In the R33 phase, we will conduct a randomized controlled trial (RCT) to evaluate the effectiveness of the PSS intervention component (R33 Aim 1), and extend our modeling framework developed in the R61 phase in order to a) evaluate the population impact and cost-effectiveness of the PSS intervention on preventing fatal overdose (R33 Aim 2a) and b) explore improvements to MHC protocols in order to increase effectiveness of MHC-based interventions for OUD (R33 Aim 2b). With opioid overdose deaths doubling over the past 2 years nationally and in SC, there are no signs that the epidemic is slowing down. Our sustainable framework has potential to prevent hundreds to thousands of opioid overdoses in SC alone, and can be scaled up in other regions to save many more lives.

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Data collection will be performed at MHC located in rural settings with underserved populations with OUD.

This project will produce data collected from qualitative interviews and surveys with PSS and OUD patients and pilot data. Data will be pooled from approximately 75 interviews using a cross-sectional design with both open-ended, free response qualitative questions and Likert-scale, quantitative survey questions. Using aggregated data, we anticipate a validated intervention protocol with demonstrated acceptability, fidelity, and efficacy for MOUD initiation and retention outcomes.

Using integrated health system, statewide, and publicly available data sources, we will establish real-time surveillance and population-specific epidemiological measures which will be incorporated into a dynamic modeling framework to predict which communities will benefit most from MHC services.

A web-based, direct data entry and management system (RedCap) will be used to collect and manage data. All data will be entered into RedCap without personal identifiers, and source documents will identify participants by study ID. Access to computers used for data entry, management, and analysis will be password protected and limited to the study personnel. Data control procedures will be conducted for all data collected. Data quality monitoring will be facilitated with periodic downloads using SAS. The data manager will provide descriptive reports to the multiple PIs monthly until study procedures have ceased.

Aggregate participant data, study protocols, and data collection instruments will be made accessible to facilitate interpretation of data.

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Question not answered.

All data and related documentation/tools that can be shared will be exported and/or shared and stored in the NIMH Data Archive repository.

NIMH Data Archive repository will be linked to the HEAL Ecosystem, which provides searchable study-level metadata for dataset discovery. NIMH Data Archive assigns DOIs as persistent identifiers, and has a robust preservation plan to ensure long-term access. Data will be discoverable online through standard web search of the study-level metadata as well as the persistent pointer from the DOI to the dataset.

Once the study is completed, results will be uploaded to clinicaltrials.gov. Results will be submitted no later than 1 year after the completion date (referred to as the primary completion date) in accordance with NIH regulations. All participants will be informed in the informed consent form that information about the study, and study results, when obtained, will be available on clinicaltrials.gov.

To help the dissemination of our study results, we will present the results from this proposed study at at least two national conferences: The College on Problems of Drug Dependence and the American Psychological Association. We will also share the results of this study at the statelevel through the SC Governor's Opioid Summit. Additionally, we will present results locally through departmental meetings as well as at conferences.

The results of this study will also be disseminated through papers published in high impact journals. All final peer-reviewed manuscripts resulting from the proposed clinical trial will be deposited in PubMed Central.

There are no anticipated factors or limitations that will affect the access, distribution or reuse of the scientific data generated by the proposal.

Data will be submitted and stored in the NIMH Data Archive. The repository requires an NDA user account creation or login and submission of a data access request.

Per the NDA, they have the following types of groups that may access data; "Broad Use Permission Groups consist of one or multiple NDA Collections that contain data that all have consented for broad research use. Controlled Access Permission Groups consist of one or multiple NDA Collections that contain data with the same subject consent-based data use limitations. Open Access Permission Groups consist of one or multiple NDA Collections that contain data that all have been consented for broad research use and can be accessed by users who are not affiliated with an NIH-recognized research institution." U.S. Department of Health and Human Services. (n.d.). NDA - Getting Access to Shared Data. National Institutes of Health. <https://nda.nih.gov/nda/access-data-info>

In order to ensure participant consent for data sharing, IRB paperwork and informed consent documents will include language describing plans for data management and sharing of data, describing the motivation for sharing, and explaining that personal identifying information will be removed.

To protect participant privacy and confidentiality, shared data will be de-identified.

Once we receive the approval from the Institutional Review Board and prior to initiating any study procedures, we will register this study on clinicaltrials.gov. The PIs (Rennert and Litwin) will be the contact persons regarding the study. The PIs will be responsible for keeping the information updated in clinicaltrials.gov.

A Data Submission Agreement (DSA) will be completed and submitted within six months of the Notice of Award issue date. De-identified data will be shared through the NIMH Data Archive (NDA). A list of data items to be collected in the project and the clinicaltrials.gov NCT number will be submitted in the Data Expected Tab of the NDA Collection within six months of the Notice of Award issue date. All data will be deposited within the second submission cycle from the Notice of Award and submitted every cycle thereafter.
