CTN-0116: Implementing a Pharmacist-Integrated Collaborative Model of Medication Treatment for Opioid Use Disorder (PharmICO)

BRIEF STUDY OVERVIEW

BACKGROUND AND SIGNIFICANCE

There is evidence that pharmacists in the U.S. are prepared and positioned to expand the provision of care for Opioid Use Disorder (OUD) to levels that have not been realized by other combinations of efforts to address the opioid epidemic. Important contributions have been made by community pharmacists in prescription opioid screening, prescription management, patient education (including brief educational interventions) and treatment referrals, but practice models that fully incorporate and leverage these capabilities are developing too slowly. Although studies have engaged pharmacists in dispensing medication treatment for OUD (MOUD), few studies have evaluated collaborative care models in which pharmacists are an active, integral part of an OUD care team. As "today's medication-use leaders", pharmacists are well-positioned to extend their role, beyond offering siloed consultative services, to creating truly integrated approaches to managing patients' medication needs across a care continuum. Indeed, integrated clinical teams have been among the most successful models of care for OUD. When pharmacists engage in patient care to their full capacity, physician time can be saved, access to care is expanded, clinical outcomes may improve, and payers may view the economic implications more favorably. In addition, pharmacists may be available to participate in new roles that support providers given an anticipated 35% expansion in the pharmacist workforce by 2025.

One model of pharmacist-integrated care for MOUD was systematically developed by an interdisciplinary team led by pharmacist Dr. Felicity Homsted and psychiatrist Dr. Trip Gardner at Penobscot Community Health Care (PCHC; a system of federally qualified health centers comprising 15 sites and serving approximately 70,000 patients across Maine). In this standard care model of **P**har**r**macist-**I**ntegrated **M**edication treatment for **O**UD (PrIMO), an integrated primary care clinical team, including primary care physicians, psychiatrists, nurse practitioners, behavioral health clinicians, pharmacy staff, work collaboratively in offering a full continuum of healthcare to persons with OUD. In this model, the pharmacy staff's role is not limited to medication preparation/dispensing but rather they engage in all key team activities at the primary care site as an embedded care team member, including meeting with patients at the clinic, in addition to the dispensing role performed within the pharmacy. In this process, they bring their in-depth knowledge about MOUD to the primary care setting and provide detailed education to patients about these medications. In so doing, pharmacists help to engage/retain patients in OUD care and, importantly, increase capacity to introduce/maintain OUD care in primary care. The pharmacists also regularly participate in team clinical meetings ("team huddles") at the primary care site as an embedded member of the primary care team. And, they may help advise on medication induction; transition from a long-term prescription opioid to buprenorphine; medication interactions and/or precautions and the medication management of adverse events and withdrawal; insurance coverage, cost associated with medication, coordination of prior authorizations; and other chronic disease care (e.g., Hepatitis C co-management; naloxone training; mental health medication co-management; vaccinations; smoking cessation; contraception; STDs).

BRIEF PROJECT SUMMARY

This project will implement the PrIMO model at four diverse sites across the US. We will employ a longitudinal mixed-methods approach to evaluate the feasibility, acceptability, and impact of implementing this model at the four sites.

The **primary aim** of this study is to evaluate the feasibility of implementing the PrIMO model across four clinical sites.

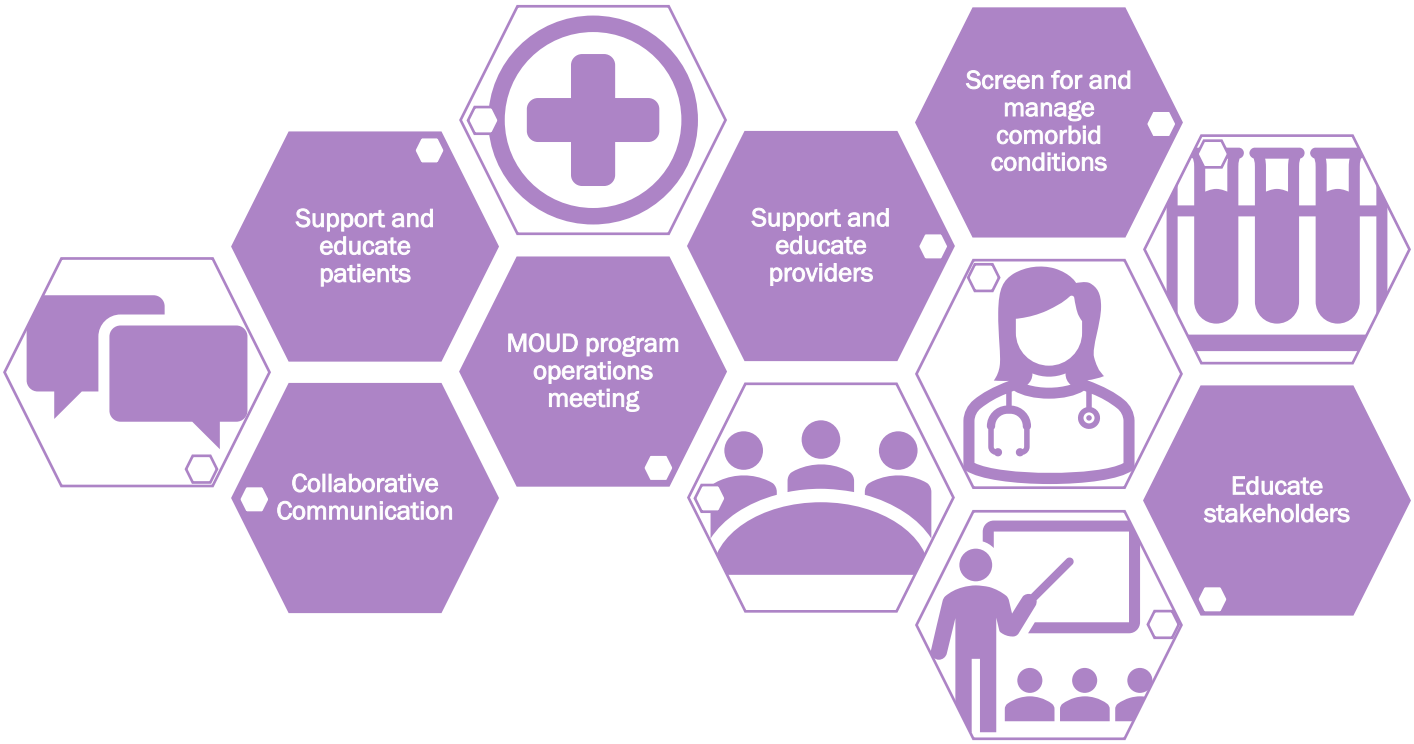
The **secondary aims** of this project are to evaluate the acceptability and impact of the PrIMO model.

- Acceptability of the PrIMO model: stakeholder perceptions of implementation of the PrIMO model (i.e., barriers/facilitators, acceptability, adoption, reach/access, leadership, support, etc.), sustainability, biases in treating OUD, and stigma. We also expect to characterize acceptability as it relates to model fidelity and cost of implementing PrIMO at each site.
- Impact of the PrIMO model: treatment outcomes for patients exposed to the PrIMO model (e.g., MOUD treatment retention, medication regimen adherence, and opioid abstinence), and capacity for treating patients with MOUD (e.g., the number of patients in MOUD treatment, providers waivered to prescribe or prescribing MOUD, and patients in MOUD treatment per waivered/prescribing provider) via EHR data extraction from one-year pre-PrIMO launch to one-year post-PrIMO launch.

To achieve these aims, the study will be conducted with five interlocking elements: 1) site-level implementation measurement, 2) implementation facilitation, 3) research assessments with a subset of site staff and patients exposed to the PrIMO model, 4) model fidelity measurement, and 5) EHR data extraction.

THE PrIMO MODEL

There are 6 Core Components to the PrIMO model that sites will be expected to implement. While this is an integrated model, the bulk of new responsibilities will be designated for the pharmacist champion and other pharmacy staff.



Collaborative Communication: Regular collaborative communication among all members of the care team is the cornerstone of this integrated model.

MOUD Program Operations Meeting: At least weekly, the clinical care team providing MOUD at the site will meet to discuss operations of the treatment program, specific patient needs, and clinic or workflow needs related to the PrIMO model.

Support and Educate Providers: The pharmacist will help to support and educate providers and other site staff on a variety of topics that fall under their realm of expertise. For example, pharmacists may assist in the induction to MOUD for patients with complex needs, both assisting the provider and clinical team in selecting the appropriate medication, dosing, and ongoing management.

Support and Educate Patients: At least once every three months (though more frequently is preferred), the pharmacist will offer to meet with patients one-on-one to discuss medications, concerns (including insurance coverage and needed prior

authorizations), co-management of other health conditions alongside MOUD, and specifics of the medication prescribed (correct dosing or administration, how the medication works, ongoing medication effectiveness, etc.).

Screen for and Manage Comorbid Conditions: The PrIMO team will develop a health screening order set to screen for comorbid conditions. The screening can include blood tests as well as clinical assessments for risk of many health conditions that patients with OUD often comanage (i.e., HCV, HIV, STDs, complete blood count, metabolic panel, pregnancy, etc.). The PrIMO team will work to address these comorbid conditions and their associated treatment, preventative measures for at-risk conditions (including immunizations), and coordinate referrals to specialty providers outside of the clinic if needed.

Educate Stakeholders: As integrated MOUD care providers, the PrIMO team at the site will be expected to share learning opportunities with other stakeholders at the clinic and/or within the local community.

PrIMO TEAM MEMBERS	DESCRIPTION
Core Team Members	Pharmacist At least one prescriber Behavioral health specialist
Ancillary Team Members	Case manager/social worker Medical assistants Program or office manager
Occasional Support members	As needed, depending on clinic and community needs Examples include dentists, cardiologists, vocational therapists, residents, etc.

SITE CRITERIA

Participating sites must be primary care clinics serving adult patients and meet the following criteria to be selected:

- Have a clinic-based pharmacist and retail pharmacy (employed or owned by the clinic organization; co-located with the clinic is optimal).
- Have one pharmacist and one primary care provider to serve as champions for the study.
- Agree and be able to provide non-identifiable clinic and pharmacy EHR data to the study team.
- Have shared access for the pharmacist to the clinic's EHR system.
- Reflect a diverse patient population (e.g., gender, race, ethnicity, geography).
- Already be prescribing MOUD, including buprenorphine, with at least one active X-waivered provider.
- Agree to cede oversight to the study's single IRB, The Biomedical Research Alliance of New York (BRANY).

Commercial or private community pharmacies will not be included unless they already work very closely with the clinic and can have, or already have, EHR access.

Potential sites will be excluded if they already have a model of integrated MOUD with a pharmacist or are providing an adequate volume of MOUD to their community, to be determined by the Site Selection Executive Committee as part of the site selection process.

SITE NEEDS

A budget will be provided to both the clinical site and the local Node to cover expenses for staff time, research staff, supplies, and participant compensation for the completion of research assessments.

Approximations of needs for this study are listed below; please note, these are *estimations only* and plans can be made to customize for a given site. A budget template will be provided to potential sites at a later stage of Site Selection.

ROLE	DESCRIPTION	ANTICIPATED EFFORT
Pharmacist Champion	PharmD or RPh employed at the site, serving in the role of pharmacist. The Pharmacist Champion will support the study in all aspects and champion its implementation among the pharmacy team (pharmacy technicians and local pharmacy leadership)	20% FTE
Provider Champion	Waivered primary care provider employed at the site. The Provider Champion will support the study in all aspects and champion its implementation among the primary care clinic team, including other providers, support staff, and administrators.	10% FTE
Information Technology (IT) Specialist	Team member familiar with the clinic and pharmacy EHR systems. The IT Specialist will extract data from applicable systems, prepare, and share with the Lead Team according to the terms of a Data Use Agreement specific for this study. The IT Specialist will be asked to join meetings about EHR data and related extraction, potentially on a weekly basis. This FTE can be split by multiple IT team members if needed.	40% FTE
Site Principal Investigator (PI)	Clinic team member (MD, PhD, or equivalent experience) employed at the site with the ability to provide oversight and leadership to the project. The Site PI will delegate study responsibilities to adequately trained staff and oversee collection and documentation of research data. Prior research experience is preferred but not required. Note, this role cannot be shared with one of the Champions in this study; it is possible that sites may not have a Site PI, if contracting can continue without one.	5% FTE

Additional support will be provided to the site's local Node of the National Drug Abuse Treatment Clinical Trials Network to assist with research tasks in this study, thereby allowing the clinic to primarily focus on implementing the PrIMO model. If potential sites are not affiliated with a local Node, considerations will be made.

Sites will be expected to conduct the following activities:

STUDY ELEMENT	DESCRIPTION	ANTICIPATED ROLE
Implementation measures	Enter dates of implementation milestones into a web-based dataset (the Stages of Implementation Completion measure)	Pharmacist Champion
Implementation Facilitation	Participate in at least weekly meetings (some team members will be expected to participate in additional meetings, to be determined with the Lead Team)	Pharmacist Champion Provider Champion
Participant Assessments	Work with their local CTN Node to assist in the recruitment of study participants (both site staff and patients)	Limited; potentially Champions or leadership
PrIMO fidelity measure	Complete a weekly survey related to the site's fidelity to the PrIMO model	Pharmacist Champion
EHR data extraction*	Meet approximately weekly with the Lead Team to refine and implement EHR data extraction procedures (i.e., develop and manage a site-specific Data Dictionary) throughout the study period	IT specialist

**Refer to the EHR Data Extraction Summary document for further details.*

FURTHER INFORMATION

Completed Site Selection Surveys are due to the Lead Team by Friday, October 1, 2021. Please email Northeast.Node.CTN@Dartmouth.edu to submit.

The Lead Team will review submissions and set up interviews with potential sites throughout October/November 2021. In attendance at these videoconference-based interviews should be at least the following proposed team members:

- Pharmacist Champion
- Provider Champion
- IT Specialist (or representative)
- Site PI or a member of the organization's leadership
- Other voices of importance to the site
- Local CTN Node team

The Lead Team anticipates that sites will be proposed to the Center for the Clinical Trials Network in November 2021 with the goal of having sites confirmed in December 2021 and beginning study preparation in January 2022. Subawards are also anticipated to begin in January 2022, though may be retroactive depending on the funding process at the site.

An informational session will be held on **Thursday, August 26, from 12-1pm EDT**. You can access that session by clicking this link: https://dartmouth.zoom.us/j/99675333704?pwd=0EJCNS93VjhmbkhROGJicUt1NDhZdz09&from=addon

This session will also be recorded and posted to the Northeast Node's website: www.ctnnortheastnode.org