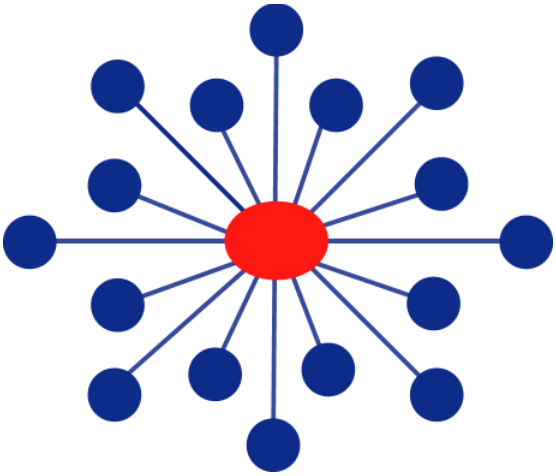

NIDA CTN 0076-ot

Clinical Decision Support for Opioid Use Disorders in Medical Settings: Pilot Usability Testing in an EMR (COMPUTE)

Statistical Analysis Plan

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1.0 STATISTICAL DESIGN AND ANALYSES FOR 0076-ot

1.1 General Design

1.1.1 Study Hypothesis

A web-based EMR-integrated point-of-care CDS tool for OUD is both feasible and usable in the primary care setting.

1.2 Primary and Secondary Outcomes (Endpoints)

Primary Aims:

1) To program an OUD-CDS tool based on a NIDA-Blending Initiative white paper "Clinical Decision Support for Opioid Use Disorders: Working Group Report" and national guidelines (VA (VA 2015), ASAM (ASAM 2015)) for use in an EMR.

   Measure 1. Demonstrate that the OUD-CDS is functional and accurate through:
   a) Testing in the EMR test environment,
   b) Chart audit validation of CDS output, and
   c) Approval of the tool by specialty addiction physician and PCP pilot testers prior to the full rollout.

2) To descriptively analyze PCP acceptability, satisfaction and use rates high enough to demonstrate proof of concept

   Measure 2A. By the end of the 6-month pilot intervention, the monthly PCP use rate of the CDS for targeted high-risk patient encounters for PCPs with CDS access will be >60%.

   Measure 2B. By the end of the 6-month pilot intervention, >60% of PCPs with CDS access will report feeling confident in assessing and treating OUD

   Measure 2C. At the end of the 6-month pilot intervention, >80% of PCPs with CDS access will rate the OUD-CDS $\geq$4 on a 5-point Likert scale of likeliness to recommend use of the tool to their colleagues.

Secondary Aims. We will examine the usefulness of the OUD-CDS tool by comparing pre- and post-intervention rates of screening for OUD in high-risk patients, TAPS use, OUD diagnosis, use of medication-assisted therapy, as well as treatment referral patterns, for 3 groups of PCPs: (1) those with CDS access and buprenorphine certification, (2) PCPs with CDS access but without buprenorphine certification, and (3) PCPs without CDS access.

2.0 RECRUITMENT

PCPs will be voluntarily recruited from HPMG and PNMG in person and via emailed invitations. We will recruit all PCPs who have or will soon have buprenorphine waivers, as they will be able to use the entirety of the OUD-CDS tool. In our invitation to participate in the study, we will inform PCPs that they will receive $150 (PCPs without CDS access) or $300 (PCPs with CDS access) each to compensate them for their time in completing emailed surveys at the beginning and end of the 6-month pilot intervention phase (all PCPs), and for their time in submitting feedback via the feedback tab in the CDS (PCPs with access to the CDS).

3.0 RANDOMIZATION AND FACTORS FOR STRATIFICATION

PCPs who are recruited and are buprenorphine-certified will be placed into the group of PCPs who have OUD-CDS access. PCPs who are recruited and do not have buprenorphine certification will be randomized to receive or not receive access to the OUD-CDS. We will be aware of practice location, patient panel size and number of patients for whom the CDS-OUD was triggered and can analyze results based on individual practice location or panel, but given the small nature of this pilot project we do not anticipate statistically meaningful information from these factors.

4.0 PREDICTION MODELS

Not applicable.

4.1 Rationale for Sample Size and Statistical Power

4.1.1 Projected Number of Sites

This study will occur at PNMG and HPMG, both of which are divisions of HealthPartners. This pilot intervention will occur at primary care clinics at which one or more eligible PCPs have consented to participate. We anticipate a total of 37-43 PCPs from twenty primary care clinics will participate.

4.1.2 Projected Number of Participants per Site

We anticipate 37-43 PCPs from approximately twenty primary care clinics will participate.

4.2 Statistical Methods for Primary and Secondary Outcomes

This pilot study for OUD-CDS feasibility and usability will not have a statistical endpoint. Provider characteristics, patient characteristics, and OUD-CDS use rates will be tracked and described. Pre- and post-intervention surveys of provider confidence in OUD assessment and treatment as well as satisfaction and usability of the OUD-CDS will be described.

4.3 Significance Testing

This pilot study for OUD-CDS feasibility and usability does not entail statistical testing or power calculations. Provider characteristics, patient characteristics, and OUD-CDS use rates will be tracked and described.

4.4 Types of Analyses

Provider characteristics, patient characteristics, and OUD-CDS use rates will be tracked and descriptively analyzed.

4.5 Interim Analysis

Not applicable for a pilot study that will be in the field for 6 months.

4.6 Exploratory Analysis

MAT has been shown to reduce adverse outcomes, such as overdoses, hospitalizations and deaths, for patients with OUD (Mohlman 2016; WHO 2013). As a quality measure to inform future implementation studies of this OUD-CDS, we will collect available EHR data to examine overdoses, ER visits, hospitalizations and deaths for patients with OUD treated by PCPs with and without CDS access. While

this information will likely not be useful for statistical considerations, trends observed could be hypotheses-generating and inform future study needs.

4.7 Missing Data and Dropouts

All eligible providers may not respond to surveys or to particular survey questions. In order to minimize survey non-response we will administer the survey electronically in a format that will prompt PCPs to answer missed questions. We will also send multiple reminders of the survey and provide PCPs who do not have CDS access an incentive of $150 to complete baseline and 6-month surveys, and PCPs who do have CDS access an incentive of $300 to complete baseline and 6-month surveys and submit feedback via the CDS feedback tab.

4.8 Demographic and Baseline Characteristics

Baseline demographic and practice variables (e.g., years in practice, size of patient panel, etc.) will be summarized for PCPs enrolled in this study.

4.9 Safety Analysis

In this pilot study, we are not trying to change the standard of care for OUD treatment in primary care, but rather helping PCPs achieve this standard of care in OUD treatment. PCPs are trained that, as with other CDS tools, the OUD-CDS is meant to supplement but not supersede clinical judgment. PCPs can choose to follow or not follow the guidance of the CDS at any given time for any given patient encounter, and PCPs are trained to let the research team know via the Feedback tab in the CDS when their clinical judgment is inconsistent with the CDS recommendations. This feedback will be monitored by the treatment team and the CDS algorithms adjusted if indicated.

An independent CTN DSMB will monitor this study. The DSMB will communicate regarding what type of reports will be needed, as well as frequency.