**PROJECT TITLE:** Project MIMIC (Maximizing Implementation of Motivational Incentives in Clinics)

**PRINCIPAL INVESTIGATORS:** Sara Becker, PhD

Bryan Garner, PhD

**CLINICALTIALS.GOV IDENTIFIER:** NCT03931174

**DOCUMENT DATE:** Created for Brown University IRB December 12, 2018

Uploaded to ClinicalTrials.Gov on November 22, 2024

**Project Title:** Implementing Contingency Management in Opioid Treatment Centers across New England: A Hybrid Type 3 Trial

**Principal Investigators:** Sara J. Becker, Ph.D.

## 1. Lay Summary

Overdoses and deaths due to opioid use disorders (OUDs) have been declared a public health emergency in the United States, bringing to light an urgent need for highly effective OUD treatments. There are currently five FDA-approved medication formulations, which relative to placebo have demonstrated effectiveness in helping patients attain abstinence from opioids. Nonetheless, patients' opioid abstinence rates are sub-optimal: even when treated with the newest extended-release formulations only about 40% of patients maintain abstinence during the first 6-months of treatment.

Contingency management (CM; i.e., motivational incentives for achieving pre-defined treatment goals) is one of the only behavioral interventions shown to improve patient abstinence from opioids when combined with FDA-approved pharmacotherapy. Unfortunately, however, uptake of CM in OUD treatment centers remains low. In response to the urgent need for evidence-based behavioral OUD treatments, we propose a large-scale trial comparing two comprehensive strategies to promote CM implementation as an adjunct to pharmacotherapy within OUD centers. Across New England, 30 OUD treatment centers will be randomized to either an enhanced strategy to implement CM (E-ATTC experimental condition) or to the standard staff training model used by a network of federally-funded training centers (ATTC control condition). This study will experimentally compare the effect of the two conditions on implementation outcomes and on patient outcomes. The ultimate goal is to improve how treatments are implemented in OUD treatment centers, which could help increase the quality of care in this extraordinarily high-need setting.

## 2. Specific Aims and Detailed Study Methodology

### A) Specific Aims

The goal of this study is to compare two comprehensive strategies to promote CM implementation as an adjunct to pharmacotherapy within OUD centers. Using a cluster randomized design, 30 OUD treatment centers across New England will be randomized to one of the two implementation conditions: 1) ATTC control condition: SAMHSA-funded Addiction Technology Transfer Centers (i.e., didactic workshop + performance feedback + staff coaching); 2) E-ATTC experimental condition: ATTC strategy enhanced by external leadership coaching (ELC; i.e., leadership coaching focused on sustainment planning) and pay-for-performance (P4P; i.e., monetary bonuses for achieving pre-defined implementation goals). Specific research aims of the study are:

1. **Primary Aim:** To test effectiveness of E-ATTC, relative to the ATTC condition, on implementation outcomes.
    a. Primary Hypothesis: Relative to ATTC, E-ATTC will achieve superior: CM Exposure (i.e., patient-level measure of number of CM sessions received during 9-month Implementation phase) CM Competence (i.e., staff-level measure of CM quality during 9-month Implementation phase), and CM Sustainment (i.e., patient-level measure of number of CM sessions received during 12-month Sustainment phase).

2. **Secondary Aim:** To test effectiveness of E-ATTC condition, relative to ATTC, on patient outcomes.
    a. Secondary Hypothesis: Relative to ATTC, E-ATTC will achieve superior: Opioid Abstinence (i.e., days of abstinence) and Opioid-Related Problems (i.e., count of problems) at 3 and 6-month follow-up.
3. **Exploratory Aim:** To test the extent to which theorized mechanisms of change (i.e., implementation climate, leadership engagement) mediate the implementation condition (i.e., ATTC vs. E-ATTC) to outcome (i.e., implementation outcome, patient outcome) relationship.
    a. Exploratory Hypothesis: Implementation climate and leadership engagement will partially mediate the relationship between implementation condition and each outcome in the Primary and Secondary Aims.

## B) Detailed Study Methodology

1. **Study Purpose.** The primary purpose of this study is to experimentally evaluate two different comprehensive training models to train opioid treatment centers in an evidence-based behavioral treatment called contingency management (CM), which is the provision of motivational incentives for reaching specific treatment benchmarks. An exploratory goal of this study is to test whether theorized mechanisms of change – implementation climate and leadership engagement – mediate the effect of implementation condition on outcomes. Conduct of this study will address critical public health needs by (a) informing how CM, an evidence-based practice, should be implemented in OUD treatment centers, (b) improving the outcomes of OUD patients receiving treatment in the community, and (c) advancing knowledge about why and how implementation strategies work.

2. **Overview of Study Design.** A Type 3 Hybrid Trial will be conducted collecting data on both implementation and patient outcomes. We will use a 3-cohort staggered cluster RCT design. The unit of randomization will be opioid treatment centers. Centers will receive one of two comprehensive training conditions: the standard training provided by the New England Addiction Technology Transfer Center (ATTC training) or an enhanced condition that also provides leadership coaching and provider incentives (E-ATTC training). The primary research activities will be measuring the effectiveness of the training initiatives by gathering data from organizations, providers and patients.

    Every 12-16 months, 10 OUD centers will be randomly selected to initiate study activities (10 centers X 3 cohorts = 30 centers). Prior to randomization, each center will complete a Baseline Organizational Assessment (described further in the Measures section) to collect organizational background data (e.g., years in operation, number of patients served annually, number of staff, medications prescribed, implementation readiness). Using these data, urn randomization procedures (balancing on number of patients served and percent of patients receiving methadone) will be used to randomize centers to either the ATTC or the E-ATTC condition. Centers in both conditions will complete a 5-month Preparation phase, a 9-month Implementation phase, and a 12-month Sustainment phase (26 months total). In both conditions, providers will record their delivery of CM in the electronic medical record and will audio record one CM session per month.

    Because this is an implementation trial, the goal is to help opioid treatment centers in both conditions to integrate CM into their routine clinical care. CM is a well-established, evidence-based behavioral intervention for the treatment of opioid use disorder; in fact, it has the strongest evidence base of any behavioral intervention. Its effectiveness as an

adjunct to medication has been documented in multiple systematic reviews and meta-analyses, it has large to very large effects, and in head to head comparisons, it has outperformed other behavioral interventions. Opioid treatment centers that participate in this study will receive training designed to help them universally offer CM to **all** newly admitted patients. In addition, front desk staff at the opioid treatment centers will be asked to give consent to contact forms to all newly admitted patients. Research staff will then make contact with interested patients and will obtain informed consent from up to 25 CM patients at each organization (25 patients * 30 organizations = 750 patients). Patients that provide informed consent will complete follow-up assessments at 3-months and 6-months post intake, to help assess whether the organizational training had positive effects on patient outcomes. Patients that do not wish to enroll in the study will still be eligible to receive CM sessions. In addition, those patients that do not wish to receive CM sessions can decline to receive CM or opt out of CM prize draws at any time. All patients will receive the standard of care at the opioid treatment center, which may or may not include CM.

3. **Study Participants.** Our primary unit of recruitment is OUD treatment centers. Within each center, we recruit a small number of providers to complete measures of organizational climate and functioning, to submit audio recordings of their sessions, to receive performance feedback on their sessions, and (for those randomized to E-ATTC) to receive performance incentives. We also consent 25 patients per center to complete study assessments so that we can track if our organizational intervention has a positive effect on patient outcomes.
   a. *Community-based OUD treatment centers (Centers)***.** A total of 30 centers will be included as part of the proposed study (see Attachments: Letters of Support). Centers were selected because they met the following inclusion criteria: a) prescribe FDA-approved medication to treat adult patients with OUDs; b) enroll 5+ new patients per month; and c) have at least 2 staff who provide psychosocial support to OUD patients.
   b. *Community-based OUD treatment center providers (CM Providers)***.** Drs. Becker and Garner will work with each participating opioid treatment center to identify front-line treatment providers and leaders eligible for the study.

      **Eligible providers** will be any front-line treatment provider who has: a) been involved in providing psychosocial support to OUD patients on pharmacotherapy, b) an active caseload, c) been employed by the opioid treatment center at least 3 months, and d) willingness to commit to 14 months of CM training and support. All eligible treatment providers at the centers will be invited to receive the CM didactic training. However, centers will nominate 2-5 providers to serve as “CM champions”: the “CM champions” will complete periodic measures of organizational climate (described further in Measures), submit monthly audio recordings of their sessions, receive performance feedback on their audio recordings, and (for those randomized to E-ATTC) will receive performance incentives. In our experience with centers in a recent pilot study, none had more than 5 staff, so for the vast majority of sites, we expect to be able to invite all staff to participate. Thus, between 60-150 CM Providers (30 centers x 2-5 CM Providers per center) will complete measures across the three cohorts (20-50 CM Staff per cohort).

      **Eligible leaders** will be: a) responsible for supervising frontline CM Staff, b) have been employed by the opioid treatment center at least 6 months, and c) be willing to commit to 14 months of external leadership coaching. Thus, in addition to the 60-150 CM providers, another 60 leadership staff (30 centers x 2 leaders per center) will provide data.

      There is an annual staff turnover rate of approximately 30% among substance use disorder treatment providers and 20% among leadership staff. Although we invite 2-5 front-line providers from each center to participate in the study, we allow each center to send as many providers to the CM training as desired. Given the likelihood that about

one of three trained CM staff will turnover during the project's first two phases, each center will be required to identify one or more replacement CM staff. Thus, if one of the initially trained CM staff withdraws from the study for any reason during the Preparation or Implementation phase, a replacement CM staff will be immediately trained.

c. *Community-based OUD treatment center patients (Patients)***.** Each center will agree to deliver CM to all patients newly admitted over a 6-month period. In addition, each center will be asked to enroll approximately one eligible CM patient per week to complete research assessment measures. Eligible patients will be: a) adult patients, b) newly admitted to the opioid treatment center within the past 30 days, and c) prescribed any FDA-approved OUD medication. To optimize ecological validity, exclusion criteria will be minimal and will only include issues that could interfere with the ability to complete a brief intake interview including acute intoxication, acute psychosis, acute mania, or cognitive impairment (prohibiting comprehension of the consent process), as reported by opioid treatment center staff or observed by research staff. We focus on newly admitted patients as opposed to those established in treatment because the need is highest among these patients: drop-out rates and missed doses are higher during the first 6 months of treatment (i.e., the "induction phase") than any subsequent period.

d. *Inclusion of women and members of minority groups***.** Women and members of minority groups will be eligible and actively recruited for this study. They may be recruited as opioid treatment center CM providers, opioid treatment center leadership, and/or as opioid treatment center patients. We expect an approximately even split between males and females among opioid treatment center CM providers and opioid treatment center CM leadership, and a higher representation of males among opioid treatment center patients. Rates of opioid use disorders are higher in males than females, with an estimated male-to-female ratio of 1.5:1 (60% vs. 40%) for disorders due to prescription pain relievers and a ratio of about 3:1 (75% vs. 25%) for disorders due to heroin;[1] however, recent data suggest that heroin rates among women are rising rapidly.[2] Based on prevalence rates and data from the participating OUD treatment centers, we expect about 37% of OUD treatment center patients to be female. Furthermore, based on data from the participating treatment centers, we expect 73% of the study participants to be White Non-Latinx and the remainder of the participants to be members of racial/ethnic minority groups. These rates are reflective of the demographics of New England.[3] Of note, meta-analyses have found that CM is equally effective regardless of biological sex[4] and race/ethnicity.[5]

**4. Organization Participation and Patient Enrollment.**

a. *Centers*. Thirty OUD treatment centers have provided preliminary commitment to participate the current study (see Letters of Support). During September and October of this year, we have conducted interviews with frontline providers and leaders at 12 of these centers as part of an NIDA-funded Center Grant (P20GM125507- Project 3, Project Lead/Principle Investigator of Research Project: Becker). Once the IRB approves our Organization Participation Form and study protocol, we will meet with centers to conduct a detailed review of the study protocol, to ensure that centers are still interested in participating in the study and to obtain a signed and dated Organization Participation Form. If any center decides not to participate, we will recruit alternate centers in the New England region. We will only work with 10 centers at a time (3 cohorts of 10 centers will participate), and the first 10 centers to sign Organization Participation Forms will be enrolled in the first cohort. The signed Organization Participation Agreement form will describe the expectations for each center and for the designated CM staff based on the protocol funded by NIDA.

b. *Staff*. All 30 centers have confirmed the availability of at least 25 CM providers and at least 2 leaders meeting the project's eligibility criteria. We expect the treatment centers to only select providers and leaders meeting eligibility, but as a safeguard, research staff will confirm eligibility using the brief **Provider Screener**. Per the guidance provided from the Brown IRB, providers will not need to sign informed consent form, since consent will be provided on behalf of the entire organization and on behalf of specific staff in the Organization Participation Agreement Form.
c. *Patients*. Front-desk receptionist staff in each of the participating centers will give new patients that present to treatment a consent to contact form. Patients that are interested in participating and sign a consent to contact form will then receive a call from the local research team to set up a time to complete the consent and baseline assessment process. It is expected that opioid treatment centers will only refer eligible patients. But as a safeguard, at the start of the call, research staff will confirm eligibility for the study using the brief 3-item **Patient Screener**. To reduce the amount of PHI stored at each treatment center, consent forms will be administered to eligible patients electronically and will use electronic signatures. Patients will have the option of completing the consent process via phone at a location of their choosing if they have access to the internet and can review the consent form during the phone call, via phone in a private room at the opioid treatment center with a study research tablet that contains the consent form, or in person with research staff at the opioid treatment center. Patients will receive a copy of the form electronically or via mail: their preference will be assessed in the consent form. Estimates from the 30 participating centers indicate the average patient flow is 17 new patients per month or 102 patients per 6-month period. Our recruitment targets conservatively estimate that 25% of new patients will be enrolled, for a total of 750 patients (30 clinics x 25 clients per center). If necessary to reach our target sample size (750), we will oversample from larger centers; if so, we will monitor patient enrollment and ensure a balanced number of patients are assigned to the two implementation conditions (ATTC vs. E-ATTC).

5. **CM Procedures.** CM is a behavioral treatment in which providers deliver motivational incentives to patients for attaining specific treatment benchmarks. CM protocols have demonstrated effectiveness across various *reinforcement schedules* (immediate vs. delayed), *delivery schedules* (biweekly vs. weekly), and *behavioral targets* (abstinence vs. compliance).[1,2] We will train staff from participating organizations in how to deliver a flexible, evidence-based CM protocol, which **targets compliance with opioid treatment** and provides **immediate reinforcement using escalating prize draws**. This protocol is supported by a robust literature that has shown: a) immediate reinforcement is associated with larger effect sizes than delayed;[3] b) more frequent reinforcement is linked to better patient outcomes than less frequent or intermittent reinforcement;[2] and c) prize draws are less expensive, yet as effective (more cost effective) as vouchers.[5] In addition, we completed pilot data collection with 12 opioid treatment centers as part of a NIDA funded pilot study (P20 GM125507) and centers indicated that they preferred to incentivize treatment compliance over abstinence or attendance at sessions.

The minimum goal will be for participating organizations to provide reinforcement in the form of a prize draw to patients at least once per week. Staff in the organizations will be responsible for monitoring patient compliance (defined further below) as part of the CM protocol.

For this study, we will train staff from participating OUD centers in a flexible CM protocol adapted from an evidence-based CM protocol initially created by Dr. Nancy Petry, an international expert in CM delivery. Leadership of all participating organizations will define opioid treatment compliance as follows: Compliance rate = number of completed clinical

contacts per week / number of expected clinical contacts per week. Clinical contacts can be broadly defined as including medication doses, counseling sessions, and urine screens. Organizations will be allowed to determine the minimal compliance benchmark, and the weighting of clinical contacts to fit their organizational needs and preferences. In both conditions, organizations will be required to develop a clear CM compliance benchmark for earning prizes and a clear equation for how compliance would be calculated.

For instance, Treatment Center A might report that they expect opioid patients to present daily for doses of opioid medication (i.e., methadone) and do not expect patients to have any other clinical contacts. Treatment Center A might also determine that their CM compliance benchmark is 80%: in other words, Treatment Center A will only reward patients who attain 80% compliance. Compliance at Organization A would be outlined as follows: Compliance rate = number of clinical contacts completed / number of clinical contacts (7 medication doses) expected to be completed. A patient who received 6 of 7 doses would have a compliance rate of 86% (6 / 7 = 86%). This patient would receive a prize draw because they surpassed the 80% benchmark. By contrast, a patient who received 5 of 7 doses would have a compliance rate of 71% (5 / 7 = 71%). This patient would not receive a prize draw because they did meet or surpass the 80% benchmark.

Another treatment center, Treatment Center B, might report that they expect opioid patients to present weekly for opioid medication doses (i.e., buprenorphine), monthly for a counseling session, and monthly for a urine screen. This center might set a CM compliance benchmark of 100%: in other words, patients must attend 100% of expected clinical contacts to earn a prize draw. The number of expected clinical contacts would vary on a weekly basis. In some weeks, Organization B would have only 1 expected clinical contact (a dose of buprenorphine). In these weeks, Compliance at Organization B would be as follows: Compliance rate = number of completed clinical contacts / number of expected clinical contacts (1 dose). Patients who presented for buprenorphine would have a monthly compliance rate of 100% (1 / 1 = 100%) and would earn a prize draw. Patients who did not presented for their buprenorphine would have a monthly compliance rate of 0% (0 / 1 = 0%) and would not earn a prize draw.

In other weeks, patients at Organization B might have 3 clinical contacts expected (e.g., 1 medication dose, 1 urine screen, 1 counseling session). In these weeks, a patient who presented for only buprenorphine would have the following compliance rate: 1 actual visit / 3 expected visits = 33%, and would not receive a prize draw. Likewise, a patient that presented for only buprenorphine and a counseling session but missed the urine screen would have the following rate: 2 actual visits / 3 expected visits = 66%, and would not receive a draw. Patients would have to attend all 3 clinical contacts to receive a prize draw.

The CM protocol that staff will be trained in will consist of the following actions: 1) Review patient compliance for the week with patient using the organization definition of number of expected clinical contacts; 2) Clearly inform the patient if their compliance for week exceeded the organizational CM benchmark; 3) Clearly state the number of prize draws (if any) earned in the current session; 4) Administer CM prize draws as appropriate; 5) State number of draws patient can earn at the next session (goal-setting); 6) Praise patient's efforts towards compliance (even if the compliance benchmark was not met); and 7) Communicate confidence that patient's efforts will yield success in the future.

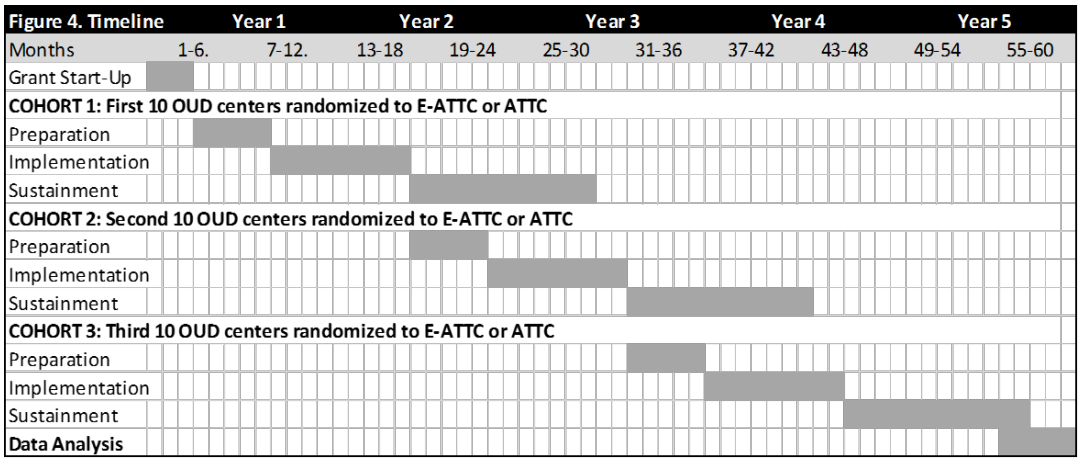
The evidence-based CM protocol[6-8] that staff will be trained in will provide patients with increasing opportunities for winning cost-neutral (i.e., praise), $1, $20, and $100 prizes for each week during which the CM compliance benchmark was attained. Draws increase by one for each week that compliance was attained. Failure to attain the benchmark or failure to attend the prize draw session resets draws for the next week down to one, with draws again escalating for sustained compliance. Patients will receive prize draws for up to 12 weeks, which is the median duration of the induction phase at participating centers (range

from 4 to 26 weeks). This progression will yield a maximum of 78 draws (1+2+3+…+12). Fishbowls will contain 500 slips; 250 state "good job!" but are not associated with a prize, 209 state "small," 40 state "large," and one "jumbo." Using these probabilities and magnitudes of $1, $20, and $100 for the three respective prize sizes, each draw has an average cost of $2. Thus, for a 12-week protocol, each patient could earn 78 draws X $2/draw = $156 in prizes.

6. **Phases of Implementation.** Both conditions proceed through three phases (see Figure 4), consistent with the widely used EPIS framework, which contains four phases: Exploration, Preparation, Implementation, Sustainment.[9]
   a. *Exploration / Preparation*. Both implementation conditions begin with a 5-month combined Exploration and Preparation phase. In the first month, organizations will work with the CM trainer to develop a CM compliance definition and benchmark. Following that decision making, all participating centers will receive the standard ATTC strategy: workshop training, performance feedback, and staff coaching. Workshop training includes a full day training led by a New England ATTC trainer using a CM training protocol adapted by Co-I Hartzler.[10,11] Performance feedback will be provided based on at least two role plays with other staff or supervisors (i.e., "practice cases"), which will be submitted via Virtru dual-authenticated encrypted email, an approach to encrypting sensitive information recommended by Brown Computing Information Services. Finally, staff coaching consists of monthly condition-specific group calls to prepare for implementation (i.e., all staff in the ATTC and E-ATTC conditions will be invited to join monthly condition specific calls with one call for ATTC and one for E-ATTC). For OUD centers in E-ATTC, the Preparation phase also includes an in-person Planning Visit with center leadership as well as monthly group leadership calls with the ELC, which focus on preparing for implementation, including selection of prizes used as patient reinforcement and finalization of P4P incentives.
   b. *Implementation*. During this 9-month phase, trained CM providers in both conditions begin implementing the CM protocol with patients. Additionally, in both conditions, CM providers will submit an audio recording of at least 1 CM session per month and will receive ongoing performance feedback on their CM competence from an ATTC trainer. More specifically, each month one CM session recording per CM will be submitted for review using Virtru encrypted email. Once received, a research staff member will rate the session using the 9-item **CM Competence Scale** (CMCS) for Reinforcing Compliance.[12] Once the rating has been done, CM providers will be emailed feedback reports. Staff will also participate in condition-specific monthly group coaching calls.

      Centers randomized to E-ATTC will receive two additional elements of support: (1) ELC and (2) P4P incentives. Throughout Implementation, as part of ELC, each center leadership will participate in monthly center-specific coaching calls. As part of P4P, CM providers will receive monetary bonuses for achieving two pre-defined goals based on benchmarks in RCT research with OUD counselors: (a) CM Exposure[13] (i.e., meeting a target number of 10 sessions per patient) and (b) CM Competence[10] (i.e., meeting a target score of 5.8 on the CMCS). The provider incentive structure is described more in depth in Section 7b. One month before the end of the Implementation phase, the ELC will return for an in-person sustainment-centered planning meeting.

c. *Sustainment***.** No ATTC or E-ATTC activities will be provided during this 12-month phase, though sustainment of activities will be actively measured.




**7. Implementation Conditions:** ATTC vs. E-ATTC**.**

a. *ATTC***.** Participating staff from all centers will receive the ATTC strategy, under Dr. Becker's oversight.

Workshop training. A New England ATTC trainer will lead a full-day CM workshop for each cohort. Participating CM providers will receive continuing education credits for attendance. The first half of the day will consist of a variety of best practices in training including didactic instruction in CM principles, review of videotaped exemplar CM sessions, and demonstration of CM compliance monitoring. Before and after the first half-day workshop, CM providers will complete a 20-item multiple-choice test of general **CM knowledge**. The second half-day workshop will consist of practice with CM role-plays using standardized patient scenarios. All CM staff scoring $\geq$ 16 (75%) on the multiple-choice test will be paired up and assigned role-plays; CM staff will take turns acting as the patient. Providers earning < 16 will be grouped with the ATTC coach for further basic CM demonstrations and review, before being paired up for the role-plays. Role-plays cover a range of possible scenarios including situations in which CM providers would have to a) describe CM to a new patient, b) provide increasing reinforcement to a patient demonstrating compliance, and c) withhold reinforcement from a patient not meeting the compliance benchmark. Training concludes with an overview of how CM Exposure and CM Competence is evaluated, as well as review of the schedule for submitting recordings and receiving performance feedback.

Performance feedback. Only after completing necessary HIPAA compliance procedures, participating CM providers will begin to submit digital session recordings via the Brown CIS-recommended solution of dual authenticated Virtru encrypted email. During the Preparation phase, CM staff will be required to submit at least two audio recordings of "practice" CM sessions, which will be role play cases completed with other CM providers or supervisors and will not contain any PHI. CM staff are required to earn an overall score of at least 4 on the CMCS in both consecutive sessions to be assigned actual patients. During the 9-month Implementation phase, CM staff will be required to submit recordings of at least 1 CM session per month. Sessions must be from that calendar month and will be due on the last day of the month. If providers submit more than 1 session, then 1 CM session per month will be randomly selected and rated by a trained ATTC raters using the CMCS. De-identified performance feedback summaries will be emailed to CM providers within 2-4 weeks of each session's submission

containing detailed ratings of therapist competence and feedback on exposure. In all cases, performance feedback sessions will be sent within 1-2 months of each session.

CM provider coaching. Monthly condition-specific group coaching calls will be provided to CM providers during the last two months of the Preparation phase and each month during the 9-month Implementation phase. These calls are intended to allow CM staff to share lessons learned, troubleshoot barriers to CM delivery, and discuss plans to improve implementation effectiveness (i.e., consistency and quality of CM delivery).

b. *E-ATTC***.** Centers randomized to E-ATTC will receive two additional types of support: ELC and P4P.

ELC**.** Drs. Becker and Garner will train and supervise the ATTC coaches in the ELC strategy used in Becker's pilot trial[14], which is consistent with principles of organizational management coaching[15] as well as the VA's external facilitation approach.[16] ELC activities vary by study phase. More specifically, during the Preparation phase, immediately after treatment centers are assigned to a cohort, each organization will complete the Baseline Organizational Form. For those centers randomized to E-ATTC, the ELC will provide an organizational performance feedback summary on each center's replies. Next, the ELC will meet with each center's leadership for an upfront planning meeting to: a) review the performance feedback summary, b) identify barriers and facilitators to implementation, and c) provide an overview of the project's P4P protocol. In the final two months of the Preparation phase, leaders will also receive center-specific monthly coaching calls to discuss increasing organization preparedness for CM training. During the Implementation phase, organizational leaders will continue to receive monthly coaching calls. Before the end of the Implementation phase, the ELC will lead an in-person implementation review and sustainment-centered planning retreat to: a) review center performance (e.g., data on both CM staff performance and patient outcomes) during the Implementation phase, b) discuss the extent to which and how the center plans to continue CM implementation; and c) develop a concrete sustainment action plan. Given inadequate funding has been found to be a key barrier to CM implementation, a primary focus of the ELC's work will be helping organizational leadership to ensure adequate financial support for CM. The ELC will help leadership to evaluate a range of options to financially support CM including: strategies to increase center revenue (e.g., fund-raising, seeking grant support, improving insurance collection rates, increasing patient fees, increasing patient flow), strategies to decrease center costs (e.g., improving operational efficiency, renegotiating contracts), and strategies to decrease the cost of CM delivery (e.g., seeking prize donations).

P4P**.** Consistent with the P4P methods Dr. Garner found to be effective,[17] E-ATTC condition CM staff will have the opportunity to earn monetary bonuses for the achievement of two performance measures: CM Exposure and CM Competence. The use of monetary bonuses for performance is consistent with a robust literature base in the field of implementation science demonstrating that providing incentives for provider performance is an effective way to increase the uptake of evidence-based treatment.[See 17] It is also consistent with the approach increasingly taken by health insurance companies to link provider reimbursement to quality metrics. The P4P methods used here draw on a robust literature and the benchmarks are specifically set based on prior research. Based on benchmarks attained by OUD counselors after CM training in prior RCT research,[10] CM providers will earn US $200 for each patient that receives 10 or more CM sessions (i.e., CM Exposure). This is similar to the behavior and incentive combination (i.e., $200 for threshold level of treatment exposure) that Garner and colleagues found to be effective.[17] Each site will recruit 25 patients and the number of providers will vary from 2-5. For a provider with 10 patients, the maximum amount a provider could receive or CM Exposure is 10 patients * $200/patient = $2,000.

Moreover, providers will earn $50 each month that they demonstrate competent delivery of the rated CM session, defined as a mean score of at least 5.8 on the CMCS (i.e., CM Competence). This is again the same behavior and incentive combination (i.e., $50 for competent delivery) that was found to be effective in prior research.[17] The maximum incentive a provider could receive for CM Competence is 9 months * $50/month = $450.

Incentive amounts are designed to enable staff to, on average, earn bonuses that during a 12-month period would comprise about 6% of their mean annual base salary of US $45,000. Prior P4P research[18,19] has suggested that bonuses between 4 and 7% are large enough to significantly improve staff performance, yet modest enough to be practical for community treatment centers to implement. Provision of incentives will follow the exact same schedule of provision of performance feedback reports described in 7a. Sessions must be submitted by the last day of the month and must be from that calendar month. Within 2-4 weeks following submission of recordings, providers in the E-ATTC condition will receive email notifications from research staff containing their performance feedback reports, as well as confirmation of their achievement of CM Exposure and CM Competence for the prior month. CM staff enrolled in the E-ATTC condition will receive payments via cash, check, or Clincard.

**8. Data Collection Procedures.**

a. *Organizational background form.* Prior to randomization, leaders at each center will collaboratively complete an Organizational Background Form via Qualtrics. Data collected will include, but not be limited to: number of patients, proportion of patients on different OUD medications, number of staff, average staff tenure, and years in operation.

b. *Staff surveys.* After randomization, CM staff and leadership staff will complete two online Qualtrics surveys: one at the start of the Preparation phase and one at the midpoint of the Implementation phase. The first survey (30-45 minutes) will contain the following measures: Provider Demographics, Organizational Readiness for Change, Attitudes towards CM, and putative mediators (i.e., Implementation Climate, Leadership Engagement). The second survey (15-30 minutes) will only evaluate the putative mediators. Participating staff will receive $25 for the first and $20 for the second survey. We attained 82% or higher completion rates on comparable staff follow-up surveys in the New England ATTC pilot.

c. *Patient assessments.* Patients will complete assessments at baseline and at 3 and 6 months post-intake. Brief baseline assessments will be conducted by research staff either in person at the participating centers or via phone. Multiple strategies will be used to prevent attrition. At baseline, multiple sources of contact information will be recorded for patients. Contact information will be updated by periodic phone calls. In addition, patients will provide detailed contact information of two friends or family members (“locators”) who can be contacted if research staff is unable to reach them. Reminders will be made via phone, text, and email: the reminders will not contain any details about the study and will simply note a reminder about an upcoming appointment. Patients who cannot be reached over the phone for follow-up will be identified as needing follow-up from the designated outreach team, who will attempt in-person contact in at the patient’s home or OUD center. Patients will receive a slightly escalating schedule of compensation in the form of a Clincard, a reloadable Mastercard card for completing the baseline ($20), 3-month ($20), and 6-month follow-up ($25) assessments. Our analysis plan assumes 80% completion of patient follow-up assessments.

d. *Electronic medical record (EMR)*. All 30 sites have agreed to document CM session delivery in their medical records (using the Post-Session Self-Report Form) and to extract patient data into an online Qualtrics template created for this project (using the Medical Record Data Extraction Form). Providers will enter session data into the Post-Session Self-Report Form in the medical record. Data will be extracted from the medical record from staff at the participating opioid treatment centers at two timepoints: a) end of 9-month Implementation phase and b) end of 12-month Sustainment phase.
e. *Audio recordings of CM sessions.* CM staff in both implementation conditions will be required to submit audio recordings of CM sessions once per month in order to receive performance feedback and P4P incentives. Submissions will be made using the Brown CIS recommended solution of Virtru encrypted email. A Brown research staff member will email each site a reminder that audio recordings are due using Virtru encrypted email: as long as providers reply to this email, audio recordings will be encrypted. Use of Virtru will be demonstrated during both the upfront didactic training and the ongoing monthly coaching calls.

**9. Key Measures.**

a. *Implementation outcomes.* Our **Primary Aim** tests the effectiveness of the two implementation conditions (ATTC vs. E-ATTC) on CM Exposure, CM Competence, and CM Sustainment.
   i. CM Exposure. This is a patient-level measure of the number of CM sessions delivered per patient during the 9-month Implementation phase. As described above, at each site, data will be extracted from the medical record (by center staff blind to condition) and entered into the Medical Record Data Extraction Form for the 25 patients enrolled in the study (25 patients * 30 sites = 750 patients) at the end of the Implementation phase. A Medical Record Data Extraction form will be filled out for every Self-Report Data Form completed in the patient medical record. Based on empirically derived benchmarks from prior RCTs,[10] 10 or more complete CM sessions per patient (out of a maximum of 24) is the target level of CM Exposure to merit P4P incentives. To reach the target level of CM Exposure for a given patient, at least 10 Medical Record Data Extraction forms must be completed.
   ii. CM Competence. This is a staff-level measure of staff's skill in CM delivery during the 9-month Implementation phase. Each month, CM staff will submit audio-recordings, one of which will be randomly selected for rating by coders blind to implementation condition using the CM Competence Scale[12] (CMCS). The scale contains 9 items scored from 1 to 7, with 7 denoting excellent competence. Based on empirically derived benchmarks from prior RCT research,[13] an average CMCS score of 5.8 across items is the target to earn P4P incentives. A continuous measure of CMCS scores will be created for each staff on a monthly basis.
   iii. CM Sustainment. This is a patient-level measure of the number of CM sessions delivered per patient during the 12-month Sustainment phase. Using the same protocol as for CM Exposure, data will be extracted at the end of the Sustainment phase from 25 randomly selected patients meeting eligibility criteria (i.e., newly admitted to OUD pharmacotherapy during the Sustainment phase; 25 patients * 30 sites = 750 patients). A continuous measure of the number of sessions received, as counted by the number of Medical Record Data Extraction forms completed, will be created for each patient.

b. *Patient outcomes.* Our **Secondary Aim** tests the effectiveness of the two implementation conditions (ATTC vs. E-ATTC) on two patient outcomes: Opioid Abstinence and Opioid-Related Problems.
    i. Opioid Abstinence. Patient abstinence from opioids will be assessed via 3- and 6-month post-baseline interviews, during which patients will self-report days of abstinence using the Timeline Followback (TLFB).[20] Abstinence will be corroborated via dip urine screens from Redwood Toxicology testing for: heroin/opiates, oxycontin, benzodiazepines, cocaine, methamphetamines, and THC. In addition, at the request of participating centers, single-panel screens will test for fentanyl, a highly lethal opioid not detected in multi-panel screens. A urine screen negative for all opioids (heroin/opiates, oxycontin, fentanyl) will be required for coding of 90 days abstinence. Other drug use detected via the TLFB or urine will be examined as covariates in the analysis.
    ii. Opioid-Related Problems. Opioid-related problems will be assessed via patient self-report at 3- and 6-months post-baseline using the Substance Problem Index,[21] which is a count of DSM symptoms experienced by the patient (range from 0 to 11). Both Drs. Becker and Garner have successfully used this index[22-24] in prior studies. The index will be tailored to focus specifically on problems due to opioids.

c. *Putative mediators.* Our **Exploratory Aim** tests putative mediators of implementation outcomes: implementation climate and leadership engagement. Organization-level scoring is described in ***Analytic Plan***. The putative mediator scales are measured at the start of the Preparation phase and the midpoint of the Implementation phase.
    i. Implementation climate. A 6-item measure of CM staff and leadership shared perceptions regarding the extent to which the innovation being implemented (i.e., CM) is expected, supported, and rewarded within their center. [25] Each item is scored on a 5-point Likert scale. This well-validated, brief measure was developed by Jacobs and colleagues, and following published guidelines, we calculate a scale mean for each staff member.
    ii. Leadership engagement. A 4-item measure of CM staff and leadership shared perceptions regarding the extent to which leadership is committed to, involved in, engaged in, and accountable for the implementation of the innovation (i.e., CM). Each item is scored on a 5-point Likert scale. Developed and validated as part of Dr. Garner's current NIDA-funded project, this measure has demonstrated excellent internal reliability (alpha = .94) and has been shown to be a significant predictor of staff-level implementation fidelity ($\beta = .18$, $p < .05$).[26]

d. *Covariates.* We measure potential baseline covariates at the patient, staff, and organization level. These measures are only administered at baseline. Specific measures used include:
    i. Baseline organization form. A form measuring baseline characteristics including years of operation, number of patients served, and medications prescribed.
    ii. Implementation Readiness. A well-validated 12-item pragmatic measure developed by Shea and colleagues[27] will assess readiness to implement CM.
    iii. CM Attitudes. A brief measure of attitudes towards CM, as well as providers' perception of its effectiveness and acceptability will be administered. This measure was developed by the NIDA Clinical Trials Network and has been used in multiple NIDA funded studies.
    iv. Provider demographics. At the provider-level, we measure staff tenure, education level, and attitudes towards CM.

v. Patient demographics. At the patient-level, we measure biological sex, race/ethnicity, age, and problem severity.
vi. Patient clinical characteristics. At baseline, we administer a general measure of global health functioning. This scale was developed by the NIH funded patient-reported outcomes study and is used in multiple NIH funded studies.

e. *Other Measures.* As noted in prior sections, we also collect some additional measures.
   i. *Patient contact information*. At the baseline assessment, we collect multiple forms of patient contact information, which will be stored separately from other study data. We gather this information from patients either over the phone or via face-to-face sessions and store it on paper forms kept in locked filing cabinets separate from other study measures.
   ii. *Patient locator forms*. At the baseline assessment, patients complete locator forms and sign locator letters with contact information of 2-3 close family members or friends in order to enable us to retain participants for the follow-up assessments. These data will be stored separately from other study data. We gather this information from patients from patients either over the phone or via face-to-face sessions and store it on paper forms kept in locked filing cabinets separate from other study measures.
   iii. *Provider CM knowledge*. Immediately following the full day training, providers will complete a measure of CM knowledge to ensure that they have sufficient understanding of CM principles to proceed to role plays. Providers that do not score at least 16 out of 20 will receive additional customized support from the ATTC trainer.

**10. Analytic Plan.**

a. All analyses will be conducted following intent-to-treat principles.[28,29] Missing data will be multiply imputed following recommendations of the National Research Council.[30] We will test the appropriateness of assumptions underlying the use of multiple imputation using sensitivity analyses.[31]

b. For the **Primary and Secondary Aims**, we test a series of multilevel models in which patients (Level 1) are embed within staff (Level 2) and within centers (Level 3). Consistent with Raudenbush and Bryk's multilevel modeling approach,[32] the proportion of variance to-be-explained at each level will be examined as an initial step. Next, following a decomposed-first strategy that advocates for starting with moderation-focused hypotheses to avoid biases associated with conflated effects,[33] we conduct multilevel regressions testing the extent to which our covariates significantly moderate the hypothesized relationship between condition and outcome. We test covariates at three levels: organizational (e.g., years of operation, number of patients, medications prescribed, implementation readiness), staff (e.g., tenure, education, CM attitudes), and patient (e.g., age, race, biological sex, problem severity). If moderation is not found, covariates will be controlled for as predictors. Condition assignment (ATTC vs. E-ATTC) will be the primary independent measure of interest for analyses. In addition to reporting statistical significance, we will report the effect size (ES) using Cohen's *d*.[34]

c. For the **Exploratory Aim**, we again test a series of 3-level models. For each mediator, the average correlation within group ($r_{wg}$) will be computed to determine whether aggregation of staff level responses to the organizational-level is warranted. Values of $r_{wg}$ range from −1.00 to 1.00, with values $\geq$ .60 representing acceptable agreement.[35] Centers with $r_{wg}$ values < .60 will be excluded from analysis. Exploratory analyses will apply a Baron and Kenny[36] style mediation approach,

which uses centering within context and includes a group mean at level-3 (CWC[M]).[37] Procedurally, first the outcome will be regressed on the condition variable (ATTC vs. E-ATTC) in a multi-level regression. Next, the outcome will be predicted by both condition and the group mean centered mediator (e.g., implementation climate) in a multi-level regression. Third, the mediational effect will be calculated by subtracting the estimated coefficient associated with condition in step two from the estimated coefficient associated with condition in step one. This method will allow the between-group mediation effect to be partitioned from the within-group mediation effect, which is important since between-group mediation is the effect of interest. Although significance of the mediation effect will be calculated using the Freedman and Schatzkin[38] *t* statistic, we also will report ES, which are not influenced by power.