Justice Community Opioid Innovation Network (JCOIN)
Coordination & Translation Center
Aim #1 Protocol

Fostering MOUD Use in Justice Populations

PIs: Todd Molfenter, Ph.D.
Faye Taxman, Ph.D.

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Principal Investigators:

Todd Molfenter, Ph.D.
University of Wisconsin - Madison
Industrial Engineering
1513 University Avenue, ME Bldg. Suite 4103
Madison, WI 53706
608-262-1685; todd.molfenter@wisc.edu

Faye Taxman, Ph.D.
George Mason University
4087 University Blvd, Ste 4100
Fairfax, VA 22030
703-993-8555; ftaxman@gmu.edu

Researchers:

Jee-Seon Kim, Ph.D.
University of Wisconsin - Madison
Educational Psychology
1025 W. Johnson Street, 1057 Educational Sciences
Madison, WI 53706
608-262-0741; jeeseonkim@wisc.edu

Nora Jacobson, Ph.D.
University of Wisconsin-Madison
Institute for Clinical and Translational Research
Community Academic Partnerships Program
608-262-8034; najacobson@wisc.edu

Randy Brown, Ph.D., MD
Dept of Family Medicine & Community Health
University of Wisconsin School of Medicine & Public Health
1100 Delaplaine Ct., Rm 3834
Madison, WI 53715
608-263-6558; rtbrown@wisc.edu

Alex Breno, M.A.
Center for Advancing Correctional Excellence!
George Mason University
4087 University Blvd
Fairfax, VA 22030
703-993-5222; abreno@gmu.edu

Study Coordinator:

Jessica Vechinski, MSW
University of Wisconsin-Madison
Industrial Engineering
1513 University Avenue, ME Bldg. Suite 4155
Madison, WI 53706
608-262-4378; jvechinski@wisc.edu

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Contents

1. BACKGROUND

The need for treatment and prevention of overdose is a national priority according to the Centers for Disease Control (CDC) which lists expanding access to addiction treatment services as an essential component in the response to the opioid overdose epidemic.[1] Less than 10% of justice-involved individuals are able to access behavioral health services on any given day regardless of setting (i.e. jail, probation, etc.),[2-5] however the Criminal Justice System (CJS) has some constitutional driven needs to provide behavioral health care (i.e., mental health and substance use) to the largest concentration of U.S. adults with behavioral health needs. Nearly 11 million individuals pass through local jails each year,[6,7] 5 million individuals are on parole or probation,[8] and 1.5 million are in state and federal prisons.[6] Among CJ populations, the rate of past-year substance use disorder (SUD) (66%),[1,9-19] lifetime opioid use (15%),[1] and pain medication dependence (11%)[1] are dramatically elevated compared to the non-criminal justice population, resulting in overdose,[12] suicide,[20-22] disabilities and physical disorders,[23–25] homelessness,[26] and death.[27,28]

While pharmacotherapy holds great promise, medications are underutilized in SUD treatment, both in and out of the CJS. [29,30] Of the three most common medications for opioid use disorders (MOUDS)--methadone, injectable naltrexone, and buprenorphine-- all possess evidence that they increase retention in treatment, reduce self-reported use of opioids, and reduce criminal activity and mortality.[3] Approximately 80% of those with opioid use disorders (OUD) do not receive appropriate treatment.[4,5] Utilization of MOUD among justice populations is even lower[31] with justice referred patients being one-tenth as likely to receive agonist MOUD as other patients.[32] Addressing justice system actors' attitudes is important for expanding use of medications[33] and for guiding implementation.

The CJS offers an opportune setting to disseminate and implement evidence-based practices (EBPs) because of the gap between evidence and practice, potential return on investment in order to reduce fatalities, reduced burden on the health and criminal justice (CJ) agencies, and improved quality of life. The pressing question is how best to facilitate dissemination, adoption, implementation, and sustainment of EBPs for CJ populations.

2. STUDY SYNOPSIS

The current timeframe from research lab to practice is 17 years, with only 14% of clinicians reporting use of evidence-informed knowledge in their clinical practice.[34] Complexities of the CJ or health systems coupled with interagency features present challenges to the effective dissemination, adoption, implementation, and sustainment of evidence-based practices. Coaching is a favored implementation strategy, yet coaching dosage and mediums have not been adequately tested or assessed in CJ settings. Scaling up in CJS, particularly MOUD utilization, presents a challenge given staffing resources available, acceptance of addiction treatment, and historical preference for behavioral therapy-based treatment practices that often do not include use of MOUD. In this trial, we will test two implementation interventions being applied to MOUD dissemination and implementation in justice settings for justice-involved populations: NIATx Coaching and the Extension for Community Healthcare Outcomes

(ECHO) model. NIATx Coaches provide expertise in MOUD implementation and organizational change to help treatment organizations and staff make, sustain, and spread MOUD. The ECHO platform focuses only on the provider side by connecting the primary care provider with expert MOUD prescribers to promote high-quality MOUD practices. This will be the first trial that assesses the comparative effectiveness of these approaches overall, and in justice settings.

The trial will be conducted with a combination of 48 jails and community-based organizations that treat individuals with OUDs post-incarceration. Sites will be randomly assigned to one of four study arms, with 12 sites in each arm: High-Dose Coaching/ECHO, Low-Dose Coaching/ECHO, High-Dose Coaching/No ECHO, and Low-Dose Coaching/No ECHO. The intervention period will be over a 12-month span with an additional 12-months for sustainability.

3. STUDY OBJECTIVES

The specific aim of this study is to compare High-Dose NIATx Coaching/ECHO, Low-Dose NIATx Coaching/ECHO, High-Dose NIATx Coaching/No ECHO, and Low-Dose NIATx Coaching/No ECHO. Impact will be measured using the RE-AIM framework:

- *Reach* (primary aim) measured as the percent of eligible justice involved patients who 1) are initiated onto any MOUD (buprenorphine, extended-release injectable naltrexone, or methadone), and 2) engaged with MOUD use.
- *Effectiveness* measured in terms of impact of MOUD involvement on re-arrest rates.
- *Adoption* measured as the percent of eligible clinicians in jail and/or community providers who use MOUD.
- *Implementation* measured by an organizational readiness for MOUD implementation over time and intervention fidelity scale (*for* NIATx and ECHO).
- *Maintenance* measured as the likelihood of organizations sustaining provision of MOUD utilization (organizational sustainability scores at 12 and 24 months of intervention) and we will continue to collect Reach, Effectiveness, and Implementation measures during the maintenance phase (Ms 12-24).

Study Coordination

The UW-Madison Center for Health Enhancement Systems Studies (CHESS) and George Mason University Center for Advancing Correctional Excellence! are the coordinating sites for this study. George Mason holds the grant award for the larger study this research is embedded in. The UW site will oversee all recruitment and study implementation activities which includes:

- developing organizational site-specific recruitment and data collection processes that meet study objectives;
- training staff on protocol procedures prior to start of recruitment and continuous monitoring to assure compliance with the protocol and human subjects regulation;

- communicating with clinic site staff as needed via conference calls to monitor progress, inform of protocol changes/distribute new version of protocol, and address unanticipated issues or challenges;

- manage all study data;
- oversee analysis; and
- oversee publications and presentations.

4. SELECTION OF SUBJECTS

This study will engage jails and post-incarceration community-based organizations serving justice involved persons including correctional and health staff and medical teams at those sites/organizations.

Organizations: Up to twelve (12) jails and community-based organizations from around the country, eighteen (18) jails and community-based organizations in Wisconsin, and eighteen (18) jails and community-based organizations in Virginia, with a total of forty-eight (48) sites will be recruited for this study.

Participating sites will receive $1,000 in Year 1 and again in Year 2 for participating in the study and for submitting organizational and staff data. The funds will be used to pay for study data and/or study material.

Sites to be approached for recruitment will be: sites that have expressed interest in the grant, organizational sites that provide post incarceration addiction treatment services, and jails that provide addiction treatment services within the jail. Once sites have been identified, they will be asked to sign an IRB approved Information Sheet (Memorandum of Understanding) to indicate their understanding of the study protocol and willingness to participate in the study.

Pre-Requisites for Site Participation:

- Have an interest in embedding or increasing the use of MOUD within their site.
- Have the funds to pay for medications for the duration of the study (24 months); whether it be from grants, insurance or private pay.
- Sites agree to implement or continue to use at least one medication, although they will be encouraged to offer more than one medication.
- Have leadership support at all levels.
- Sign a Memorandum of Understanding (MOU) or Information Sheet.
- Agree to provide data described in the MOU or Information Sheet.

Executive Sponsor, Change Leader & Team: Each site will be asked to identify an Executive Sponsor to represent their respective site. This individual will be in a leadership role such as Director, CEO, Sherriff, etc. The Executive Sponsor will be responsible for identifying a 'Change Leader' or 'site liaison' (someone in a management role), willing to coordinate the study elements. It is then up to the Executive Sponsor and Change Leader to identify up to 7 staff members that will be a part of the 'Change Team' in the jail setting. Members of the Change

Team for purposes of community linkage should include CJ staff (jail or probation), health provider representative, medical provider/prescriber (i.e. nurse, physician, etc.) to ensure that the team has reach to various pertinent audiences. Additional members on the Change Team can hold a variety of positions including counselor, nurse, social worker, case manager, etc. Change teams will also be present in the post incarceration community-based provider jail SUD partner sites and will also include variety of positions including counselor, physician, nurse, social worker, case manager, etc. Once participating staff is identified by role in the jail and post-incarceration CB provider sites, recruited staff will be emailed invitations to complete organizational/staff surveys and/or a phone interview along with a study consent form. Any staff member may formally decline to participate during the training portion of the study or any time thereafter.

5. REGISTRATION PROCEDURES

Organizational and Staff Recruitment

Organizational Surveys: The Executive Sponsor (or their designee) will complete the organizational surveys and may be asked to complete a short qualitative phone interview.

Staff Survey: The staff surveys will be completed by staff that are a part of the Change Team.

Physician Survey: The Physician Survey will be completed by physicians/prescribers working at the sites.

The Executive Sponsor will not have access to the survey data nor will they receive any data feedback or summaries from the surveys. The IRB approved consent form will describe that completing the staff or organizational survey infers their consent. For those who do not complete the survey, the survey will not be recorded and no record of the person not wanting to participate will be made. The consent form will be the first portion of the on-line survey to be administered through REDCap.

All surveys will be accessed through REDCap, a secure web-based platform, licensed by University of Wisconsin, that is used for building and managing online databases and surveys.

6. STUDY & TREATMENT PLAN

Study Design

The proposed study will implement a cluster randomized block design where staff are nested within sites. The community-based provider sites and jails will be grouped into homogeneous blocks and then randomly assigned into 2x2 design for each block. The forty-eights sites will be assigned to one of four study arms using a matching strategy within the blocks that groups four jail-clinic combination together prior to randomization. Each jail and CB treatment provider (or clinic) in these combinations will be treated as a site. For instance, if a jail has two post incarceration CB treatment providers (or clinics) in the trial, this will be 3 total sites (of the 48 sites). Within the matching block of 4 jail-clinic combinations, one jail-clinic combination will be randomized to an arm of the study. Twelve sites (that will consist of jails or post incarceration

CB treatment sites) will be assigned to each arm. The number of jails and post-incarceration sites per arm are expected to be balanced, with an anticipated 4 jails and 8 post-incarceration CB provider sites per arm.

Matching will be based on; a) number of clinic sites the jail will be including in the study (as part of the jail-clinic combination), population of the county where the jail is located, and whether or not the jail is currently providing MOUD to CJ population, and if so, what type of MOUD. The blocking procedure will reduce variability within treatment conditions and yield more precise estimates of treatment effects. This strategy will allow for the study team to examine the effects of High versus Low-Dose coaching and ECHO on MOUD use rates in large and small settings. In the study design, there will be a 12-month implementation period followed by 12 months to track sustainability. Data will be collected at baseline, 12 months and 24 months.

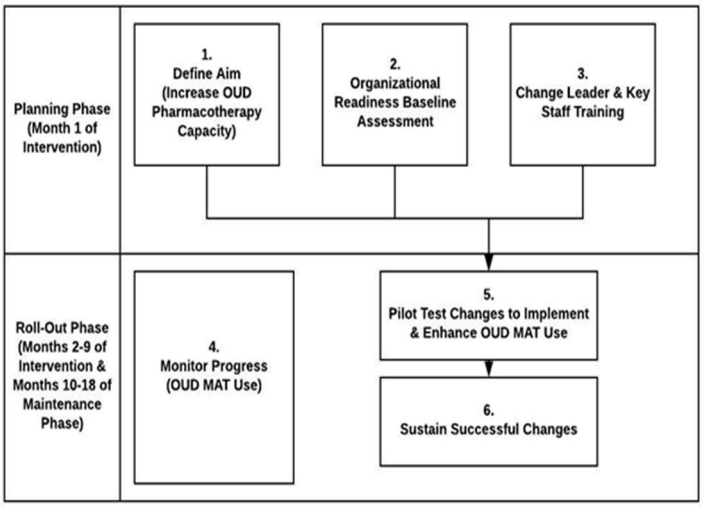
Intervention

There will be two "scaling-up practices" used in this study; NIATx Coaching and ECHO Clinical Mentoring. The study will look at combination of these two practices to create four intervention study arms;

1) High-Dose Coaching/ECHO,
2) Low-Dose Coaching/ECHO,
3) High-Dose Coaching/No ECHO, and
4) Low-Dose Coaching/No ECHO

Scaling up Practice #1: NIATx Coaching. NIATx framework provides each participating site with a NIATx Coach who is an expert in MOUD implementation and organizational change and will help the organization adopt, implement, and increase the use of MOUD. Coaches help the sites think through key issues, offer process improvement training, and suggest changes. NIATx coaches in the High-Dose and Low-Dose arms will interact with the organization described in Figure 1. The High-Dose coaches will conduct an on-site visit with the site Change Team and complete 11 monthly one-hour calls (months 2-12 of intervention) following the kick-off meeting. Coaches in the Low-Dose arm will hold a one-hour introduction call with the Site Change Team and conduct a two-hour NIATx training via webinar and three quarterly, one-hour calls at months 4, 8 and 12 with the Change Team following the kick-off meeting.

Figure 1: NIATx Coaching (During 12-month Intervention Period)



Step1. *Define Aims*: Executive sponsor briefing on project during an in-person Kick-off meeting with Study Team & other Executive Sponsors.

Step 2. *MOUD Baseline Assessment:* Baseline will include buprenorphine, naltrexone & methadone capacity and Organizational Readiness Baseline Assessment. Assessment and reporting will be completed by Executive Sponsor or an administrator.

Step 3. *Train Change Leader & Change Team:* One Change Leader and up to 7 members identified by the organization (Change Team) will be trained to implement MOUD during the site visit or introductory call with the site change team.

Step 4. *Monitor Progress:* Track the number of buprenorphine, naltrexone & methadone capacity and use.

Step 5. Pilot Test Changes to implement MOUD using Plan Do Study Act (PDSA) approach.

Step 6. *Sustain Successful Changes*: Implement a plan to institutionalize gains to not revert to old ways. Leadership and medical team will be trained to sustain changes made.

Scaling up Practice #2: ECHO. The ECHO model connects MOUD prescribers and experts with primary care providers and medical teams to promote high-quality MOUD practices. ECHO is provided monthly through videoconferences. Experienced MOUD prescribers address topics such as counseling strategies, urine test interpretation, and transitioning from buprenorphine, naltrexone and methadone. Prescribers assigned to the two study arms that include ECHO will participate in 12, one-hour monthly ECHO Videoconferences.

Ten to eleven prescribers from the two study arms will be asked to volunteer to submit case studies. Prescribers who volunteer will receive instructions on how to write the case study and will receive a $50 gift card as an incentive. One case study will be reviewed during each ECHO videoconference call in addition to a subject presentation.

Kick-Off Meeting

Prior to the start of the intervention(s), the Executive Sponsor and/or Change Leader (may also include Change Team members), as well as other key stakeholders, will be invited to attend a half-day in-person Kick-Off Meeting. The following material will be discussed; 1) Overview of Study and AIMs, 2) Current practices at sites, 3) Best Practice Examples, 4) Ways to Expand Capacity, and 5) NIATx Process.

We anticipated holding up to and no more than eight kick-off meetings. Meeting locations will be determined based on grouping participating sites that are in close proximity to each other to keep travel minimal.

Table 1: Outline of the Four Study Arms & Site Responsibilities:

ARM	NIATx Coach	ECHO

High-Dose Coaching & ECHO	• Key stakeholders attend an in-person Kick-Off Meeting with Study Team & Coaches
	• 4-hour onsite visit
	  ○ 1-hour meeting w/Executive Sponsor & tour facility
	  ○ NIATx training with Change Leader/Team
	• 11 monthly (one-hour) coaching calls
		• Prescribers participate in 12 monthly (one-hour) video conference calls

Low-Dose Coaching & ECHO	• Key stakeholders attend an in-person Kick-Off Meeting with Study Team & Coaches • One-hour conference call with Executive Sponsor • Two-hour NIATx webinar training with Change Leader/Team • Three (one-hour) coaching calls at months 4, 8, and 12 with Change Leader/Team	• Prescribers participate in 12 monthly (one-hour) video conference calls

High-Dose Coaching / No ECHO	• Key stakeholders attend an in-person Kick-Off Meeting with Study Team & Coaches
	• 4-hour onsite visit
	  ○ 1-hour meeting w/Executive Sponsor & tour facility
	  ○ NIATx training with Change Leader/Team
	• 11 monthly (one-hour) coaching calls	

Low-Dose Coaching / No ECHO	• Key stakeholders attend an in-person Kick-Off Meeting with Study Team & Coaches • One-hour conference call with Executive Sponsor • Two-hour NIATx webinar training with Change Leader/Team • Three (one-hour) coaching calls at months 4, 8, and 12 with Change Leader/Team	

Data Source

Table 2 shows a complete list of Measures, Sources, and Tool/Frequency. The Executive Sponsor, Change Leader and Change Team at each jail and community-based provider site will be asked to complete one or two of the three main surveys based on their role(s) within the study: Organizational Survey, Staff Survey, and Physician Survey. Site staff participants will be sent links to complete the survey(s) via REDCap. Each organizational site will receive a $1000 stipend per year for two years once all organizational, physician, and staff surveys have been completed.

The trial has 4 study arms that will have staggered starts in order to have sufficient training resources for the trial. Each arm will have 12 organizations/sites with N=48 total.

Organizational Surveys & Data:
Organizational surveys will be completed by Executive Sponsor (or their designee) three times during the project (baseline, 12 months and 24 months). The baseline survey will be conducted by phone interview with all 48 sites. To increase survey completion rates for the organizational surveys, the research team at UW will conduct follow-up phone calls and e-mails with the Change Leaders at Week 1 of post-survey distribution to assure the survey receipt, then at Weeks 4 and 12-post survey distribution if surveys are not complete.

We will assess Organizational Traits, Client Traits, Staff Characteristics, and number of prescribers at the sites at three points during the study - at organizational baseline (baseline), at end of the intervention period (month 12) and at end of sustainability period (24 months) using a mix of organizational and administrative data.

Each survey will take approximately 45 minutes to complete. This will result in 48 unique staff participants at baseline, and 4 new people per round at post-intervention (m12) and post-sustainability (m24), assuming 10% turnover at each round. This will result in a total of 56 unique participants and 144 total surveys.

Staff Surveys & Data:
The designated Executive Sponsor or the Change Leader at each site will manage staff member recruitment to construct a change team of up to a seven (7) member Change Team. Upto two of the team members will be physicians. Each member of the change team as well as the change leader will be asked to complete staff surveys at baseline, 12m, and 24ms for a total of 8 “staff” surveys per site. Information on the implementation process will be gathered from site staff members during surveys and interviews.

The full Staff Survey including Organizational Readiness for Implementing Change (ORIC), Organizational Climate-Stress, Attitudes toward MOUD and Program Sustainability, will be administered three times during the study (baseline, 12m, 24m). Each survey is expected to take approximately 20 minutes or less to complete. Staff completing the surveys will receive consent documents when they are sent the survey link via REDCap. To increase survey

completion rates for the Staff Surveys, the research team at UW will conduct follow-up phone calls and e-mails with the Change Leaders at Week 1 of post-survey distribution to assure the survey receipt, then at Weeks 4 and 12-post survey distribution if surveys are not complete. Each survey cycle, at months listed above, will include up to 384 people per cycle. The 384 staff will include up to 8 participants from the 48 sites and will include the Change Leader (supervisor/member of the leadership staff), and up to 7 team members part of the Change Team (CJ staff, prescribers, clinicians, nurses, counselors, social workers, etc). Since many of the same staff will likely complete surveys in successive cycles, 536 unique staff are expected for survey completion across all three cycles. The 536 unique people projected assumes 20% or 76 new people per round occurs post-intervention and post sustainability round. There will be a total of 1,152 surveys.

Physician Surveys & Data:

Collecting physician attitudes toward MOUD will occur at months 0, 12, and 24. An average of two prescribers are anticipated per site. Each survey will take 15 minutes or less to complete. Staff completing the surveys will receive consent documents when they are sent the survey link via REDCap. To increase survey completion rates for the Physician Surveys, the research team at UW will conduct follow-up phone calls and e-mails with the physicians at Week 1 of post-survey distribution to assure the survey receipt, then at Weeks 4 and 12-post survey distribution if surveys are not complete. This will result in 96 unique prescriber participants at baseline, and 9 new people per round at post-intervention (m12) and post-sustainability (m24), assuming 10% turnover at each round. This will result in a total of 114 unique prescribers and 288 surveys (@ 96/cycle).

The grand total of organizational surveys, at n=144, staff surveys at n=1,152, physician surveys at n=288. TOTAL will be N=1,584.

Administrative & Site Aggregate Data:

Administrative Jail Data will be collected from all 24 jail sites once every year for two years. We anticipate the data will include de-identified screening, assessment and/or intake data, demographic information, date entered/exited jail, sentence and length, etc.
Administrative State Criminal Justice Data will be obtained from state databases for all states that have a jail/community-based provider participating in the study. De-identified data will be provided once every year for two years for the participating jail jurisdictions (e.g. in Wisconsin it is counties). Data may include arrest dates, arrest offenses, court outcomes, sentence and length, etc.
Health and Treatment Provider Data will be provided by all 24 community-based treatment providers once every year for two years. De-identified data for jail based referrals would include number of referrals to OUD care, number of referrals to behavioral therapy or counseling, dates/type of care, MOUD units received, Medicaid payment data, etc.
Monthly Tracking Data will be provided by all 48 jails/community-based treatment providers on a monthly basis via spreadsheet provided by study team. Captured data for the jails will include MOUD treatment data, number screened for OUD, number receiving MOUD, number of

individuals who received naltrexone, buprenorphine and methadone and number of injections/slots. Captured data for the community-based treatment providers will include number referred from the jail for OUD, number receiving MOUD, number of individuals who received naltrexone, buprenorphine and methadone and number of injections/slots.

All suggested data requirements are included in the Information Sheet provided to each site prior to participation in the study.

Table 2: Measures, Sources, and Tool/Frequency

Measurement	Measure Source	Data Source/Frequency
Descriptive Statistics		

Organizational traits (survey source): Admissions (state), Rural v. Urban (state), organizational readiness (staff), MOUD type (org), funding (org), # of practitioners (org)
 	
Client traits: Age, gender, ethnicity, highest education level, employment indicator, place of residence, type of offense, Medications/Treatment offered (date(s) receiving MOUD), mental health comorbidity, OUD history, Disciplinary actions/incident reports, types of offenses
 	
Staff Characteristics: Age, Gender, Ethnicity, Certification or education level, years of training, tenure on the job
	Organization & Administrative Data	• Organizational Survey
		  ○ Baseline, 12m, 24m
		• State CJ Database & Jail Administrative Database
		  ○ Baseline, 12m, 24m
		• Monthly Tracking Site Spreadsheet
		• Organizational Survey
		  Baseline, 12m, 24m

Reach		
% of patients initiated/begin MOUD; Days engaged in MOUD	Organization	• Monthly Tracking Site Spreadsheet ○ Completed by Jail/Clinic Manager/Data Liaison • Or State Databases
Effectiveness		
Re-Arrest Data: Arrest dates, Arrest Offense (charge), Felony/Misdemeanor indication, Outcome (convicted, not convicted, sentence, start and end date of sentence),	State Database	• State CJ databases ○ Baseline, 12m, 24m

Adoption		
% of prescribers using MOUD	Organization	• Organizational Survey ○ Baseline, 12m, 24m
Staff Attitudes Toward MAT	Knudsen, Ducharme, Roman & Link[42]	• Staff Survey ○ Baseline, 12m, 24m
Physician Satisfaction with MOUD	Modified Physician Worklife Survey	• Physician Survey ○ Baseline, 12m, 24m
Implementation		
Organizational Readiness for MOUD	ORIC[39]	• Organizational Survey ○ Baseline, 12m, 24m
Organizational Climate: Stress	TCU SOF[41]	• Staff Survey ○ Baseline, 12m, 24m
Maintenance		
Likelihood of MOUD sustainability	Program Sustainability Assessment Tool[40]	• Staff Survey ○ Baseline, 12m, 24m
NIATx Fidelity & ECHO Fidelity	Organization (using a scale designed for this study)	• Organizational Survey ○ Baseline, 12m, 24m

Qualitative Interviews

Qualitative data will be gathered from organizational staff at two points; pre-intervention (baseline) and post-intervention (12 months).

Baseline qualitative phone interviews will be completed with leadership staff at 24 randomly selected sites, six sites within each study arm. Interviews will last approximately 30-45 minutes in length and will be conducted with up to two people at each site. The interviews will be audio-taped (with staff participant permission), but the staff person's identity will be protected and in no way be linked to the results. Interviews will be semi-structured and gather information that is not included within the organizational surveys that will be completed throughout the study. This includes information about site structure and process, culture surrounding justice-involved clients, motivation for serving OUD population and approaches to organizational change. Examples of open-ended questions that will be asked;

1. Please walk me through how a justice-involved client comes to your service?
2. Are your justice-involved clients integrated into your general clientele?
3. Please tell me about the last time your organization made a change to its processes?

Post-intervention qualitative phone interviews at 12 months will be conducted with the Change Leader at 24 selected sites. Interviews will last approximately 20-30 minutes and will be audio-taped (with staff participant permission), but the staff person's identity will be protected and in no way be linked to results. Sites will be chosen by taking the three highest achieving sites and the lowest achieving sites in each of the four arms, providing for 24 interviews. Sites will be ranked based on the percentage of eligible individuals who received MOUD within the 12-month intervention period. During the interview, Change Leaders will be asked to review their site outcome data and provide their experience and feedback about the implemented intervention(s).
Example of open-ended questions included;

1. What do you see when you look at this data from your site?
2. What helped you to achieve these results?
3. What barriers got in the way?

We will use University of Wisconsin Box to store data received from all sites.

Unanticipated events

Should any unanticipated problems arise, they will be reported to WIRB per the appropriate IRB's guidance on unanticipated problems and reportable events.

Privacy and Confidentiality

Since community-based organizations and jail sites will play a role in the testing of the NIATx and ECHO interventions, we view staff members as human subjects. For the project's evaluation plan, we will address human subjects' protection for staff. Clients are not being addressed since they are not the focus of the intervention, while the organization's leadership, staff and prescribers are. The data to be collected in the evaluation will come from existing de-identified client data collected in state administrative databases as well as organizational and staff surveys, and staff interviews. Table 3 (below) briefly describes the individuals referred to in the protection plan who will have access to the project data and their level of access.

Table 3: Research Participant Overview

Title	Affiliation	Access
Scientific Directors (PI)	UW-Madison & George Mason University	Limited Data Set client administrative data, survey, and interview data
Project Team (researchers/students)	UW-Madison & George Mason University	Limited Data Set client administrative data, survey, and interview data
State database administrators	States with participating sites	They will not receive or view any administrative, survey, or interview data
Executive Sponsor (Site staff member in administration, executive or management role)	Participating sites	They will not receive or view any administrative, survey, or interview data
Change Team Leader (Site staff member in a management role)	Participating sites	They will not receive or view any administrative, survey, or interview data
Change Team (Site staff members-Prescribers (at least one), clinicians, nurses, counselors, social workers, etc)	Participating sites	They will not receive or view any administrative, survey, or interview data

7. POTENTIAL RISKS

Staff level:

Staff members could feel pressure to participate in the study. It will be made clear, through written materials and oral instruction, that staff participation in the project's evaluation is completely voluntary. The cost and implementation analyses and their purpose in understanding the feasibility of implementing NIATX and ECHO will be explained. Staff responses to interviews will be coded and responses will be accessible only by evaluation team members (survey and interview data will not be accessible to other clinic staff members). In addition, the Executive Sponsor for each site will be notified of the importance of staff not feeling coerced to participate in the study or complete staff surveys.

The potential risk for staff is that the information they provide could be offensive to members of management or their peers. Hence, protecting staff confidentiality is an important element of our protection plan. Researchers (Jacobson, Vechinski, Breno) trained in protecting consumer confidentiality will conduct interviews. Data collected in the interviews and surveys will have a code number assigned (as previously defined) attached prior to storing in the project dataset. In this way, we can ensure that

the interviewer (in the case of interviews) and the University of Wisconsin database administrator (in the case of surveys) will be the only person who can identify the interviewee's responses. Also, managers or other members of the organization will not see transcripts of interviews.

In summary, during the on-line consent, potential subjects will be informed of (1) the nature and purpose of the study, (2) the types of data that will be collected from, (3) measures taken to insure the confidentiality of data collected (4) their right to leave the study at any time, and (5) the timeline of the study. Consent will be documented by obtaining online IRB-approved consent forms containing all of the above information. Consent forms will be digitally based. Consent forms will be stored at the University Wisconsin – Madison on a secure server. The consumer can download a PDF of the consent form.

A Certificate of Confidentiality has automatically been granted by virtue of this study being funded through the National Institutes of Health. This provides an additional level of protection for participant data.

8. MEASUREMENT OF EFFECT

All scales used in this study, except for the Fidelity scales developed for this study, have good tested psychometric properties with similar populations. Listed below are the factors to be measured and measurement instruments with references to validation studies.

Descriptive Statistics - Organizational traits such as admission and rural v. urban will be obtained via Organizational Survey and database. Client traits such as age, gender, ethnicity, treatment offered and CJ status will also be obtained at three points during the study via the Organizational Survey and database. Staff traits such as gender, ethnicity, and certification or education level will be obtained via the Organizational Survey at three points.

REACH - The percent of patients initiated on MOUD and length of engagement will be obtained through monthly spreadsheet data completed by organizational staff or state databases.

Adoption – The percent of prescribers using MOUD will be collected through the Organizational survey at 3 points during the study. The organizations readiness for MOUD will be collected using the Organizational Readiness for Implementing Change (ORIC) scale and the Organizational Climate: Stress measure will be collected at two points in the study.

Effectiveness – Re-arrest rates will be obtained through state police databases on a yearly basis.

Maintenance –The organizational survey, which will be administered at three points during the study, will assess the likelihood of MOUD sustainability. The Physician Survey will be completed by physicians at 3 points during the study.

9. STUDY PARAMETERS

The 48 participating jails or community-based organizations will be assigned to one of four study arms;

- High-Dose Coaching & ECHO; community-based organizations (n=9), jails (n=3)
- Low-Dose Coaching & ECHO; community-based organizations (n=9), jails (n=3)
- High-Dose Coaching & No ECHO; community-based organizations (n=9), jails (n=3)
- Low-Dose Coaching & No ECHO; community-based organizations (n=9), jails (n=3)

We will use a matching strategy that groups four clinics together prior to randomization. One clinic from each four-clinic matched group will be randomized to each study arm. The matching criteria, using organizational characteristics traits, are:

a) Referral Source

b) Whether or not currently providing MOUD to CJ populations

c) Admissions per year

d) Urban vs Rural

10. STATISTICAL CONSIDERATIONS

Sample Size & Power:

Regarding the two intervention factors, coaching and ECHO, in 2x2 factorial design conditions, we will recruit 48 programs, including 16 jails and 32 community-based organizations in the criminal justice system (CJS). This number provides reasonable power to detect the effects of coaching and ECHO on primary outcomes, as previous research indicates estimated effect sizes for the former as medium and the latter as large. A buprenorphine implementation study conducted in 48 treatment agencies in Ohio found that NIATx coaching increased MOUD adoption rates by 24.8% (Molfenter, Quanbeck, et al 2013). More recently, PI Molfenter found that High vs. Low-Dose coaching provided significantly different results on increases in buprenorphine use among 20 organizations (31.5% vs. 2.5%, $p = .001$, Cohen's $d = .5136$). Other researchers have found large effects for ECHO, including a 10-fold increase in buprenorphine waivered physicians (Komaromy M, Duhigg D, Metcalf A, et al. 2016). Therefore, our power analysis focuses on detecting High- vs. Low-dose coaching effects with an estimated effect size of $d = .51$. Patient outcomes within the same programs may not be independent due to the clustered nature of the data. Based on previous studies, we anticipate the intra-class correlation (ICC) to be around 0.10. Although the number of patients within programs will likely vary over time, our current and previous studies with similar populations and designs suggest that we can anticipate the number of participating programs to be mostly stable during the study period. To increase survey completion, programs will be given a $1,000 bonus for providing a year of data per site; for government agencies we will provide program materials such as wrist bands, stress balls, or other items to share with participants. This approach is yielding a return rate of 89% in a current study. With 42 programs at the end of the study after 11% attrition and 75 or more patients per program, we will be able to detect coaching effects at a power of .85 or higher in our proposed study with a Type I error rate of 0.05. The corresponding power for ECHO would be greater (.90+) with the same number of programs and patients. Power analysis software developed for clustered data, Optimal Design, was used to calculate power.

Data Analysis Plan:

Initial exploratory analyses of MOUD initiation and use will assess standard summary statistics and examine graphical representations of the data and will compare baseline characteristics among the 48 participating programs in this study**,** including patient age, ethnicity, nature of SUD, criminal justice status, organizational readiness for change, and MOUD. Chi-square and t-tests will be used to test for statistically significant baseline differences. Descriptive statistics and figures will display the distribution of each analytic variable collected at each time point.

The rates and frequency of MOUD use (buprenorphine, methadone and injectable naltrexone) will be measured repeatedly, and these values will be correlated over time. Instead of assuming independence (i.e., zero correlation) or a compound symmetry covariance structure (i.e., a constant correlation regardless of the proximity of measurement time points), we will allow errors to be auto-correlated or Toeplitz-structured, denoted as AR(p) or TOEP(p), in growth curve models. The best-fitting covariance structure will be determined based on heuristic model comparison criteria such as AIC and BIC.

Intervention and Sustainability:

For MOUD and implementation outcomes at 12 month and at 24 month, mixed-effects models (random effects of programs; fixed effects of treatment condition and time) will be used for data analysis. Mixed-effects models, also known as multilevel or hierarchical linear models, are suitable because MOUD patients are nested within programs. Using a multilevel modeling framework, separate models will be applied for the percentage of patients and clinicians using MOUD and their frequency of use (for patients only). Program covariates as well as variables showing noticeable changes between phases will be included in the models as covariates to properly and efficiently estimate the effects of coaching and ECHO. We will examine the coaching and ECHO effects at each time point using cross-sectional multilevel models and will also implement growth curve models across time that include the coaching (high vs. low) and ECHO (present vs. absent) effects, time (baseline, post intervention, follow-up), and interactions between the intervention and time factors, while controlling for relevant time-varying and time-constant covariates. The rates and frequency of MOUD use (by buprenorphine, methadone and injectable naltrexone) and clinical and implementation outcomes will be measured repeatedly for the same programs, and it is expected that these values will be correlated over time. Therefore, instead of assuming independence (i.e., zero correlation) or a compound symmetry covariance structure (i.e., a constant correlation regardless of the proximity of measurement time points), we will allow errors to be auto-correlated or Toeplitz-structured,[82] denoted as AR(p) or TOEP(p), in the growth curve models. The best-fitting covariance structure will be determined based on heuristic model comparison criteria such as AIC and BIC.

Mediational analysis:

We will examine the mediating effects of organizational factors on MOUD use through: NIATx Fidelity, ECHO Fidelity, the Organizational Readiness for Implementing Change (ORIC), Program Sustainability Assessment, and the Organizational Climate (Stress) measure. These factors will be analyzed using mixed-effects models. Through a mediation analysis, we can estimate the direct (NIATx and ECHO) and indirect effects (Adoption - # of prescribers) of each implementation arm.

We will test the mediation effect of each potential mediator at each time point as well as across time. The R package 'mediation,' will estimate the causal mediation effects, examine moderated mediation effects, and conduct sensitivity analysis.[70]

Effectiveness analysis:

We will compare MOUD use and retention rates in the 4 different arms using hierarchical linear models, where arm membership is used as the treatment assignment. We will examine the distribution of this outcome measure and will implement an appropriate transformation or nonlinear link function when appropriate (e.g., logistic, Poisson, exponential). Monthly data collection of the Effectiveness as well as Reach (MOUD use) measures, allows for analysis after each stage of NIATx and ECHO.

Table 4: Initiation & Retention

	Data	Source
Initiation	• # of clients initiated on MOUD • # on MOUD	Organizational Spread Sheet
Retention	• # of injections • # of weeks on Buprenorphine (30-Day Discontinuation) • # of methadone doses	State Database

Qualitative Analysis:

The qualitative analysis will be conducted by project staff, supervised by the qualitative methodologist, who will ensure that proper and consistent interviewing and analysis techniques are used. Project staff will conduct the interviews, which will be audio recorded and transcribed verbatim. Interviews with leadership personnel will focus on organizational culture, including the organization's approach to making process changes, as well as motivations and expectations for working with justice-involved populations. Interviews with staff will focus on the staff's perspectives on their organizations' experiences with identifying and implementing process changes. Project staff will conduct a directed content analysis of these data. Qualitative data will be summarized and analyzed to detect patterns in individual and clinical approaches to change that have been successful. This description will enhance our understanding of how the NIATx and ECHO models work in criminal justice settings and criminally involved populations, promoting valuable insights that can be applied to future dissemination and implementation of evidence-based practices.

11. RECORDS TO BE KEPT

- Organizational traits
- Staff/client traits
- Survey results (Organizational, staff and physician surveys)

12. ACRONYM LIST

BJA	Bureau of Justice Assistance
CFIR	Consolidated Framework for Implementation Research
CJ	Criminal Justice
CHESS	Center for Health Enhancement System Studies
CSAT	Center for Substance Abuse Treatment
D/I	Dissemination and Implementation
EBPs	Evidence-Based Programs
ECHO	Extension for Community Healthcare Outcomes
MAT	Medication Assisted Treatment
MOUD	Medications for Opioid Use Disorder
NIATx	Network for the Improvement of Addiction Treatment
OCM	Organizational Change Manager
OUD	Opioid Use Disorder
PDSA	Plan-Do-Study-Act
RCT	Randomized Control Trials
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
SAMHSA	Substance Abuse and Mental Health Services Administration
SUD	Substance Use Disorder
TAU	Treatment as Usual

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