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## Stepped-wedge randomized controlled trial of a novel opioid court to improve identification of need and linkage to medications for opioid use disorder treatment for court-involved adults

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### Abstract

In response to the opioid crisis in New York State (NYS), the Unified Court System developed a new treatment court model—the opioid intervention court—designed around 10 Essential Elements of practice to address the flaws of existing drug courts in handling those with opioid addiction via broader inclusion criteria, rapid screening, and linkage to medications to treat opioid use disorder (MOUD). The new court model is now being rolled out statewide yet, given the innovation of the opioid court, the exact barriers to implementation in different counties with a range of resources are largely unknown. We describe a study protocol for the development and efficacy-test of a new implementation intervention (Opioid Court REACH; Research on Evidence-Based Approaches to Court Health) that will allow the opioid court, as framed by the 10 Essential Elements, to be scaled-up across 10 counties in NYS. Using a cluster-randomized stepped-wedge type-2 hybrid effectiveness-implementation design, we will test: (a) the implementation impact of Opioid Court REACH in improving implementation outcomes along the opioid cascade of care (screening, referral, treatment enrollment, MOUD initiation), and (b) the clinical and cost effectiveness of Opioid Court REACH in improving public health (treatment retention/court graduation) and public safety (recidivism) outcomes. Opioid Court REACH has the potential

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to improve management of individuals with opioid addiction in the court system via widespread scale-up of the opioid court model across the U.S., should this study find it to be effective.

## Keywords

Court-involved adults; Medications for opioid use disorder; Opioid court; Implementation science

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## 1. Introduction

### 1.1. Background

In the context of a nationwide opioid epidemic, rates of opioid misuse, opioid use disorder (OUD), and overdose disproportionately affect those in the justice system (Binswanger et al., 2007; Boutwell et al., 2007). Between 2005 and 2015, rates of drug court participants with a primary heroin problem more than doubled across urban (from 7% to 19%), suburban (12% to 21%), and rural (4% to 24%) courts (Huddleston & Marlowe, 2011; Marlowe et al., 2016). Yet despite an indication that medications to treat OUD (MOUD; e.g. buprenorphine, extended-release [XR] injection naltrexone, and methadone) reduce continued justice involvement (Ball & Ross, 1991; Johnson et al., 2000) and that agonist MOUD is more protective against overdose than nonagonist MOUD (Wakeman et al., 2020), many drug courts hold negative perceptions of MOUD, prohibit agonist MOUD, or only allow nonagonist medication (e.g. XR Naltrexone) (Andraka-Christou et al., 2019; Andraka-Christou & Atkins, 2020; Csete & Catania, 2013; Festinger et al., 2017; Matusow et al., 2013). Therefore, standard drug court models do not adequately deliver best practices for managing defendants with OUD and reducing their risk of overdose.

In 2017, New York State (NYS) launched the first opioid intervention court in the U.S. to address the needs of defendants with opioid misuse, aiming to reduce overdose, opioid dependence, and recidivism via *rapid* screening, linkage, and initiation of MOUD. During the recommended 90 days that a defendant is in the opioid intervention court, the prosecution of his/her case is temporarily suspended; participation is voluntary and is decided before a plea is entered at arraignment. In 2018, the NYS Unified Court System (UCS) began to expand this model to other counties (NYS Unified Court System, 2018a). Drawing from the evidence base of drug court evaluation studies and lessons learned from the first opioid intervention court, in 2019 a national panel of experts—in collaboration with the statewide court system—convened to discuss the opioid court model and developed the Ten Essential Elements of Opioid Intervention Courts to guide court practice: (1) broad legal eligibility; (2) immediate screening for risk of overdose; (3) informed consent after consultation with defense counsel; (4) suspension of prosecution or expedited plea; (5) rapid clinical assessment and treatment engagement; (6) use of recovery support services (peer advocates and family support navigators); (7) frequent judicial supervision and compliance monitoring; (8) intensive case management; (9) program completion and continuing care; and (10) performance evaluation and program improvement (NYS Unified Court System, 2018b).

These Ten Essential Elements cover both judicial and clinical aims, providing guidance for moving from the court to the community for treatment at each step. Thus, a central piece of the opioid court model is collaboration between justice and treatment systems to ensure that court participants receive evidence-based treatment, with a particular emphasis on MOUD (Essential Element #5). However, cross-system collaboration can often be hindered by conflicting missions and distinct cultures or belief systems (Fletcher et al., 2009; Lehman, 2009). In the justice system, researchers have successfully used implementation science as a framework for improving justice and treatment system collaboration (Friedmann et al., 2012; Shafer et al., 2014). Thus, in the context of a new court model, of which the cornerstone is cross-system collaboration, an implementation intervention is needed to guide the scale-up of opioid intervention courts to maximize their effectiveness across county contexts and permit widespread scalability.

The current study capitalizes on a unique real-world scale-up of an innovative opioid court to develop and test an implementation intervention called Opioid Court REACH (Rigorous Evidence-Based Approaches to Court Health). Opioid Court REACH'S goal is to optimize the ability of the opioid court to identify court-involved individuals who misuse opioids, assess their needs, and facilitate enrollment into treatment/MOUD via use of two overarching implementation strategies: interagency change teams and external facilitation. Interagency change teams are well suited to the implementation of cross-system initiatives in which organizational cultures and priorities may be barriers to the practice change process, and change teams may serve as program champions (Aarons et al., 2014; Fixsen et al., 2009). External facilitation (including technical assistance) can further assist change teams (e.g., court stakeholder group) to achieve their goals and address barriers to change (Berta et al., 2015; Lessard et al., 2015). In particular, if the external facilitator can maintain a neutral or impartial position with a unique focus on practice change, the facilitator may effectively negotiate differences between agencies and achieve inter-agency consensus to achieve practice change goals. In this paper, we describe the theoretical model and framework used to guide the development of the implementation intervention as well as the study protocol currently underway.

## 1.2. Study objectives

The goals of the project are to 1) develop and refine the Opioid Court REACH implementation intervention and 2) conduct a trial testing (a) the implementation impact of Opioid Court REACH in improving implementation outcomes along the opioid care cascade (screening/identification, referral, treatment enrollment, MOUD initiation), and (b) the clinical and cost effectiveness of Opioid Court REACH in improving public health (treatment retention/court graduation) and public safety (recidivism) outcomes, exploring defendant gender, race/ethnicity, age, and charge, with county urbanicity and county overdose rates as moderators.

The first goal will be accomplished using mixed methods to determine barriers to implementation across early adopter counties who established opioid courts before 2019 and developing implementation strategies that support practice and process improvement to help counties better align their court practice with the 10 Essential Elements. Then,

using a stepped-wedge, cluster-randomized hybrid effectiveness-implementation type 2 trial (Curran et al., 2012), we will compare Opioid Court REACH to treatment as usual (TAU; drug courts). This trial leverages the scheduled state roll-out of the opioid intervention court model in 10 new adopter NYS counties. We will use a multistage implementation paradigm—from readiness to adoption to sustainability—to evaluate the impact of Opioid Court REACH.

## 2. Materials and method

### 2.1. Theoretical framework and study design

The proposed study uses the exploration, preparation, implementation, and sustainment (EPIS) framework, which identifies necessary structures and processes within systems to support implementation of evidence-based practice (Moullin et al., 2019). EPIS comprises four sequential phases of implementation: exploration (determining needs and available programs); preparation (planning how to integrate the program into an organization); implementation with fidelity; and sustainment. The framework considers the multilevel nature of service systems and addresses outer (e.g., county funding, overdose rates) and inner contexts (e.g., organizational functioning, staff attitudes), allowing for exploration of barriers to implementation and sustainability. Implementation frameworks are limited by a failure to describe *how* organization- and provider-level factors interact to affect implementation. Therefore, we also use social cognitive theory (SCT) to explore how proximal/cognitive variables (e.g., staff attitudes and beliefs about opioid court) and environmental factors influence delivery of the opioid court (Bandura, 1989). The 10 Essential Elements map onto steps of the opioid care cascade (Fig. 1), and as such, the opioid care cascade will be used to guide the detection of gaps in care and to identify opportunities for intervention, in addition to framing the evaluation of the opioid court model and the implementation strategies.

### 2.2. Study sites and participant characteristics

Sites will be drawn from counties across NYS. Early adopter sites ( $n = 5$ ) will be recruited from sites that established an opioid court before 2019. New adopter sites will be recruited from remaining counties that have established opioid courts since 2019 or will do so. To be eligible, new adopter courts must also have existing drug courts.

We will recruit the study sample from the opioid court stakeholder group, county court staff, and partnering treatment agency staff from the 10 new adopter counties. The opioid court stakeholder group comprises local stakeholders who play a role in development or improvement of the courts. Stakeholder group members may comprise court and treatment staff as well as other key stakeholders (e.g., law enforcement; community supervision). For each county stakeholder group, we anticipate enrolling  $n = 4-5$  court staff,  $n = 3-4$  treatment staff,  $n = 1$  or 2 members who are not included in either the court or treatment staff groups (e.g., law enforcement, probation). Furthermore, we anticipate recruiting an additional  $n = 5$  court staff and  $n = 6$  treatment staff (i.e., line staff) who are not members of the stakeholder group but who are employed by legal/county or treatment agencies that support the courts in each county. Across all 10 counties, and participant types (i.e., line staff, stakeholder group

members), we anticipate enrolling a total of  $n = 100$  court staff,  $n = 100$  treatment staff, and an additional  $n = 20$  noncourt or treatment stakeholder group participants.

### 2.3. Recruitment and consent

Study staff will invite court and treatment line staff to participate in surveys and webinars. An email from the research team explaining the project and staff participation in relevant study activities will be sent to court or treatment agency leadership who will then distribute it to their staff, instructing the staff to contact the research team directly with questions.

Opioid court stakeholder group members will be invited to participate in the research aspects of the project (e.g., surveys, webinars, focus groups, monthly site check-ins) during an initial introductory meeting. Prior to the meeting, stakeholder group members will receive an information sheet outlining the main study goals and explaining the research activities as separate from opioid court stakeholder group activities, which are a standard part of their jobs. Staff participating in the stakeholder group will be instructed to individually contact the research team after the introductory meeting if they do not wish to provide consent for participation. Consistent with court and behavioral health agency policies, the study will not provide staff remuneration for their participation.

### 2.4. Procedures

After a formative phase, we will implement the four phases of Opioid Court REACH that coincide with the EPIS model. As described, Opioid Court REACH will utilize two primary implementation strategies: technical assistance (TA; i.e., external facilitation) and local change teams (i.e., the stakeholder group). Table 1 presents detailed descriptions of each phase of the protocol.

**2.4.1. Formative phase (6 months)**—The research team will first interview the 5 early adopter county stakeholder groups to discuss facilitators and barriers for each step of the opioid care cascade. Next, using administrative record data from the five counties from the court system's centralized information system, the Unified Case Management System (UCMS), study staff will generate a snapshot of opioid care cascade outcomes for the initial 12-months of opioid court implementation (e.g., % eligible screened, % linked to treatment). These data will be integrated in order to identify specific areas of focus and refinement.

**2.4.2. Exploration phase (5 months)**—The exploration phase will comprise the following four TA activities, which the research TA team will lead.

**Court readiness survey.** The survey explores current court processes, planning, and operation. The study will deliver this via a secure Qual-trics weblink to the court liaison for completion.

**In-depth interviews with stakeholder group.** In-depth interviews with all members of the court stakeholder group focus on the court process around implementing the 10 Essential Elements, and challenges and facilitators to court and treatment system collaboration.

**Community provider capacity building.:** Lack of availability of MOUD is a common Problem; therefore, the research team will map treatment agencies that provide MOUD within counties using public databases and information obtained during in-depth interviews with treatment providers. Study staff will identify federal and regional initiatives to help agencies expand MOUD.

**Needs assessment report:** The research TA team will prepare a needs assessment report integrating all data from the exploration phase to present to each county's opioid court stakeholder group in the preparation phase.

**2.4.3. Preparation phase (up to 6 months)**—The research TA team will provide in-person and remote practice and process improvement planning to help the stakeholder group operationalize the 10 Essential Elements, achieving balance between fidelity to the guidelines and fit to the local context.

A 2-day in-person meeting with the court stakeholder group, which the research TA team will lead, will focus on practice improvement, goal selection support, and process improvement planning. The needs assessment report will guide the creation of an action plan detailing steps to develop a refined court protocol. The research TA team will then lead and document bi-weekly check-in calls with the opioid court stakeholder group to assist with completion of action plans and finalization of protocols.

**2.4.4. Implementation phase (18 months)**—While implementing the court strategic plan, the stakeholder group will receive a data report from the research team every 3 months on opioid care cascade outcome data. The 6- and 12-month reports will form the basis for Plan Do Study Act (PDSA) cycles, for which the research TA team will conduct in-person meetings with the stakeholder group to develop an action plan with new performance improvement goal steps as necessary.

**2.4.5. Sustainment phase (6–18 months depending on wave)**—In the sustainment phase, data reports will continue every 3 months without other external facilitation. Any stakeholder group activities following receipt of feedback reports will be documented via bi-monthly calls by research staff.

## 2.5. Treatment as usual – drug court

The TAU arm will comprise participants who entered the drug court program between 3 and 15 months prior to the intervention start in each county; range is due to the stepped-wedge design. The drug court model does not focus solely on opioid use and differs from the opioid intervention court model in three key ways. Drug court participation occurs after a (guilty) plea to a charge has been entered and the participant agrees to enter the drug court program in response to the plea. This may occur several months after arraignment. In contrast, opioid court enrollment happens pre-plea, at or before arraignment and so occurs sooner in the court process; and prosecution of the original case is suspended during the individual's participation in opioid court. Failing to complete drug court treatment mandates can result in legal consequences whereas opioid court participation is voluntary and focused on stabilizing the participant to reduce their risk of overdose via rapid entry into treatment

and care. If a participant does not successfully enroll and remain in opioid treatment, there are no legal consequences; opioid court participation ends and the prosecution of their original charge resumes. Finally, participation in drug court is typically longer, lasting between 6 months and 1 year (18 months in many cases) as opposed to 90 days. Similarities include the screening and identification of a substance use problem and linkage to treatment and care. Prior to opioid courts in the study counties, individuals who used opioids and who met criteria for drug court would have potentially entered the drug court. Drug courts in all counties have been in operation for several years and will not receive any aspect of the intervention. Because the study is drawing data from drug courts prior to intervention start, any contamination of intervention activities into drug courts will not be captured.

## 2.6. Randomization

The study will randomize counties, stratified by population density/urbanicity, county opioid overdose and misuse, and court operation (newly established versus planning) to one of 5 waves of Opioid Court REACH at 2-month intervals.

## 2.7. Primary and secondary study outcomes

We will examine the clinical and cost effectiveness of Opioid Court REACH on retention in community-based treatment for >60 days/court program completion and recidivism 6 months after court termination/completion. Additional outcomes include achievement of outcomes along the opioid care cascade. We will examine differences on these outcomes and recidivism between matched defendants with opioid use from the TAU condition (drug courts) with opioid court participants.

The outcome of the cost-effectiveness analysis will be the incremental cost-effectiveness ratio (ICER), calculated as the difference in mean costs between the study arms, divided by the difference in mean effectiveness between the arms. The primary measure of effectiveness for the economic evaluation will be *Abstinent years*, operationalized as the predicted proportion of the year that the participant was abstinent from opioids (Murphy & Polsky, 2016).

Implementation outcomes include uptake and sustainability, fidelity, and feasibility and acceptability of the opioid court (Proctor et al., 2013).

**2.7.1. Uptake and sustainability**—The study will assess uptake and sustainability using the Stages of Implementation Completion (SIC) tool (Saldana, 2014; see Data sources), a measure of the completion of the EPIS phases, and via administrative records from the UCMS to document continued screening and court enrollment of participants, referral and treatment enrollment, 12 months after the implementation phase ends (see Data sources and Measures; Table 2).

**2.7.2. Fidelity**—We will use benchmarks (e.g., 75% of those clinically appropriate initiate MOUD) for the 10 Essential Elements as set by court stakeholder groups to measure fidelity and compare benchmark performance across the study counties. Facilitator fidelity

will be measured by the TA team (via self-report checklists) and by research team members who will observe the TA workshops.

**2.7.3. Acceptability and feasibility**—The study will assess acceptability and feasibility quantitatively in bi-monthly check-ins with county liaisons and qualitatively via stakeholder committee focus groups after the sustainment phase (see Data sources and Measures; Table 2).

## 2.8. Data sources and measures

**2.8.1. Opioid and drug court participant data**—The research team will securely receive de-identified administrative record data for court participants for the study's 10 counties from the UCMS, which tracks defendant information on drug and opioid court operations—e.g., court plan/mandate, treatment referral location, attendance, urine toxicology results, and program completion dates.

**2.8.2. Staff surveys**—Court and treatment staff and opioid court stakeholder group members will complete a survey at the beginning of the exploration phase and at the end of the sustainment phase, which they will receive via email. Guided by EPIS and SCT, survey data will address theoretically defined inner-, outer-, and individual-level factors that may influence implementation. Table 2 presents all measures, categorized by main outcomes, EPIS, and SCT constructs.

**2.8.3. Monthly status check-in**—Members of the research TA team will meet with the opioid stakeholder group's site liaison monthly via phone to document participant activities and implementation challenges and successes.

**2.8.4. Cost effectiveness**—The estimation of the implementation and ongoing management costs of the opioid court will be guided by the Drug Abuse Treatment Cost Analysis Program (DATCAP; French, 2003). The study will estimate the necessary resources using a combination of macro- and micro-costing analyses; and non-intervention costs will be estimated using the resource costing method (Drummond et al., 2015; Neumann et al., 2017). Unit costs will be derived from sources reflecting “real-world” costs faced by the criminal justice system (McCollister et al., 2010), including data from surveys and check-ins.

**2.8.5. Stages of implementation completion tool**—The study will assess each organization's implementation progress using the Stages of Implementation Completion (SIC) tool (Saldana, 2014). The SIC, with demonstrated validity and reliability, assesses 8-stages of program implementation from engagement with intervention developers to achievement of practitioner competency. Three scores can be calculated for each SIC stage: duration (amount of time in a stage), percentage of activities completed, and stage score (last stage reached).

**2.8.6. Focus group**—At the end of the sustainment phase, study staff will invite the court stakeholder group to participate in a 1-hour focus group to explore acceptability and feasibility of the intervention. Topics will include stakeholder experiences working with the

research team, working with external facilitation/TA assistance, and implementing an opioid court. Topics will also cover experiences with/knowledge of screening, identification, and linkage; and use/access for a range of opioid services for court-involved individuals.

## 2.9. Power analysis

Power calculations for a stepped-wedge design take into account the total number of people monitored pre- and post-implementation, the number of sites, and the within-site intraclass correlation (ICC). Based on preliminary data from the first opioid court and our 25 site-years of opioid court follow-up coming from our 10 total sites (180 months of implementation and 120 months of sustainment across all 10 sites), we estimate enrollment of 3000 defendants in the opioid court (10 participants per month). During the baseline (pre-opioid court) period, which is in total 8 site-years, we expect 1200 drug court defendants to be screened. Using a standard design effect formula for stepped-wedge clustered randomized trials (Hemming & Taljaard, 2016), we calculate the detectible effect sizes (odds ratios) under the assumption of a conservative ICC of 0.05, in addition to alpha of 0.05.

## 2.10. Data analysis

In this stepped-wedge design, the study will compare data gathered during the implementation and sustainment phases in the study counties to baseline data from defendants in the same county matched on age, gender, race/ethnicity, and opioid use. We will use standard generalized linear mixed-effects modeling (GLMM) for stepped-wedge designs to test the effect of the opioid court on each of the outcomes in the opioid care cascade (Hemming et al., 2017). If descriptive analyses identify large differences in the case mix of background characteristics for the defendants in the TAU vs. opioid court periods, we will use propensity score matching, which provides finer control than simply including covariates and has been used in similar studies to address possible selection bias (De Allegri et al., 2008). We will also explore the role of inner and outer context variables as mediators and effect modifiers of the opioid court's impact on outcomes using GLMM.

For the economic analyses, we will first estimate the service utilization and resulting costs associated with implementing and sustaining the opioid court. Second, we will estimate the value of the court relative to the usual drug court model. We will model the monthly person-period, and we will estimate the multivariable GLMMs to predict the mean value for each resource and outcome, at each time period, by study arm. The study will use the statistical method of recycled predictions to obtain the final predicted mean values (Glick et al., 2014). Then, we will estimate abstinent years using the area under the curve methodology (Glick et al., 2014; Neumann et al., 2017). *P*-values and standard errors will be estimated for differences in each cost and effectiveness point estimate, via nonparametric bootstrapping techniques within the multivariable framework.

## 2.11. Trial registration, ethics approval, and trial status

The New York State Psychiatric Institute Institutional Review Board reviewed and approved this study. We registered the study on [ClinicalTrials.gov](https://clinicaltrials.gov) on 12/19/2019 (NCT04216719). Formative Phase activities are complete. Recruitment of main subjects began September 2020, and the trial will reach completion, tentatively, in July 2024.

## 2.12. COVID-19 adaptations

In the advent of the COVID-19 pandemic, changes to study procedures have become necessary. The study will conduct all in-person activities remotely via a web-based platform. In addition, in response to the “pause” in NYS, treatment courts reverted to seeing participants remotely and continue to do so. Thus, TA related to engaging and connecting with participants must have a “remote” focus. Finally, in the wake of COVID-19, opioid court census has dropped, which may impact the study’s power.

## 3. Discussion

To our knowledge, this study is the first to systematically develop and test the efficacy of an opioid court implementation intervention and simultaneously examine the effectiveness of the opioid court model across 10 counties, following the rollout of a new opioid court model across NYS. Courts are an ideal point of intervention to identify OUD and overdose risk, and link defendants to treatment/MOUD (Brinkley-Rubinstein et al., 2018). The opioid intervention court is an improvement on traditional drug court handling of those with OUD because it operates pre-plea and allows for rapid screening, with the aim of achieving quicker access to MOUD and reduced overdose risk.

Implementation science aims to identify effective strategies for translating evidence-based practices into real-world settings (Powell et al., 2012). The proposed implementation intervention—Opioid Court REACH—is best conceptualized as a blended strategy wherein discrete evidence-based implementation strategies for addressing barriers at multiple levels will be combined and manualized into a blueprint strategy. If successful, this implementation intervention will guide court and treatment agencies, meet the goals of the opioid court, and improve management of defendants with OUD. The final product will be an opioid court implementation guideline, which will promote widespread implementation of the opioid court model, should this study find it to be effective.

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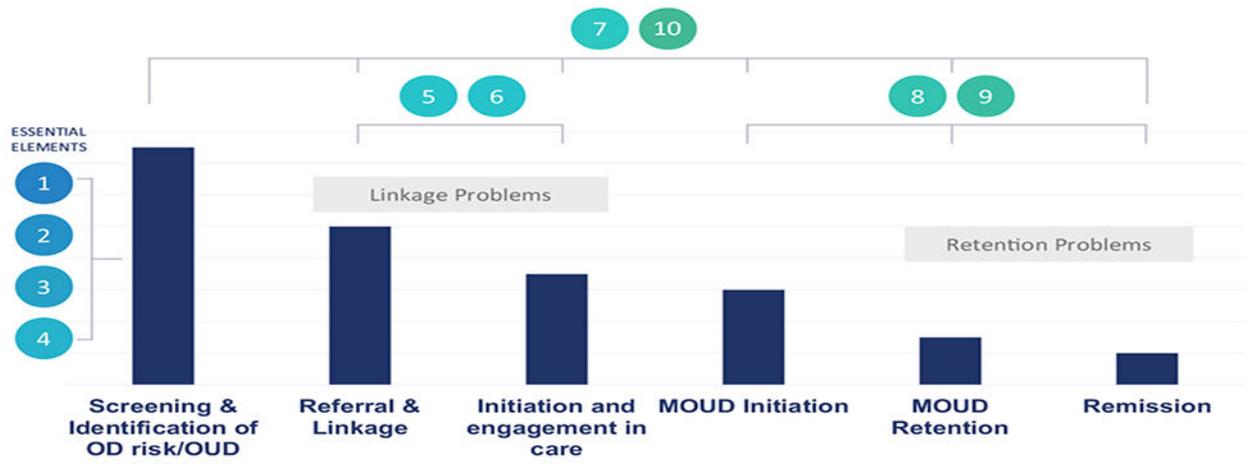
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**Key of Essential Elements**

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|---|--|
| <ul style="list-style-type: none"> <li>1. Immediate screening and assessment</li> <li>2. Broad legal eligibility criteria</li> <li>3. Universal access and transfer of identical cases</li> <li>4. Suspension of prosecution during stabilization</li> <li>5. Rapid engagement in evidence-based treatment</li> </ul> | <ul style="list-style-type: none"> <li>6. Use of recovery advocates and family support navigators</li> <li>7. Frequent judicial supervision</li> <li>8. Intensive case management</li> <li>9. Opportunities for continuing care</li> <li>10. Performance evaluation and program improvement</li> </ul> |
|---|--|

**Fig. 1.** Opioid cascade of care and 10 essential elements.

**Table 1**

Opioid court REACH.

<p><i>Formative phase (6 months)</i>– Collect and review information about Early Adopter counties</p>
<p><b>Expert panel report.</b> Respondents: Court leadership from 5 Early Adopter counties. <i>Goals/Activities:</i> To identify how early opioid court adopters assembled their court team, stakeholder group, developed policies and procedures, how they implemented their court, and lessons they ve learned in the process, and gather the information into a report. <i>Format:</i> 1-day on-site meetings or review of previously completed interview transcripts (collected by the research technical assistance [TA] team).</p>
<p><b>MOUD care cascades.</b> According to the <i>Ten Essential Elements of Opioid Courts</i>, court participants should be quickly linked with the treatment they need, including medications for opioid use disorder (MOUD). Data from the five Early Adopter counties was drawn from the centralized management information systems of the court system, the Unified Case Management System (UCMS), and used to generate a snapshot of opioid care cascade outcomes (e.g., % eligible screened, % accepted, % rapid MOUD initiation) in the initial 12-month opioid court adoption period. These UCMS data and the Early Adopter information collected for the expert panel report will then be integrated to identify specific areas of focus and refinement for Opioid Court REACH.</p>
<p><i>Exploration phase (5 months): Implementation Goal 1</i> - Conduct county system capability and needs assessment</p>
<p><b>Court readiness survey.</b> An opioid court designee (likely the court treatment coordinator) will receive the court readiness survey, which explores current court processes, planning, operation, and functioning. This will be delivered and completed via a secure Qualtrics weblink. <i>Goals/activities:</i> Identify court staff capacity and funding; available community treatment partners (including those that can prescribe MOUD); anticipated training needs; onsite screening, assessment, and treatment capability; court resources (e.g., wifi, telemedicine capability); description of all opioid court stakeholders and degree of engagement; potential facilitators/barriers to opioid court rollout.</p>
<p><b>In-depth follow-up interviews.</b> After reviewing the court readiness survey data, the research staff will conduct in- depth follow-up interviews with members of the court stakeholder group (n = approximately 10 individuals per county) to deepen understanding of the survey data focusing on court process around implementing the 10 Essential Elements and to explore how the court and treatment systems collaborate, exploring challenges and facilitators to interagency collaboration.</p>
<p><b>Interagency system mapping exercise.</b> After reviewing the court readiness survey data, the research staff will conduct in-depth follow-up interviews (remotely, via phone call or video call) with select members of the court stakeholder group (including court and treatment agency leadership) and other key stakeholders (e.g., OASAS regional representatives, defense/prosecution representation) to 1) Map existing court flow (including court to treatment system transition and legal decisions/procedures related to opioid-involved defendants); 2) identify court and treatment-system capacity/shortfalls in treatment for opioid problems; 3) understand problems in identifying/linking defendants with opioid problems to services; 4) identify ways to improve screening for opioid use/overdose risk, enrolling defendants into the opioid court, and linking opioid court participants to treatment.</p>
<p><b>Community provider capacity building.</b> Because lack of availability of MOUD is a common problem in suburban and rural areas, the research team will map locations of available treatment agencies within a given county using provider locator databases. When identified, the research team will connect treatment agencies with relevant SAMHSA-funded regional training initiatives (e.g. Addiction Technology Transfer Center [ATTC]) to help agencies expand MOUD access.</p>
<p><b>Needs assessment report.</b> The research/TA team will prepare a needs assessment report integrating the data gathered from the Exploration phase activities to present to each county’s opioid court stakeholder group in the Preparation Phase to guide development of an implementation plan for the county.</p>
<p><i>Preparation phase (up to 6 months): Implementation Goals 2 and 3</i> - Achieve stakeholder consensus; operationalize the 10 Essential Elements, train the opioid court stakeholder group and develop the court action plan.</p>
<p><b>2-Day technical assistance workshop.</b> A 2-day (remote) TA workshop with the court stakeholder group led by the TA team will provide an overview of the 10 Essential Elements and the opioid court model as well as a review and verification of the needs assessment results generated from the exploration phase activities. The workshop will focus on practice improvement, goal selection support and process improvement planning. Goal selection support strategies and related quality assessment/quality improvement techniques with significant performance improvements in health care delivery (e.g., Plan Do Study Act [PDSA] cycle).</p>
<p><b>Opioid court action plan.</b> The results from the 2-day technical assistance workshop will be used to create an opioid court action plan, which will include goals and objectives as well as specific steps to achieve the development of a court protocol and guidelines. A toolbox of TA practices, informed by Formative and Exploration Phase activities, will be developed and TA strategies will be drawn from that toolbox to assist in preparing the court to implement the action plan.</p>
<p><b>Bi-Weekly check-ins.</b> The TA external facilitator will thereafter lead and document bi-weekly phone check-in calls with the Opioid Court Stakeholder Committee to ensure action plans and related goal steps have been created and completed to prepare the site for opioid court roll-out with finalized protocols, necessary materials (e.g. referral and tracking forms), etc.</p>
<p><b>Web-Based Training.</b> County court staff, partnering community treatment agency staff, and other related systems involved in the opioid court (e.g. law enforcement) will be invited to take a web-based training comprising three modules focused on (1) an overview of the opioid epidemic and the court response, (2) MOUD and related behavioral treatments for opioid use disorder, and (3) the opioid</p>

court model. Staff will be emailed links, via their supervisors, to the voluntary web-based training, which will remain live throughout the remainder of the trial. Pre- post quizzes will also be administered to assess utility of the trainings enabling learners to receive continuing education credits.

**Implementation phase (18 months)**

**Opioid Court action plan implementation, with facilitation.** The stakeholder group will implement the action plan it created during the preparation phase with facilitation from the research TA team.

**Feedback reports with ongoing facilitation.** County opioid court and treatment agency leadership and the stakeholder group will receive a report every 3 months on opioid care cascade outcomes; progress in meeting benchmarks; strengths and weaknesses in current performance; and areas for improvement. Reports will be sent to county leadership via email by the research TA team. The first and third reports will be briefly discussed via a Skype/phone call. With the second and fourth report, the research TA team will conduct remote (with video) meetings to discuss and interpret data with the stakeholder group, and to revise the action plan with new performance improvement goal steps for the first PDSA cycle. The research TA team will continue to work with the stakeholder group to implement its PDSA cycle, via documented phone/Skype calls and meetings. At the next data feedback report, the data will be discussed in light of the change plan; continued process improvement plans (goals and goal steps) will be developed and implemented as needed during the final feedback report which will begin the second PDSA cycle.

**Sustainment phase (6–18 months; average 12 months per wave)**

**Opioid court action plan implementation, without facilitation.** The stakeholder group will continue implement the action plan in its county for 12 months without facilitation.

**Feedback reports.** The research team will continue to receive opioid court data from the UCMS and send the counties data feedback reports, via email, every 3 months as above, without external TA/facilitation. Any change plans and stakeholder group activities made following receipt of feedback reports will be documented via bi- monthly site check-in calls by research staff; facilitators will not assist in these plans.

**Table 2**

Study assessments by domain.

<b>Domain</b>	<b>Variable description</b>	<b>Source (respondent)</b>
Primary outcomes		
Implementation impact	Screening and identification Referral Treatment enrollment Mediations for opioid use disorder (MOUD) Initiation	Unified Case Management System (UCMS) Data
Clinical and cost effectiveness	Retention: >60 days in treatment, via termination date Court completion Abstinence/negative urine screen	UCMS data
	Recidivism: re-arrest within 6 months of completion/dropout	New York State Division of Criminal Justice Services (NYS DCJS) Data
Secondary outcomes		
Implementation process outcomes	Acceptability	Focus group (stakeholders)
	Uptake-adoption of court (Saldana, 2014)	Stages of implementation completion (SIC; research team) Focus group (stakeholders)
	Fidelity	10 Essential Elements guidelines; UCMS data
	Sustainability of court 12 months post-implementation	UCMS Data; SIC; Focus group (stakeholders)
Staff knowledge, attitudes, and beliefs (KAB) ( <i>Inner context</i> )	Staff demographics Knowledge and attitudes of MOUD (Polonsky et al., 2015; Springer & Bruce, 2008) Self-efficacy (Wasserman et al., 2008; Wasserman et al., 2009) Perceived importance of opioid care cascade behaviors Perceived potential sustainability of opioid court (Luke et al., 2014)	
Court and treatment agency organizational characteristics ( <i>Inner context/ environment</i> )	Organizational climate, support and functioning (Patterson et al., 2005; Rhoades et al., 2001) Interagency organizational features (e.g. challenges to collaboration; communication quality) (Texas Christian University Institute of Behavioral Research, 2005).	Court and treatment staff survey (stakeholders)
	Structural characteristics: Facilitators, barriers to implementation	Bi-monthly site check-in (court liaison)
	Defendant characteristics: Demographics (e.g. age, gender, race/ethnicity), current SU, arrest.	UCMS Data
County characteristics ( <i>Outer context/ environment</i> )	MOUD service availability	Office of Addiction and Services and Supports (OASAS) Data
	Opioid use disorder treatment need	OASAS Data
	Poverty % county residents <18y below Poverty Rate (Bureau, U.S.C, 2010) Urban: % population in county designated as urban (Bureau, U.S.C., 2010)	United States Census United States Census