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Extended-release naltrexone and drug treatment courts: Policy and evidence for implementing an evidence-based treatment

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A B S T R A C T

With insufficient access to treatment and a tradition of criminalizing addiction, people with substance use disorders — including opioid dependence — are more likely to be incarcerated than they are to receive the treatment they need. Drug treatment courts aim to address this problem, engaging their participants in substance use treatment in lieu of incarceration. Drug courts offer an especially important window of opportunity to connect opioid-dependent participants to extended-release naltrexone (XR-NTX), at a time when they are under highly-structured court supervision and required to detoxify from opioids to participate. Given the high cost of XR-NTX and high rates of uninsurance in the drug court population, new rigorous cost-effectiveness evidence is needed to demonstrate the extent to which XR-NTX improves program outcomes, including by reducing recidivism. With that new evidence, drug courts and the counties in which they are situated can make informed and difficult policy decisions about funding XR-NTX for some of their highest-risk community members.

Millions of adults with substance use disorders enter US jails and prisons each year (Mumola & Karberg, 2006; Karberg & James, 2005; Steadman, et al., 2009). With insufficient access to treatment and a tradition of criminalizing addiction, people with substance use disorders (SUDs) are more likely to be incarcerated than they are to receive the treatment they need (Mumola & Karberg, 2006; Karberg & James, 2005; Steadman, et al., 2009; Substance Abuse and Mental Health Services Administration, 2015a; Kaeble, Glaze, Tsoutis, & Minton, 2015). There have been a growing number of bipartisan initiatives, however, among US policy makers and leaders of behavioral health and criminal justice systems that aim to address this problem through programs, policies, and legislation, based on a consensus that the long trend of over-incarceration has been counterproductive and unsustainably costly.

Drug treatment courts comprise one of the most promising approaches to diverting offenders with SUDs away from the justice system, offering offenders with non-violent misdemeanor or felony convictions the opportunity to engage in community treatment while under court supervision in lieu of traditional adjudication. There are over 2700 drug courts across the United States, with several variations on the core model, including family drug courts, juvenile drug courts, and most recently, Veterans treatment courts (National Association of Drug Court Professionals, 2016). The fundamental design is a specialty docket that aims to reduce recidivism and substance use among participants through a non-adversarial approach, supervised treatment, frequent drug testing, and use of sanctions when participants violate program requirements. (National Association of Drug Court Professionals, 2016)

Drug courts provide a leading — and relatively rare — example of a true collaboration between the treatment and criminal justice system, with the shared objective of getting offenders with SUDs into recovery and out of the justice system. When successful, drug courts are a "win-win" for the two systems — yielding reductions in crime, which bodes well for elected judicial officials, and reductions in drug-related morbidity and mortality, which otherwise radiate destructively through families and communities.

The evidence base for drug courts is mixed and nuanced, with some studies demonstrating strong benefits, but others indicating room for significant improvement in program success rates. Meta-analyses and systematic reviews of drug court outcome studies have generally shown that drug court participation significantly reduces re-arrest and incarceration (Wittouck, Dekkers, de Ruyver, Vanderplasschen, & Vander Laenen, 2013; Brown, 2010; Krebs, Lindquist, Koetse, & Lattimore, 2007; Mitchell, Wilson, Eggers, & MacKenzie, 2012; Sevigny, Fuleihan, & Ferdik, 2013; Gottfredson, Najaka, & Kearley, 2003; Gottfredson & Exum, 2002). Reductions in recidivism average 50% among participants compared to 38% among comparison groups receiving typical criminal sentencing. Shortcomings, however, are also evident — approximately 40% of drug court participants drop out of treatment prematurely, and only 50% graduate from the program (Marlowe, DeMatteo, & Festinger, 2003). Predictors of poor outcomes include inadequate length and intensity of treatment, (Evans, Huang, & Hser, 2011) low treatment motivation, (Evans, Li, & Hser, 2009) and heroin use. (Evans et al., 2009)

The stakes are only getting higher for drug courts as the opioid epidemic worsens. Nationally, rates of opioid dependence among drug court participants have increased up to 300% over the past decade.

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(Huddleston, Marlowe, & Casebolt, 2008; Huddleston & Marlowe, 2011) In one North Carolina drug court, the prevalence of opioid dependence among program participants was approximately 25% in the last couple of decades; today it is over 50% (Robinson, 2016). With that, the leading predictors of program failure are more potent than ever, and require the best, evidence-based treatments available to overcome them.

Medication-assisted treatment (MAT) — medications for treating substance dependence paired with psychosocial treatment — demonstrates strong benefits in achieving abstinence and long-term recovery in both general and justice-involved community populations (O'Brien, 2008; Minozzi et al., 2011; Mattick, Breen, Kimber, & Davoli, 2014; Mattick, Breen, Kimber, & Davoli, 2009; Rösner et al., 2010; Kennedy et al., 2010; Bouza, Angeles, Muñoz, & Amate, 2004; Boothby & Doering, 2005; Jørgensen, Pedersen, & Tønnesen, 2011; Anton et al., 2006; Gastfriend, 2011; Pettinati et al., 2011; Krupitsky et al., 2011; Schwappach et al., 2012; Connock et al., 2007; Walters, Connor, Feeney, & Young, 2009; Zarkin et al., 2008; Finigan, Perkins, Zold-Kilbourn, Parks, & Stringer, 2011; Gryczynski et al., 2012; Lee et al., 2012; Lee et al., 2016). But it is also a mode of treatment that has been vastly underutilized, especially in justice-involved populations (Knudsen, Abraham, & Roman, 2011; Friedmann et al., 2012; Schmidt et al., 2012; Mitchell et al., 2016; Matusow et al., 2013). Ideological objections to the medical model of addiction and pharmacologic treatment, with a preference instead for medication-free treatment is quite common in the criminal justice system, and even the behavioral health system. That stems, in part, from inadequate knowledge about the medical benefits of MAT and persistence of a non-medical model of addictions, but also concerns about misuse and diversion of these medications, especially among addicted offenders. More practical barriers include a shortage of qualified medical staff, especially for the justice-involved population, to prescribe medications that are frequently unfamiliar to physicians.

Reflecting the traditional preference for medication-free treatment, many drug treatment courts have traditionally banned the use of MAT among their clients, despite its compelling evidence base, FDA approval, and strong support from national public health leaders like the directors of CDC and National Institute on Drug Abuse (Volkow, Frieden, Hyde, & Cha, 2014). The policy and practice landscape related to MAT is evolving in positive ways, however, especially related to its use in drug court settings. There are many intersections of interest at play – progress in MAT implementation, generally; new, progressive federal policies and grant programs aiming to expand MAT access and availability; and the beneficial effects of Medicaid expansion under the Affordable Care Act on the drug court population's real access to MAT, given the large majority of these court clients have traditionally been uninsured, but many now newly eligible in Medicaid expansion states. (Cuellar & Cheema, 2012)

Signaling an important shift in collective thinking about addiction, and in a specific effort to improve MAT access and implementation, the Office of National Drug Control Policy instituted a new policy in 2015 requiring all federally-funded drug courts to allow eligible clients to use FDA-approved medications for the treatment of substance use disorders. (Substance Abuse and Mental Health Services Administration, 2015b) The new federal funding guidelines went further by encouraging drug courts to use up to 20% of their federal grant dollars to fund MAT for uninsured clients. The Substance Abuse and Mental Health Services Administration also allocated $11 million in 2016 to expand MAT programs in 11 states. The new policy and federal funding does not, however, provide guidance for the standards under which MAT should be used in this setting.

For most courts, the allocation of court funds to cover medication costs seems unlikely, especially for the newer, very expensive medications like extended-release naltrexone (XR-NTX). It is here where Medicaid expansion and formulary coverage — paired with the new federal drug court-MAT policy — could have a major influence in expanding access to MAT. Up to 85% of drug court clients are uninsured; and the majority of them would be newly eligible for Medicaid in states that have expanded. (Cuellar & Cheema, 2012) With that, an offender in a federally-funded drug court that has been required to lift its MAT ban, who lives in a Medicaid expansion state and has become eligible and enrolled for a first time, will gain real access to XR-NTX as part of comprehensive treatment under the program, paying, for example, a $3 monthly co-pay for the medication rather than a $1000 monthly out-of-pocket cash outlay (which essentially none could afford).

XR-NTX, one of the newest medications for treating both opioid and alcohol dependence, has strong promise for use by justice-involved adults with SUDs, including by transcending some entrenched barriers to better MAT implementation. The once-monthly injection formulation (as compared to the daily tablet form) can dramatically improve treatment adherence (Swartz, Swanson, Wagner, Burns, & Hiday, 2001); reduce cravings and block euphoric effects of opioids, allowing the individual to focus on other fundamental aspects of their recovery; and because XR-NTX has no narcotic properties, there are no concerns about misuse or diversion to secondary markets of this medication. Also, unlike methadone and buprenorphine, XR-NTX requires no special prescriber licensure, which can otherwise create a barrier to access in localities with few qualified providers. But given the high cost of XR-NTX to payers, evidence of its cost-effectiveness for this population will be essential to widespread implementation.

While progressive policies are emerging to increase drug court clients' access to MAT during program treatment, very little is known about the extent to which medications like XR-NTX can help reduce recidivism in this particular population, during this particular engagement with the court and treatment services. A 2010 pilot observational study of XR-NTX for alcohol-dependent clients in three Michigan and Missouri drug courts demonstrated very promising results, in which the XR-NTX group had 57% fewer missed court sessions, a 35% reduction in ratio of positive drug and alcohol tests to total tests, and substantial reduction in new arrests (8% with new arrests in XR-NTX group vs. 26% in standard care group) (Finigan et al., 2011).

A 2016 multi-site randomized controlled trial of XR-NTX for opioid-dependent criminal offenders demonstrated very promising results in a broader population of justice-involved adults, with the XR-NTX arm having significantly lower likelihood of, and time to opioid relapse as compared to the control group (Lee et al., 2016). The study did not, however, detect lower rates of incarceration – suggesting XR-NTX is not an unconditional "slam dunk" for public-safety related outcomes. The new XR-NTX RCT studied a general population of offenders living in the community, who were currently or recently under community correctional supervision (e.g., probation or parole) or had been released from jail in the past 12 months. While this is a highly relevant study population, its participants were not necessarily engaged in community behavioral health treatment, nor were they necessarily under court leverage to do so; the important differences in context preclude generalizing the findings to the drug court setting.

There is a compelling case to be made for the unique prospects of XR-NTX for drug court participants. Most will have detoxified, often via incarceration, which is necessary for starting XR-NTX treatment and otherwise extremely unlikely among actively-using opioid-dependent individuals in the community; and this highly effective treatment comes at a time when more typical reluctance to fully engage in treatment may be outweighed by the individual's desire to succeed in drug court and stay out of jail. The drug court setting offers a rare window of opportunity for XR-NTX in a vulnerable population that is otherwise difficult to reach and engage in treatment, at a time when they have the advantages of structure, supervision, and accountability, as well as the support of a multi-disciplinary team that aims to help move them into recovery and out of the CJ system.

More definitive research is needed that puts the promise of XR-NTX in drug court settings to the test, to determine the extent to which it can help reduce recidivism, along with relapse — and at what cost to payers. Community-based (rather than university-based), randomized

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controlled trials of XR-NTX in drug court settings could give the clearest signal of its real-world prospects for improving offending outcomes among program participants. The challenges of situating a medication trial into a complex court and community treatment setting, however, are formidable — research ethics considerations related to this vulnerable, court-involved population; client interest; and fluctuating eligibility status related to high rates of relapse are a few. But the opportunities for both treatment and research in this setting are rich, as well. Clients are accountable to the court and so potentially less likely to be lost to follow up, and they are as highly engaged in treatment as they might ever be, and for some, for the first time. Perhaps most importantly, a community-situated trial would produce evidence with strong external generalizability — albeit with some limitations to internal validity — making it maximally relevant to the drug court audience and thereby more likely to affect related policy making.

There would be several challenges to producing valid, meaningful results from a XR-NTX RCT in the larger, complex drug court setting (Wolff, 2000, 2001). Variability in drug court staffing arrangements and effectiveness could moderate the effect of XR-NTX under multisite study conditions– courts with strong, multidisciplinary teams and judges that champion the use of MAT as part of comprehensive treatment could demonstrate stronger treatment adherence among study participants than courts that communicate poorly across court and treatment staff or have a judge that is reluctant or skeptical about MAT. If particularly productive dynamics in a given drug court do indeed prop up the XR-NTX intervention, those contextual characteristics will affect the study results but not necessarily be translatable to another court expecting the same medication effects on program outcomes (Wolff, 2001). Because there are no clear standards for MAT provision to guide judges presiding over drug court programs, there is considerable variability in the role of the judges in making what are largely — if not entirely — clinical treatment decisions. Some judges may defer to their partnering clinical professionals to decide which clients are and are not appropriate for XR-NTX treatment; where other judges may engage in shared decision-making with their clinical partners, or even independently assert which clients they believe to be appropriate candidates for XR-NTX or other MAT. A judge's discretion in MAT provision for program clients would not be captured in a RCT study design.

Subject involvement also presents a challenge to conducting a XR-NTX RCT in this complex community setting (Wolff, 2001). For one, creating representative samples can be difficult in a population with complex problems – including not only opioid dependence, but most often co-occurring psychiatric disorders and varying levels of criminogenic risks that drive criminal offending behavior and would not be expected to be affected by medical treatment alone. Measuring these other key characteristics that could moderate treatment effect are essential for the RCT to understand the extent to which they may compromise the generalizability of study findings. If present, selection bias — as with any RCT — would also reduce generalizability to a larger population that may, on average, be less motivated to engage in study treatment than research participants.

A XR-NTX RCT in the complex drug court setting could be modified to address many of these challenges. A mixed methods design could be employed that builds in a qualitative component to contextualize and measure the many staffing, program, and client characteristics that would otherwise remain unmeasured, but likely affect the study results (Wolff, 2000). This would include, at each study site, measuring levels of social capital among program clients, variations in program protocols, and levels of program funding, staffing, and organization over the full duration of the study (Wolff, 2000). A segmented randomization strategy could also be warranted if clinical evidence indicates that there are bona fide therapeutic subgroups within the opioid-dependent drug court client population, and that they differ in ways that would be expected to moderate the XR-NTX treatment effect (Wolff, 2000).

To achieve truly widespread implementation of XR-NTX in drug court and other criminal justice settings, a RCT must also include cost estimation to facilitate detailed cost-effectiveness analyses. Even if XR-NTX can reduce recidivism along with clinical relapse, jurisdictions and their relevant public agencies must be able to weigh the high cost of funding this expensive medication to mostly-uninsured offenders against the expected savings to be realized through reductions in crisis-driven healthcare use such as emergency department visits and hospitalizations, and reductions in costs associated with averted arrests and incarcerations. For example, in a state that has expanded Medicaid, the public insurance program would likely fund a majority of XR-NTX in a newly-eligible drug court population. The state's Medicaid program would also then benefit from related savings associated with reductions in emergency healthcare.

A cross-system analysis of treatment investments and cost savings would be more complex, considering that, in the example above, the state's health department would fund the majority of XR-NTX treatment for this population, but that savings associated with reduced recidivism would benefit a different system, and perhaps largely the local county courts and jails. Conversely, in a state that has not expanded Medicaid, county drug courts may consider funding XR-NTX for their program participants. In that case, the cost burden of the medication would be substantial, and the healthcare-related savings would not directly benefit that local criminal justice setting. For a drug court making that funding decision, clinical improvements, alone, would not justify that large an investment in treatment; rather, reductions in offending would likely be the priority. A single county court's bottom line is likely to be: Will this treatment improve our program outcomes and save the county money?

In any case, the basic principles of cost-effectiveness suggest that the treatment-effect size associated with saving and repairing lives, and reducing recidivism attributed to such an expensive medication — that will cost court programs, state Medicaid programs, or interested correctional institutions a lot of money to provide — must be quite large to justify the sizable budgetary allocations.

Building the evidence base for XR-NTX in drug courts — both in terms of effectiveness and cost-effectiveness — could have important, actionable policy implications. The drug court setting includes a criminal justice-treatment infrastructure that could support active implementation of XR-NTX given its well-defined collaboration with the treatment system and that it is connecting many clients to treatment for a first time. This feature of drug courts is distinct from other types of community corrections, which may sometimes link individuals under their supervision to treatment, but not as a primary objective. New evidence for XR-NTX would be doubly important given MAT treatment decisions are often made, at least in part, by judges rather than only clinicians. At the very least, new evidence could help guide those medical decisions when being made by non-clinicians. Also, most drug court clients currently have very little access to XR-NTX despite its promise for optimizing program outcomes, especially in states that have not expanded Medicaid, where the large majority of court clients are uninsured and out-of-pocket medication costs are prohibitive. With the new federal drug-court funding policy that disallows court bans on MAT, an uncertain future for Medicaid expansion and state block grants that fund MAT, and individual drug courts' decisions about contributing program funds to cover treatment, now is a prime time to build rigorous evidence regarding the cost-effectiveness of XR-NTX for reducing relapse and recidivism among drug court participants.

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