



Extended-Release Naltrexone for Alcohol and Opioid Problems in Missouri Parolees and Probationers



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ABSTRACT

The purpose of this study was to compare the naturalistic outcomes of parolees and probationers with alcohol and/or opioid problems who were treated with extended-release naltrexone (XR-NTX) to those treated with other medication-assisted therapies or psychosocial treatment only. Methods consisted of using intake and discharge data collected as part of SAMHSA's Treatment Episode Data Set (TEDS) assessments, controlling for group differences using propensity scores that were based on a range of intake variables. Results showed that patients receiving XR-NTX had longer durations of care (compared to oral naltrexone and psychosocial treatment only) and were more likely to become abstinent (compared to oral naltrexone, buprenorphine/naloxone, and psychosocial treatment only). Findings were similar for the total sample and those with opioid problems. These XR-NTX results were found in the absence of significant differences in rates of self-help participation. No differences were found in employment or arrests in this relatively short time frame. This study documents the real-world effectiveness study of current FDA-approved addiction medications in parolees/probationers and encourages the use of XR-NTX in such a criminal justice population.

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1. Introduction

The rate of alcohol and/or drug dependence among individuals in the criminal justice system is alarmingly high. In 2012, 1.5 million U.S. adults were serving or placed on probation and nearly 4 million adults were serving or placed on parole (Maruschak & Bonczar, 2013). That year, the rate of illicit drug or alcohol dependence or abuse during the past year among adults aged 18 or older who were on parole (34.0%) or probation (37.0%) was significantly greater than their counterparts who were not on parole or probation during the past year (8.2%–8.6%) (SAMHSA, 2013). Although nearly one-half of male probationers and parolees need treatment, only about one-quarter receives any treatment (SAMHSA, 2014). Among federal and state prisoners, approximately half meet criteria for drug dependence or abuse (Karberg & James, 2005; Mumola & Karberg, 2006). The majority (up to 80%), however, receives no treatment (Karberg & James, 2005; Mumola & Karberg, 2006) – aside from self-help or peer counseling groups, with less than one-fifth receiving treatment from a trained professional (Mumola & Karberg, 2006; Taxman, Perdoni, & Harrison, 2007). Most graduates from prison treatment programs relapse within the first year if no

aftercare treatment is provided (Martin, Butzin, Saum, & Inciardi, 1999). This inadequate treatment contributes to re-arrests and incarceration due primarily to the association between drug use and criminal activity (La Vigne, Visser, & Castro, 2004; National Institute of Justice, 2003). This is especially true of opioid dependent individuals (e.g., Adamson & Sellman, 1998; Bennett & Holloway, 2009; Keene, 2005; Kinlock, Gordon, & Schwartz, 2011), for whom cycles of dependence, incarceration and recidivism are particularly common. Similarly, about a third of individuals arrested for driving under the influence have been arrested for these offenses previously (Nochajski & Stasiewicz, 2006).

Medication-assisted treatment (MAT) combines pharmacological interventions with substance use disorder counseling and social support. MAT has been studied in criminal justice (Dolan et al., 2005; Garcia et al., 2007; Gordon et al., 2014; Hedrich et al., 2012) and is increasingly used in drug court settings, although barriers to its implementation remain (Matusow et al., 2013). Recently, the feasibility and effectiveness of extended-release naltrexone (XR-NTX) have been documented in the treatment of multiple justice system populations: opioid dependent probationers and parolees (Coviello et al., 2012), alcohol dependent individuals within a drug court setting (Finigan, Perkins, Zold-Kilbourn, Parks, & Stringer, 2011), and repeat DWI offenders (Lapham & McMillan, 2011). Naltrexone is a non-addicting μ -opioid receptor antagonist, or blocker (i.e., works via a mechanism opposite to that of opioid agonists such as methadone or buprenorphine). Naltrexone therefore generates no euphoria, sedation, reinforcement or post-treatment withdrawal

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and is not associated with street value or diversion risk. Since its use also requires initial abstinence, naltrexone may be especially appropriate for individuals who achieve abstinence during incarceration and are at risk for relapse after discharge into the community. Oral naltrexone, however, is a once-daily medication whose effectiveness is undermined by problematic patient adherence (Minozzi et al., 2006), whereas the extended-release formulation of naltrexone requires only once-per-month injections (Gastfriend, 2011).

One published study has thus far compared a version of XR-NTX to another medication within a criminal justice population. This study (Lobmaier, Kunøe, & Waal, 2010), conducted in Norway, randomized opioid dependent prisoners to either surgically placed naltrexone implants or oral methadone and followed them after release from prison. Six of 11 patients who received methadone relapsed after discharge, while four of 16 who received naltrexone implants relapsed, suggesting some possible advantage for the naltrexone implants. The naltrexone implant formulation, however, is not available in the United States. A larger, randomized clinical trial comparing XR-NTX (a formulation that is available in the U.S.) to standard care (methadone, buprenorphine, or psychosocial treatment only) has reported interim results (O'Brien, Friedmann, Nunes, Lee, & Kinlock, 2014). Significantly lower rates of positive opioid tests over six months of treatment were found for the XR-NTX group compared to standard care. Given these promising clinical trial efficacy results, evaluation of the effectiveness of XR-NTX in real-world clinical practice settings is indicated.

The Missouri Division of Behavioral Health has facilitated MAT as one option within substance use disorder treatment facilities that receive state funding. In fact, the Division's longstanding partnership with the Missouri Department of Corrections to reduce returns to prison led to creation of a pool of funds specifically for providing MAT to offenders under probation and parole supervision. Missouri's experience with MAT, in conjunction with outcomes data collected routinely in state-sponsored outpatient clinics, provided the naturalistic opportunity to examine the comparative effectiveness of MAT agents, including XR-NTX, and no medication (psychosocial therapy only) in the treatment of parolees and probationers with an alcohol or opioid use disorder. The focus of the study was not only on abstinence from alcohol/drugs, but also outcomes of particular relevance to this high-relapse/recidivism population, specifically length of time receiving care, employment, participation in self-help groups, and rates of re-arrest.

2. Materials and methods

2.1. Study overview

This study was a retrospective analysis of naturalistic, de-identified data obtained from the Missouri Division of Behavioral Health. There was no recruitment or informed consent related to the study. All data were collected as part of normal clinical operations, and there was no direct contact with patients by any member of the research team. Only de-identified data were examined. The study was approved by the Institutional Review Board of the University of Pennsylvania.

2.2. Participants

The analysis included men and women ($N = 2882$), ages 18 and older, who reported alcohol or opioid use as their primary, secondary or tertiary substance use problem at admission and had intake data. The study group was limited to individuals who were under community supervision by the state correctional agency (i.e., on parole or probation). All patients were treated in outpatient centers that received funding from the Missouri Division of Behavioral Health during fiscal year 2013 (July 1, 2012 to June 30, 2013) in a six-county area plus the city of St. Louis. The general population of the study area is roughly two million people and includes both urban and rural environments. Approximately 9500 individuals in the study area seek substance use

disorder treatment annually (Smith, Lundy, & Rothermich, 2013). About half of the XR-NTX patients were from one treatment site that specializes in MAT and was an early adopter of XR-NTX. If patients had more than one episode of treatment in the system during the specified year, the first episode was selected.

2.3. Treatment

All patients were under the supervision of the criminal justice system at the time of admission. About 80% were referred from probation or parole officers, courts or other law-related entity. About 14% were self-referred. The remaining ~6% were referred from community, health or social-service agencies. Treatment providers typically determine the treatment plan. In the case of drug court participants, the drug court team, which includes a treatment professional, determines the treatment plan. Pharmacological agents administered to patients in the identified substance use disorder treatment programs included XR-NTX, oral naltrexone, buprenorphine, buprenorphine/naloxone, acamprosate and disulfiram. Pharmacological treatment was open-label, voluntary and combined with psychosocial treatment. During the target year, only one patient received acamprosate, and none received disulfiram, and therefore the analyses omitted these agents. Patients who received more than one medication were excluded from the final sample, with the exception that because oral naltrexone is often used as an induction to starting XR-NTX, the use of oral naltrexone was not an exclusion for the XR-NTX group. Patients were assigned to treatment groups based only on medications received during the episode of care; medications received after discharge were not included. Patients who received psychosocial treatment only were included in the dataset as a comparison group.

2.4. Data collection

Prior to de-identification, investigators at the Missouri Division of Behavioral Health combined data from a variety of sources for these analyses. Parole and probation status at treatment admission was obtained by matching data from the state correctional agency with those from the publicly funded substance use disorder treatment system. Medicaid eligibility at the time of treatment admission was retrieved from the state Medicaid eligibility rolls based on the patient's Medicaid-assigned identifying number. Both Medicaid and non-Medicaid patients were included in the study group. Since pharmacy billings for Medicaid patients are billed directly from the pharmacy to the state Medicaid agency, paid claims were retrieved from the Medicaid system for addiction medications based on the national drug codes and used to identify which medications were used. For non-Medicaid patients, pharmacy costs are billed to the Division of Behavioral Health. Number of prescriptions could be determined from the number of billings; however, days supplied are not captured in the state information system for the non-injectable addiction medications.

The study group was also matched to an incarceration listing from the state correctional agency to determine past offense, past offense type and days since release for individuals on parole. The listing included everyone incarcerated in the state at any time between July 1, 2007 and June 30, 2013. In addition, any new incarceration events for individuals on parole or probation since treatment admission were identified.

Outcomes data on abstinence, employment, self-help participation, duration of treatment episode and any arrests (past 30 days) at admission and discharge were obtained from Treatment Episode Data Set (TEDS) assessments conducted within state-funded substance use disorder treatment facilities for SAMHSA. TEDS data contain the demographic characteristics and substance use profiles of all individuals older than 12 years admitted to treatment for substance use disorders. TEDS contains two main components: 1) the Admissions Data Set and 2) the Discharge Data Set. The Admissions Data Set contains annual patient-level data on substance use disorder treatment admissions, and the Discharge Data Set is connected at the record-level to the

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