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Assessing informed consent in an opioid relapse prevention study with adults under current or recent criminal justice supervision

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ABSTRACT

Concerns persist that individuals with substance use disorders who are under community criminal justice supervision experience circumstances that might compromise their provision of valid, informed consent for research participation. These concerns include the possibilities that desire to obtain access to treatment might lead individuals to ignore important information about research participation, including information about risks, or that cognitive impairment associated with substance use might interfere with attending to important information. We report results from a consent quiz (CQ) administered in a multisite randomized clinical trial of long-acting naltrexone to prevent relapse to opioid use disorder among adults under community criminal justice supervision—a treatment option difficult to access by this population of individuals. Participants were required to answer all 11 items correctly before randomization. On average, participants answered 9.8 items correctly (89%) at baseline first attempt ($n = 306$). At week 21 ($n = 212$), participants scored 87% (9.5 items correct) without review. Performance was equivalent to, or better than, published results from other populations on a basic consent quiz instrument across multiple content domains. The consent quiz is an efficient method to screen for adequate knowledge of consent information as part of the informed consent process. Clinical researchers who are concerned about these issues should consider using a consent quiz with corrected feedback to enhance the informed consent process. Overall, while primarily useful as an educational tool, employing a CQ as part of the gateway to participation in research may be particularly important as the field continues to advance and tests novel experimental treatments with significant risks and uncertain potential for benefit.

1. Introduction

Informed consent is foundational to ethical clinical research as one important means for respecting persons and their autonomy (Emanuel, Wendler, & Grady, 2000). For informed consent to be valid, potential participants must be capable, voluntary, and adequately informed (Faden & Beauchamp, 1986). To achieve this, researchers must disclose relevant information, including information about risks, potential benefits, alternatives, and the nature of research, and ideally participants should understand the disclosed information. However, studies

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show that these ideals are imperfectly achieved across a variety of conditions (Nishimura et al., 2013; Tam et al., 2015).

Additionally, concerns persist that individuals with substance use disorders who are under criminal justice supervision, including community criminal justice supervision (e.g., probation, parole), experience circumstances that might compromise their provision of valid, informed consent for research participation (Adler, 1995; DeMatteo, Filone, & LaDuke, 2011; Dugosh, Festinger, Croft, & Marlowe, 2010; DuVal & Salmon, 2004; Edens, Epstein, Stiles, & Poythress, 2011; Festinger et al., 2007; Rounsaville, Hunkele, Easton, Nich, & Carroll, 2008). These concerns include the possibilities that desire to obtain access to treatments might lead individuals to ignore important information about research participation (Anderson & DuBois, 2007; McCrady & Bux, 1999; Vaughn, Sarrazin, Saleh, Huber, & Hall, 2002) or that cognitive impairment associated with substance use might interfere with attending to important information (McCrady & Bux, 1999). Further, provisions to safeguard sensitive information disclosed by participants and information about confidentiality protections may be especially important to individuals with substance use disorders and criminal justice system involvement who are considering research participation (DuVal & Salmon, 2004). In light of these needs, an addictions research group at the University of Pennsylvania has been using consent quizzes since the 1970s as a tool for increasing the likelihood that consent is informed (Grabowski, O'Brien, & Mintz, 1979).

Pharmacotherapy is underutilized for drug-dependent criminal justice populations (Friedmann et al., 2012) despite substantial evidence of its effectiveness in reducing opioid use (Amato et al., 2005). Some authorities in the criminal justice system view pharmacotherapy as substituting one drug for another, particularly in regards to agonist therapy (methadone and buprenorphine) for opioid use disorders. For this reason, among others, many authorities in the criminal justice system discourage persons under criminal justice supervision from pursuing pharmacotherapy, and in particular agonist therapies (Bonnie, 2005; Friedmann et al., 2012). For these individuals, and for individuals disinterested in agonist therapies, acceptable pharmacotherapeutic options are often difficult to access. When a clinical trial provides an opportunity to obtain access to an opioid antagonist medication that is otherwise expensive and potentially difficult to access, such as extended-release naltrexone, concern exists that participants desiring to gain access to it through the clinical trial might ignore risks and other important information related to research participation.

Extended-release naltrexone has a number of risks that participants must be made aware of during the informed consent process. Participants receiving naltrexone injections may experience pain or infection at the site of injection, and there is risk of overdose death if participants try to overcome the effects of long-acting naltrexone by using large amounts of heroin or other opioids. After the effects of naltrexone wear off, participants are more sensitive to the effects of opioids, and the risks of overdose and death are increased if they use the same amount as they had previously used on a regular basis. Participants in the treatment-as-usual arm incur risks as well, including the risk of overdose death after a period of abstinence. Participants in both arms also may perceive more general risks of study participation, including that authorities in the criminal justice system would disapprove of their participation. Informing potential participants about safeguards put in place to protect their confidentiality, such as not sharing information about individuals' participation with criminal justice system authorities, contributes to informed decision-making.

With these concerns in mind, each site in a five-site randomized controlled trial testing extended-release naltrexone to prevent relapse to opioid dependence among adults with a history of opioid dependence (current or prior dependence) and current/recent criminal justice system (CJS) involvement required all participants to pass a consent quiz in order to demonstrate knowledge about the study as part of the informed consent process (Lee et al., 2015; Lee et al., 2016). This requirement provided the opportunity to analyze results from an informed consent quiz implemented in a large scale, real-world study of a pharmacological intervention which was commercially available but not yet FDA-approved for opioid relapse prevention and which was very difficult to access as a treatment option for this population.

2. Methods

2.1. The XR-NTX relapse prevention effectiveness study

The primary study was a five-site randomized controlled trial (RCT) evaluating the effectiveness of monthly injections of extended-release naltrexone (XR-NTX), a sustained-release full mu-opioid receptor antagonist, in preventing relapse to opioid dependence in individuals under current or recent CJS who preferred opiate-free treatment over methadone or buprenorphine agonist maintenance treatment (Lee et al., 2015; Lee et al., 2016). A common protocol was approved by the local Institutional Review Boards (IRBs) and implemented at five independently NIDA-funded sites: University of Pennsylvania in Philadelphia, New York School of Medicine/Bellevue Hospital Center and Columbia University Medical Center in New York City, Rhode Island Hospital and Brown University in Providence, and Friends Research Institute in Baltimore (Lee et al., 2015). The Data and Safety Monitoring Board (DSMB) was hosted at the University of Pennsylvania. Participants were enrolled from February 2009 through November 2013. Oral naltrexone was initially approved by the FDA in 1984; extended-release naltrexone (Vivitrol) was FDA-approved in 2006 for treatment of alcohol dependence and received FDA approval for treatment and prevention of opioid dependence in 2010.

Participants in the primary study were individuals with a lifetime (current or prior) history of opioid dependence, as measured using structured assessment instruments based on DSM-IV criteria (i.e., MINI International Neuropsychiatric Interview and SCID Module E for Substance Use Disorders), and current or recent CJS-involvement defined as "currently serving an adjudicated sentence that includes community supervision (e.g., parole, probation, outpatient drug court programs, or other court-mandated treatment) or in the past 12 months arrested or incarcerated" (Lee et al., 2015; Lee et al., 2016). Study inclusion/exclusion criteria were chosen to maximize the potential for generalizability within acceptable safety parameters.

The control arm was treatment-as-usual (TAU) offering brief counseling and referrals to community treatment programs. For both arms, study visits were scheduled every two weeks for 6 months to gather research information, including urine tests. Follow-up visits were completed at 12 and 18 months post-baseline. In the primary outcome analysis, XR-NTX was an effective relapse prevention intervention, reducing relapse events overall and prolonging time-to-relapse. There were seven overdoses in the study, all of which occurred in the TAU arm. Study methods and outcomes have been published elsewhere (Lee et al., 2015; Lee et al., 2016).

2.2. Informed consent process

The informed consent process was approved by the local IRB at each of the five sites. Prescreening consisted of a telephone or in-person brief evaluation, during which an in-person screening visit was scheduled. At the in-person screening, individuals were informed that they needed to score 100% on a consent quiz in order to move forward in the study. They then participated in a standard informed consent process in which a summary of the study was provided and the research assistant/study coordinator reviewed the consent information with the prospective participant. Following this discussion, participants took a consent quiz (CQ) consisting of 11 True/False questions. Participants scoring <100% were provided feedback, given the opportunity to ask questions, and could re-take the CQ until they answered all questions correctly (up to five attempts). Once the participant scored 100%, he