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Perceptions of research risk and undue influence: Implications for ethics of research conducted with cocaine users

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ABSTRACT

Background: Despite the prominence of human laboratory and clinical trial research in the development of interventions for substance use disorders, this research presents numerous ethical challenges. Ethical principles outlined in the Belmont Report, including respect for persons, beneficence, and justice, have traditionally guided research conduct. Few empirical studies exist examining substance abuse research ethics. The present study examined perceptions of beneficence and respect for persons in substance use research, including relative risk and desired monetary compensation, using an online sample of cocaine users.

Methods: The study was conducted on Amazon.com's Mechanical Turk (mTurk), a crowdsourcing website used for survey-based research. Of 1764 individuals screened, 138 reported past year cocaine use. These respondents completed a battery of standardized and experimenter-designed questionnaires used to characterize each respondent's self-reported attitudes, beliefs, and behaviors about drug use and the relative risks and desired monetary compensation associated with research participation.

Results: Ratings of relative risk revealed that most respondents found common research practices as less than or equal to the relative risk of everyday life. Receiving experimental medication outside the hospital was rated as the most risky research activity, but on average was not rated as presenting more risk than everyday life. Desired compensation for research participation was associated with the perceived risk of research activities. Increases in desired compensation for participation were only observed for research perceived as much more risky than everyday activities.

Conclusions: These findings indicate that cocaine users assess risk in a way that is consistent with standard research practice.

1. Introduction

Substance use disorders present a severe and persistent public health concern, with the annual economic impact of illicit drug use estimated at $193 billion (United States Department of Justice, 2011). Cocaine use disorders pose a particularly salient concern due to the lack of currently approved effective pharmacotherapies or widely disseminated behavioral interventions. Nearly 1.5 million persons aged 18 or over were current cocaine users in 2013 and over half of those individuals met diagnostic criteria for cocaine abuse or dependence (Substance Abuse and Mental Health Services Administration [SAMHSA], 2014). Human behavioral pharmacology research is critical to identification of efficacious interventions for substance use disorders, often bridging the gap between preclinical animal studies and large-scale clinical trials. Similarly, clinical trials of putative interventions are the requisite step for treatment dissemination and practitioner adoption.

Despite the importance of human laboratory and clinical trial research in the development of behavioral and pharmacological interventions for substance use disorders, the conduct of this research presents numerous ethical challenges. Such research has traditionally been guided by the ethical principles outlined in the Belmont Report, including respect for persons, beneficence, and justice (National Commission for the Protection, 1979). Ensuring

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respect for persons requires that participants are given the freedom from excessive internal or external coercion and that researchers ensure greater protections for vulnerable participants, such as those with limited autonomy. Beneficence requires the maximization of benefits and minimization of risks, whereas the principle of justice states that the benefits and risks of research must be fairly distributed across groups, with substantial ethical reasons for inclusion and exclusion of specific groups. Substance use researchers rely on these ethical principles to establish guidelines that ensure risks are minimized before, during, and following research participation (Adler, 1995; Fischman and Johanson, 1998).

Numerous commentaries and research reviews have emphasized the principle of respect for persons when working with substance-using populations and the need for a participants' understanding of research risk (McCrady and Bux, 1999; Walker, 2005). Participants must be made aware of these risks throughout the informed consent process (e.g., the direct communication of potential drug side effects). Risks must be minimized (e.g., avoiding introducing novel routes of self-administration) and assessed by independent Institutional Review Boards (IRBs). However, little empirical data exist to delineate how target participant populations evaluate the risks associated with research procedures relative to everyday risk before enrolling in research. This gap is notable considering that the ethical acceptability of research rests on the appreciation and understanding of risk by participants throughout the informed consent process (Emanuel et al., 2000).

Another important ethical consideration is monetary compensation and the possibility for undue influence. Some data exist revealing that monetary incentives do not present undue influence (Byrne et al., 2012; Festinger et al., 2005, 2008), and that these payments do not increase drug use or purchase (Festinger and Dugosh, 2012; Kurlander et al., 2006). Although payment for participation is debated (Wertheimer and Miller, 2008), it is generally acknowledged that compensation must neither be too high (i.e., undue influence) nor too low (i.e., monetary exploitation). In this respect, a minimal level of payment is necessary (e.g., to compensate for time and out-of-pocket expenses; Fry et al., 2006), but little empirical data exist examining what constitutes exploitation. Additionally, few studies have examined the relationship between perceived research risk and monetary compensation and the existing studies have used strictly qualitative methods. For example, semi-structured interviews of African-American drug users found that evaluation of research risk was a salient determinant of the decision to enroll in research, and that this risk was not ignored in the pursuit of monetary compensation (Slomka et al., 2007, 2008).

Making a decision to participate in research requires the logical assessment of risk and monetary compensation. A growing body of literature has examined cognitive function impairments in stimulant-using populations and provided conflicting evidence (Beveridge et al., 2008; Hart et al., 2012; Potvin et al., 2014 for contrasting reviews). For example, a recent meta-analysis found insufficient evidence for executive function deficits in current cocaine users, indicating that they are capable of logical decision making (Potvin et al., 2014). Other studies report that stimulant users experience cognitive deficits (e.g., Chung et al., 2007; Kim et al., 2006), but many of these do not consider normative values when determining level of impairments (see review by Hart et al., 2012). Although minor deficits in neurocognitive function could impair risk assessment, there is no published empirical work regarding cocaine users' ability to consider research participation risk.

The present study examined perceptions of research participation in human laboratory and clinical research in cocaine users, including the relative risk of research procedures and desired monetary compensation. A battery of standardized and experimenter-designed questionnaires was used to characterize each respondent's self-reported attitudes, beliefs, and behaviors about drug use and research participation. The sample was drawn from Amazon.com's Mechanical Turk (mTurk) interface, a crowdsourcing website that has recently become a popular alternative to in-person laboratory experiments for survey-based research. Research has documented close correspondence between findings obtained using mTurk samples and traditional survey samples, including research in the field of behavioral pharmacology and substance use research (Crump et al., 2013; Johnson et al., 2015; Simons and Chabris, 2012).

2. Methods and materials

2.1. General procedure

The study survey was administered on Amazon's mTurk platform. Tasks on mTurk are advertised as Human Intelligence Tasks (HITs). To view this study's HIT, respondents were required to have a 95% or higher approval rating on all previously submitted mTurk HITs, over 100 approved HITs, and current residence in the United States. Respondents reviewed an informed consent document describing the study procedures, compensation, and the fact that anonymity would be retained throughout the study. All respondents indicated by electronic confirmation that they understood this document and agreed to participate. The IRB of the University of Kentucky approved all protocols, including the consent process.

The HIT was posted on mTurk from March 2, 2015 to April 10, 2015. The survey was closed when 125 respondents submitted a survey. Respondents were required to complete the survey in one sitting and were told that completion would take 1 to 30 min depending on eligibility (median completion duration = 13.3 min). Respondents had to report past year use of cocaine and be 18 years of age or older to qualify. A short screening questionnaire was used to determine if respondents qualified. This screening questionnaire included questions about each respondent's age, sex, and drug use behaviors. Respondents were asked if they used cocaine as well as heroin, prescription opioids, alcohol, cigarettes, marijuana, and methamphetamine in the past year (dichotomous response: yes or no). If a respondent endorsed cocaine use and was 18 years of age or older, he or she had the opportunity to complete the remainder of the survey. If a respondent failed to qualify, he or she was thanked for his or her time and provided $0.05 compensation for completing the screening portion of the study. Respondents that qualified and completed any of the remainder of the survey were compensated $1.05.

2.2. Survey materials

The study survey consisted of a battery of self-report questionnaires assessing perceptions of research risk and monetary compensation for research, drug use behaviors, and mental health status that was hosted online by Qualtrics (Provo, UT). Respondents were told that the purpose of the study was to learn about research participation and drug use. Other than this general explanation of purpose, respondents were not given any information concerning what outcomes might be expected.

2.2.1. Relative risk questionnaire. An experimenter-designed relative risk questionnaire was used to assess perceptions of the relative risk of common human laboratory and clinical research procedures (Table 1). For each research procedure, respondents were asked to rate the perceived risk as compared to the usual risk experienced in their everyday life. The 15 procedures were rated on a 5-point scale: 1 = Much Less Risk, 2 = Less Risk, 3 = Same Risk, 4 = More Risk, and 5 = Much More Risk than experienced in everyday life. Risk was