



Short communication

What adolescents enrolled in genomic addiction research want to know about conflicts of interest



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ABSTRACT

Background: Perspectives of adolescent research participants regarding conflicts of interest (COIs) and their impact on trust in researchers have not been studied. This study evaluates views of adolescent patients in treatment for substance and conduct problems compared to controls enrolled in genomic addiction research.

Methods: Participants included 273 (190 patients, 83 controls) adolescents. Participants consented or assented (with parental consent) to have their genomic information deposited in a NIH biobank that shares information globally with qualified investigators. As part of that study, participants completed a COI survey. Endorsement of each COI item was analyzed with multiple logistic regressions, evaluating group, age, sex, ethnicity, and highest grade completed.

Results: Patients and controls differed in gender, ethnicity and highest grade completed. In response to the survey, 38.4% of patients and 25.3% of controls “want to know” and 35.3% of patients and 37.3% of controls “might want to know” about COIs. Males were less likely to want/might want disclosure about COIs. Older patients were more likely to want disclosure about financial interests; patients were more likely to want disclosure about possible treatments; males were more likely to want information about monetary gains. Both groups requested between 1 paragraph and 1 page of information. Disclosure of COIs did not impact trust for most participants.

Conclusion: Adolescent patients and controls in this study want comparable information for disclosure of COIs including monetary gains, salary, publications, grants, and professional awards. Notably, the majority of patients and controls report that disclosure will not undermine trust in researchers.

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1. Introduction

Little is known about the perspectives of adolescent research participants regarding the disclosure of conflicts of interest (COIs) and the impact of disclosure on trust in researchers. After an extensive literature search, we find no research prior to this study specifically addressing the actual perspectives of adolescents or vulnerable adults (ethnic minority, criminal justice involvement, addiction) on researcher COIs or trust. This study evaluates the preferences of adolescent patients in treatment for substance and conduct problems (SCP) compared to community controls, all of whom participated in a genomic addiction research study. Due to

developmental differences of adolescents, patient interaction with criminal justice and/or minority overrepresentation, the views of this study population bring an important perspective to the discussion of COI and trust in researchers.

1.1. COIs

Among the many stakeholders in the discourse surrounding COIs, adult research participants have limited input. Studies reporting the perspectives of adult stakeholders include: scientists (Sax and Doran, 2011), industry sponsored trials (Lehmann et al., 2012; Weinfurt et al., 2010), potential research participants (Kirkby et al., 2012; Weinfurt et al., 2008; Friedman et al., 2007; Kim et al., 2004; Hampson et al., 2006), and actual research participants (Hutchinson and Rubinfeld, 2008; Gray et al., 2007; Grady et al., 2006). In summary, most potential and actual adult participants report that COIs

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should be disclosed to research participants, including information on the sponsor, investigators' financial interest, and expected monetary gain. Both potential and actual adult participants indicate that disclosure of COIs is unlikely to affect their willingness to participate in research.

Several noteworthy organizations support reporting COIs to participants (Association of American Medical Colleges, 2008; Institute of Medicine, 2009; WMA, 2008). The most recent revision of the NIH regulations for financial conflict of interest recommends reporting COIs to the institution where research is conducted, the research sponsor, and potential participants as a means of managing existing or potential financial conflicts (National Institutes of Health, 2011, 2013; Irwin, 2009). In addition, some authors maintain that researchers have an ethical and possibly a legal obligation to disclose COIs to research participants and to help them understand the information via informed consent (Resnik, 2004).

1.2. Trust

Trust in the investigator-participant relationship is vital to advancing the research enterprise (Sharp, 2009). Trust in researchers was undermined in the recent past by COIs involving pharmaceutical companies' failures to disclose compensation and/or a more likely bias to report positive findings (Insel, 2010; Okike et al., 2007). In some minority communities, the lack of trust is due to notorious abuses by researchers (Garrison, 2013). In light of publicity regarding researcher COIs, recent studies report that disclosure does not appear to undermine trust and may even help to improve or maintain trust in adult participants (Asher et al., 2011; Weinfurt et al., 2009). Adult participants report that they rely on institutions to manage investigator COIs by maintaining investigator integrity, data safety, and participant welfare (Grady et al., 2006).

1.3. Purpose

The purpose of this study is to provide data identifying COIs that are important to adolescent research participants and assessing the impact of disclosure upon participants' trust in researchers.

2. Methods

2.1. Assent/consent

Participants in this study were adolescents who were participating in genomic addiction research. During the informed consent process for this study, participants were informed that their genotypic and phenotypic data without name or other identifiers would be deposited into the National Institutes of Health repository, which shares information with qualified investigators globally. Parents or other surrogates provided informed consent for the study, with assent of the adolescent until the age of 18. Current standards for assent state that from 14 to 17, given evidence of capacity, adolescent and parent/guardians should collaborate on decisions, and the decision of the adolescent should prevail. The Colorado Multiple Institutional Review Board approved this study.

2.2. Study participants

Participants include adolescent patients in treatment for SCP and controls recruited to be similar in age and from zip code areas that frequently contribute patients to our university-based substance treatment program. Participants were of either sex and any racial/ethnic group, and all were enrolled in genomic addiction research through the Center on Antisocial Drug Dependence (CADD). As part of that study participants completed a standard battery of assessments, including demographic information (age, sex, highest grade completed, ethnicity) and a 6-item COI survey¹.

Adolescent patients: Inclusion criteria for adolescent patients were: (1) in substance treatment; (2) age 14–18 years; (3) full-scale IQ \geq 80; (4) serious substance

use problems, usually including DSM-IV substance abuse or dependence diagnoses; (5) serious antisocial problems, usually including symptoms of DSM-IV conduct disorder; (6) consent from participant or, for minors, assent from participant with consent from a parent. Exclusion criteria for patients were: (1) psychosis; (2) current serious risk of suicide, violence, or fire setting (though many patients do have these problems in their past histories); (3) insufficient English skills for assenting/consenting or completing interviews; (4) parent does not consent for minor child to participate in this study.

Adolescent controls: Inclusion criteria for controls were: (1) adolescents identified through their participation in an affiliated primary care clinic, or through online or newspaper advertisements, flyers, etc.; (2) age 14–18 years; (3) full-scale IQ \geq 80; (4) consent from participant or, for minors, assent from participant with consent from a parent. Exclusion criteria for controls were the same as for patients and additionally: (1) any current or previous treatment for conduct or substance problems; (2) obvious intoxication.

2.3. Development

Investigators conducted a focus group with nine patients to identify appropriate language with which to discuss COIs, since this is likely an unfamiliar concept to this population. Investigators then developed a 6-item survey, which 273 participants completed (190 patients, 83 controls). The survey addressed four topics: (1) Whether or not participants want disclosure of researcher COIs (response options: *I want to know/I might want to know, depending on the type of personal benefit/I do NOT want to know*); (2) For those participants indicating they want or might want to know, the survey then asked about which types of COI disclosure participants would like information (response options: *cash/stocks/researcher owns company/salary, publication, grants/professional awards*); (3) Impact of disclosure on trust (response options: *trust more/trust less/would lose all trust/trust wouldn't change*); (4) Preferred amount of information for disclosure (response options: *1 sentence/1 paragraph/1 page*). The survey did not ask about disclosure of research sponsor, since that is standard information in research consent forms. The complete survey can be found as Supplementary material².

2.4. Data collection

The survey was added near the beginning of the assessments for the CADD study. After a verbal explanation from a research assistant, participants completed the survey using a paper-pencil, self-report format. Data were entered and edited in Microsoft Access, password-protected, and stored on the secured institutional server.

2.5. Data analysis

Distributions of outcomes were evaluated and analyses were conducted in IBM® SPSS® Statistics 21 (IBM Corp., 2013). Groups (patient, control) were compared on demographic characteristics with independent *t* tests and chi square tests. Endorsement of each item on the COI survey was analyzed with multiple logistic regressions evaluating effects of group, age (in years), sex, ethnicity (white, Hispanic, other), and highest grade completed.

3. Results

Patients ($n=190$) and controls ($n=83$) were similar in age (average 16 years) but differed significantly on demographic characteristics including sex, ethnicity and mean highest grade completed. A larger proportion of patients (83%) than controls (65%) were male. More patients were Hispanic (20%) than controls (6%), and patients reported that they had completed about half a grade less than controls. See Table 1.

3.1. Survey results (see Table 2)

Preferences for whether or not participants want COI disclosure: Survey results revealed that in terms of wanting to know about COIs, 38.4% of patients and 25.3% of controls "want to know"; 35.3% of patients and 37.3% of controls "might want to know, depending on the type of personal benefit"; 26.3% of patients and 37.3% of controls "do not want to know".

Table 2.

¹ Supplementary material can be found by accessing the online version of this paper at <http://dx.doi.org> and by entering doi:...

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