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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,

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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.

Keywords

Conflict of Interest; Trust; Ethics; Genomics; Addiction; Adolescents

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 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 (Resnick, 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, 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, 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 14–17, 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.

2.2.1. Adolescent Patients—Inclusion criteria for adolescent patients were: 1) in substance treatment; (2) age 14–18 years; (3) full-scale IQ ≥ 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.

2.2.2. 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 ≥ 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.

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2.5. Data Analysis

Distributions of outcomes were evaluated and analyses were conducted in IBM® SPSS® Statistics 21 (IBM Corporation, 2011). 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)

3.1.1 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”.

3.1.2 Types of COI Disclosure—The subset of participants who indicated they want or might want disclosure (n=192) were then asked about which types of COI to disclose. In models that included group and the demographic variables, COI preferences were not related to group, ethnicity or highest grade completed but differed by sex and age. Males were less likely to want or might want disclosure about COIs (OR=0.5, p=.047) and more likely to want to know about monetary gain (OR=3.7, p=.002) Older patients were more likely to want or might want disclosure about financial interests (OR=1.5; p=.047).

3.1.3 Reasons for COI Disclosure—When asked why they wanted disclosure, patients and controls were similar in most responses. After adjusting for demographic variables, the only exception was that patients were twice as likely to want or might want disclosure if a study might produce a new treatment for addiction (OR=2.1, p=.049). Reasons for COI disclosure did not differ by demographic characteristics.

3.1.4 Amount of COI Disclosure—When asked how much information participants wanted, after adjusting for demographic variables there were no differences between patients and controls. The majority of both groups wanted more than a sentence and between a page (patients 45.3%, controls 44.2%) and a paragraph (patients 43.9%, controls 42.3%). Amount of COI disclosure did not differ by demographic characteristics.

3.1.5 Impact of COIs on Trust—Those respondents who wanted disclosure completed one question on the COI survey measuring the impact of COI disclosure on trust. After adjusting for demographic variables, patients and controls did not differ regarding the

impact of COI on trust. The majority of both groups indicated that disclosure of COI would not negatively impact their trust in researchers, but 20.0% (n=28) of patients and 26.9% (n=14) of controls reported that they would trust less or lose all trust due to the disclosure. Impact of COI disclosure on trust did not differ by demographic characteristics either.

4. DISCUSSION

All the participants in this study had previously given their DNA and other personal information to a broadly shared biobank. Thus, they already demonstrated trust in researchers. This study takes the analysis of trust a step further and measures the impact of the disclosure of researcher personal benefit on trust. It is noteworthy that 20–27% of adolescent participants indicated that disclosure of COIs entailing personal benefit could result in decreased trust or loss of trust. This finding suggests that potential research participants should be made aware of relevant COIs and afforded the opportunity to develop an opinion as to whether or not they choose to participate.

Some possible study limitations include differences between patients and controls by sex, ethnicity, and highest grade completed, possibly impacting results, although we attempted to control for this statistically. Measurement issues are also a possible limitation as the three point scale used to measure whether or not participants wanted disclosure may have introduced range restrictions. Our rationale for a three point scale was to avoid confusion for adolescents who are likely unfamiliar with conflicts of interest and may have difficulty making more subtle distinctions.

These results corroborate adult studies cited above and extend the research to adolescent participants. Both adults in prior studies and adolescent participants in this study indicate that they want disclosure of researcher COIs, and it is unlikely to affect their trust in researchers. Despite demographic differences, the majority of adolescents enrolled in this genomic addiction research want comparable disclosure of COIs including monetary gains, salary, publications, grants, and professional awards. Both patient and control adolescents request between a paragraph and a page of information. Disclosure of COIs did not influence trust for the majority of participants, and patients and controls did not differ. Future research is needed to determine reasonable thresholds for disclosure that respect the autonomy of researchers and participants without negatively impacting trust in the research enterprise.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- Study surveyed views of 273 adolescents enrolled in genomic addiction research.
- Participants were patients in treatment for substance/conduct problems and controls.
- All answered a survey on researcher conflicts of interest and the impact on trust.
- Participants (73.3% patients, 62.6% controls) wanted/might want to know about COIs.
- Most participants reported that disclosure would not undermine trust in researchers.

Table 1

Demographic Characteristics by Group

	Patients (n=190)	Controls (n=83)	Test	p-value
Mean Age in Years (SD=standard deviation)	16.0 (SD=1.1)	15.9 (SD=1.4)	t(133.2)=0.2	NS
Sex			$\chi^2(1)=10.9$	0.001
Male	83.2% (n=158)	65.1% (n=54)		
Female	16.8% (n=32)	34.9% (n=29)		
Ethnicity			$\chi^2(2)=9.1$	0.011
White	51.9% (n=98)	61.4% (n=51)		
Hispanic	20.6% (n=39)	6.0% (n=5)		
Other	27.5% (n=52)	32.5% (n=27)		
Mean Highest Grade (SD)	9.4 (SD=1.2)	9.9 (SD=1.4)	t(271)=3.7	< 0.0005

Table 2

COI Preferences, Type and Amount of COI Disclosure, and Impact on Trust by Group

COI SURVEY QUESTION	Patients	Controls
Researcher COI:	n=190	n=83
Want to Know	38.4%	25.3%
Might Want to Know	35.3%	37.3%
Do Not Want to Know	26.3%	37.3%
AMONG SUBSET WHO WANT OR MIGHT WANT DISCLOSURE	n=140	n=52
Types of COI Disclosure:		
Monetary Gain	81.4%	75.0%
Stocks	31.4%	21.2%
Researcher Salaries/Publications/Grants	53.6%	42.3%
Researcher Financial Interest in Company	34.3%	28.8%
Professional Prizes/Awards	55.0%	71.2%
Why You Want to Know:		
Researcher Might Manipulate Me	35.0%	25.0%
Researcher Might Not Report Bad Outcomes	41.4%	25.0%
Study Might Produce a New Treatment	52.9%	38.5%
I Just Want to Know	74.7%	25.3%
Researcher Might Do Good Things with Money/Award	42.9%	51.9%
Amount of Information on COI:		
1 page	45.3%	44.2%
1 paragraph	43.9%	42.3%
1 sentence	10.8%	13.5%
Impact on Trust:		
Lose All Trust	3.6%	1.9%
Trust Less	16.4%	25.0%
Trust Wouldn't Change	60.7%	65.4%
Trust More	19.3%	7.7%