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Adolescents with Substance Use Disorder and Assent/Consent: Empirical Data on Understanding Biobank Risks in Genomic Research*

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Abstract

Objective—This study assessed whether a customized disclosure form increases understanding for adolescents with substance use disorder (SUD) when compared to a standard disclosure for genomic addiction research.

Method—We gathered empirical data from adolescents with SUD, family members, former patients followed since adolescence, and community counterparts. The study was conducted in four stages. Stage 1: national experts (n=32) identified current, future, speculative risks of broadly shared biobanks. Stage 2 assessed participants' (n=181) understanding of current risks as a prerequisite for rating saliency of risks via a Visual Analogue Scale. Salient risks were incorporated into a customized disclosure form. Stage 3 compared the understanding of customized disclosure by participants (n=165) at baseline; all groups scored comparably. Stage 4 conducted a direct comparison of the standard disclosure to standard disclosure plus customized disclosure (n=195). Independent t-tests compared understanding in those receiving the standard disclosure to standard disclosure plus customized disclosure within 6 groups.

Results—The customized disclosure significantly improved understanding in adolescent patients (p=.002) and parents of patients (p=.006) to the level of their counterparts. The customized disclosure also significantly improved understanding in siblings of former patients (p=.034). Understanding of standard disclosure in patients versus controls was significantly different

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Contributors

The authors on this original paper all participated in the research design of this study and the development of the questionnaire instrument; Hopfer and Sakai led participant enrollment; Raymond led data collection; McWilliams conducted data management; Michulich-Gilbertson conducted data analysis; Coors led the writing of the manuscript; and all authors reviewed the manuscript and provided comments.

Conflict of Interest

Marilyn Coors is the spouse of the Chairman of the MolsonCoors Brewing Company, and the company has not contributed any funds nor had any influence on this project. The authors have no conflicts of interest to disclose.

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($p=0.005$). The groups receiving the customized disclosure scored significantly higher. Understanding of the standard disclosure plus customized disclosure in patients versus controls was not significantly different.

Conclusion—Adolescents with addictions understand the risks of participating in genomic addiction research as well as their community counterparts when information provided is salient to them.

Keywords

adolescents with substance use disorder; biobanks; informed consent; assent; understanding; genomic

1. INTRODUCTION

Advances in understanding child and adolescent mental illnesses are likely to require large-scale studies with many participants. Currently, the National Institutes of Health funds a major initiative to biobank information on over 10,000 children in the Adolescent Brain Cognitive Development (ABCD) Study Consortium (Department HHS RFA-DA-15-015). The project proposes to follow participants longitudinally and broadly share data on brain imaging, genomics, behavior, and other biomarkers. As children in this and other studies enter adolescence, it is likely that they will engage in behaviors that are illegal and possibly stigmatizing, such as underage substance use. To what extent can adolescents or their family members understand and consent or assent to participation in broadly shared biobanks? Biobanks are unlike traditional research studies in which a known and trusted researcher or institution collects samples for a specified purpose. In contrast, biobanks store participant samples indefinitely and share them extensively with qualified researchers for purposes that are currently known and for future purposes that are unknown.

1.1. Background

A number of crucial issues arise when disclosing benefits and risks of biobank research to adolescents with substance use disorders (SUD) that are particular to this population. Adolescents with SUD are not specifically included in the category of “especially vulnerable” populations. Yet, they are vulnerable because research on their disorders includes the study of illegal behaviors (Kuthning and Hunt, 2013) and research databases may overlap criminal databases (Simoncelli, 2006). Some also suffer from cognitive impairment (Tapert and Brown, 2000). In addition, evidence indicates that adolescents with SUD are prone to be “impulsive” and “risk-takers” compared to controls (DeWit, 2009), demonstrating a lack of behavioral restraint when considering activities that may unpredictably yield reward or punishment (Crowley et al., 2010).

Several previous studies assess understanding in the informed consent process within vulnerable populations (Agre and Rapkin, 2003; Rosen et al., 2015), showing that lower levels of education and cognitive performance correlate with lower comprehension test scores in adult patients with psychotic disorders or SUD (Dunn and Jeste, 2001; Kiluk et al., 2010). This evidence does not suggest that persons with psychiatric disorders or lower literacy are incapable of providing informed consent (Davis et al., 2006; Misra et al., 2008;

Hickman et al., 2011). Rather, the data suggest that deficits in understanding correlate in part with poorly developed consent materials, and additional steps in educational interventions can improve understanding for vulnerable groups (Dunn and Jeste, 2001; Misra et al., 2008; Kuthnig and Hundt, 2013). Research involving lower-level reading consent forms report mixed results. Forms with simplified language result in lower anxiety and greater satisfaction among participants, but there is no difference in understanding when compared to standard forms (Coyne et al., 2003; Davis et al., 2006).

Research on adolescents with SUD and their family members is scant, given the central role that understanding of risks and benefits plays in the informed consent process (Unguru et al., 2010; O'Lonergan, 2011; Hunfeld and Passchier, 2012; Tait et al., 2012; Traube et al., 2013; Ott et al., 2013; Lee et al., 2013; Lally et al., 2014; Grootens-Wiegerris et al., 2015). After an extensive literature search, we find no published research related to the understanding of assent or consent in adolescents with SUD. The increased scrutiny of assent and consent in research calls for information developed with patient participation in mind, especially those from risk prone populations such as adolescents with SUD.

1.2. Purpose

The purpose of this study is to determine whether a customized disclosure describing salient risks of biobanking increases understanding for adolescent patients when compared to a standard disclosure for genomic addiction research (see Supplementary Material¹). We present empirical data from adolescents with SUD, their family members, and community-based participants in a comparable age range gathered over a three-year period. Only when we ascertain how adolescents with SUD understand the risks of broadly shared biobanks can we credibly address best research practices for assent or consent in this population (Coors et al., 2015a; Coors and Raymond, 2009; Fuentes and Martin-Arribas, 2007).

2. METHODS

The study consisted of four stages, each building upon the results of the prior stage. Stage 1 entailed a workshop to identify the risks for participants in broadly shared biobanks. Stage 2 assessed whether participants understood the risks as a prerequisite to rating the saliency of the risks. Salient risks comprised a customized disclosure form for genomic addiction research. Stage 3 assessed and compared the level of understanding of the salient risks by participants at baseline. Stage 4 conducted a direct comparison of the standard disclosure for the parent genomics study to the standard disclosure plus the customized disclosure.

Stage 1, 2 and 3 comprised the methodology leading to Stage 4, which is the main focus of this study. Analysis for Stages 2–4 were conducted in IBM SPSS 22.

The Colorado Multiple Institutional Review Board (COMIRB) approved this study.

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2.1. Stage 1: Workshop

Experts from diverse fields (n=32) met for a 1 ½ day workshop to identify the risks of broadly shared biobanks. The investigators invited persons in positions of leadership who held perspectives included in and beyond the scope of the published literature to ensure a thorough exploration of the risks. Attendees included bioethicists, patient advocates, patients, clinicians, genetic researchers, entrepreneurs, computer scientists, biobank directors, law enforcement officials, and a futurist. The proceedings were recorded with permission of the participants and transcribed.

The investigators conducted a qualitative analysis of the transcript, which included an iterative process whereby two investigators independently identified the risks and checked the transcript for consistency. When differences emerged, the investigators resolved them through consensus building after rereading the transcripts. Differences consisted of statements that expressed the same risk differently, and those were combined into one representative risk. No risks were eliminated. The investigators categorized the results into a table of 8 current risks (rare but possible at the time of this writing), 6 future risks (unlikely but possible), and 3 speculative risks (highly unlikely) as identified by experts attending the workshop (see Table S1²).

With the guidance of an educational consultant, the investigators developed an information sheet including definitions of pertinent terms related to biobanking (risk, computer hacking, DNA, genetic research, biobank) and a careful description of the 8 current risks. It included only current risks so as not to unnecessarily frighten or confuse participants. The information sheet was the prototype for the customized disclosure. A 10-item questionnaire that included brief vignettes and multiple choice questions assessed understanding of risks, plus 4 demographic questions, and a Visual Analogue Scale (VAS) to measure saliency.

2.2. Participants for Stages 2, 3, and 4

A large concurrent genomics study that focused on adolescents with SUD was the source of participants (Derringer et al., 2015). All eligible patients from a university treatment program were invited to enroll in this study separate from and prior to enrolling in the genomics study. Most of the patient population met diagnostic criteria for DSM-IV substance dependence and conduct disorder and on average were more than three standard deviations above age and sex corrected norms for such antisocial behavior (Stallings et al., 2003). A PRA recruited controls via Craigslist during the same time period from zip codes frequently contributing adolescent patients to the university treatment program. Participants were of either sex and any racial/ethnic group.

2.2.1 Inclusion criteria—(1) enrolled in a NIDA-funded psychiatric genomic research study or the parent of a minor child enrolled in the study, 2) full-scale IQ estimate >80 (within a 95% confidence interval) or no obvious intellectual deficiency for subjects not so tested, (3) 14–65 years of age; (4) for subjects 17 years of age or younger, valid consent

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from parent or guardian, together with assent from the subject, or if the subject was over 17, consent from the subject.

2.2.2 Exclusion criteria—(1) psychosis, (2) current serious risk of suicide, violence, or fire setting indicating that a potential participant presented grave danger to him or herself or others at the time of enrollment, and (3) insufficient English skills for assenting/consenting or completing interviews, excluding Spanish speaking only participants.

2.3. Stage 2: Measure saliency of risks

All participants (n=181) read the information sheet developed in Stage 1 (Section 2.1). It was important to take the time and effort to educate participants to understand the risks as a prerequisite to a valid rating of saliency.

Participants then completed the questionnaire developed in Stage 1, including the VAS to measure saliency of each risk (VAS; 0 mm=not at all important to me, 100 mm=very important to me). The VAS mean for each risk included only participants who answered the survey question specific to that risk correctly. The final customized disclosure form included only risks with a VAS greater than 50 mm.

Questionnaire data were collected and managed using Research Electronic Data Capture (REDCap; Harris et al., 2009).

2.4. Stage 3: Baseline understanding of risks

A second independent set of participants (n=165) completed the paper-and-pencil version of the questionnaire addressing the salient risks to assess understanding at baseline. Participants in Stage 3 did not receive the information sheet.

Independent t-tests compared the percent correctly understanding each risk for the following study groups: 1) adolescent patients and controls, 2) parents of adolescent patients and parents of adolescent controls, and 3) former patients followed since adolescence and their siblings.

2.5. Stage 4: Comparisons of standard disclosure and customized disclosure addition

In Stage 4, a third independent set of participants completed the questionnaire after the standard disclosure alone or standard plus customized disclosure (n=195; see Table S1³). No participant declined to enroll in the genomics study after reading the customized disclosure or completing the questionnaire.

To calculate an “understanding risk” score in Stage 4, responses to individual questions were coded as 1=correct; 0=incorrect. For the risks assessed with a single question/response, one response represented the score. For the risks assessed with 2 questions/responses, each of the answers was weighted by .5 such that the score for that risk could be 0 (0/2 correct), 0.5 (1/2 correct), or 1 (2/2 correct). Scores for each risk were summed to create a total score ranging from 0–6.

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Independent t-tests compared the understanding risk score in two important ways. First, the analysis compared the mean scores between those receiving the standard disclosure versus standard plus customized disclosure within each of the 6 study groups. Second, within each type of disclosure (i.e., standard and standard plus customized), the analysis compared the understanding risk score between adolescent patients and controls and parents of adolescent patients and controls.

3. RESULTS

3.1 Stage 2: Measure saliency of risks

Adolescents with SUD scored comparably in overall understanding of the salient risks when compared to their community counterparts: adolescent patients: $n=61$, 75.6%; adolescent controls: $n=21$, 78.9%; former patients followed since adolescence: $n=29$, 74.7%; adult siblings of former patients: $n=25$, 92.6%; parents of patients: $n=35$, 94.7%; parents of controls: $n=14$, 94.9%.

The high percentages of participants (75–95%) who understood the risks validated the saliency ratings. The majority of participants who demonstrated understanding endorsed the saliency of seven of the current risks. Saliency, as measured by the average VAS score, was above 50 for each of the current risks with one exception: time benefit too long (average VAS=44.3 mm). Therefore, the final customized disclosure form included seven salient risks.

3.2 Stage 3: Baseline understanding of risks

In the 165 participants who completed the questionnaire, baseline understanding of risks was 71–79% correct across all 6 study groups. The following groups did not differ significantly in their overall understanding: adolescent patients and community controls, parents of patients and parents of controls, and former patients and their siblings. These results demonstrated that groups had comparable baseline understanding.

3.3 Stage 4: Comparisons of standard disclosure and customized disclosure addition

In comparisons between type of disclosure for each study group ($n=195$ total participants), Figure 1 shows (via asterisk) that those receiving the customized disclosure addition understood significantly better than those receiving only the standard disclosure in 3 groups: adolescent patients ($p=0.002$), parents of adolescent patients ($p=0.006$), and siblings of former adolescent patients ($p=0.034$). There was no difference within the other 3 groups (see also Table S2⁴).

Figure 1 also shows (via connecting bracket) that for comparisons within each type of disclosure, adolescent patients receiving only standard disclosure understood less than their control counterparts ($p=0.005$); the adolescent groups who received the customized disclosure addition did not differ in understanding (NS). Similarly, parents of adolescent patients receiving only standard disclosure understood less than their control parent

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counterparts ($p=0.001$); the parent groups who received the customized disclosure addition did not differ. Thus the customized disclosure addition improved understanding scores in adolescent patients and parents of patients to the level of their community counterparts. Comparisons in understanding levels were not conducted between former patients and siblings who received standard disclosure and those who received the customized disclosure addition.

4. DISCUSSION

The expansion of biobanks such as the ABCD Study, Database of Genotypes and Phenotypes (dbGaP), and other broadly shared resources may oversample population subgroups at greater risk for uptake of substance use during adolescence. That, coupled with the increase of personal information that can be derived from genomics research, emphasizes the need to examine understanding of assent and consent in all participants, particularly those in this vulnerable population.

Adolescents with SUD comprehend the risks of participating in genomic addiction research as well as their community counterparts when information provided is salient to them. These findings underline the importance of: (1) care in the development of the assent and consent processes, and (2) efficacy of formal assessment of understanding and saliency in some vulnerable populations such as adolescent substance users (Munthe et al., 2010; Roundsaville et al., 2008). Moreover, these data offer insights for investigators to consider including several risks salient to their unique study population along with those required by local IRBs. Preliminary research demonstrates that investigators are not particularly accurate in predicting how adolescent participants with SUD will respond to information on researcher conflicts of interest and return of individual research results, despite years of experience with this population (Coors et al., 2015a, 2015b). Further research is necessary to determine how diverse populations understand the risks of broadly shared biobanks in order to address effectively best research practices for assent/consent.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- Customized disclosure (CD) improved understanding in addicted adolescents (AA) ($p=.002$).
- CD improved understanding in parents of AA ($p=.006$) and siblings of former AA ($p=.034$).
- Understanding of standard disclosure (SD) in AA v controls differed ($p=0.005$).
- Groups receiving CD scored significantly higher.
- Understanding of SD plus CD in AA versus controls did not differ significantly.

Figure 1.
Comparison of Understanding Risk Score with Standard Disclosure Versus Customized Disclosure Addition