

Original Study

Adolescent and Parent Willingness to Participate in Microbicide Safety Studies

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ABSTRACT

Study Objective: To understand adolescents' and parents' willingness to participate (WTP) in a hypothetical phase I prevention study of sexually transmitted infections, discordance within adolescent-parent dyads, and expectations of each other during decision-making.

Design and Setting: Adolescent-parent dyads were recruited to participate in a longitudinal study about research participation attitudes.

Participants: Adolescents (14-17 years old) and their parents (n = 301 dyads) participated.

Interventions: None.

Main Outcome Measures: Individual interviews at baseline assessed WTP on a 6-level Likert scale. WTP was dichotomized (willing/unwilling) to assess discordance.

Results: WTP was reported by 60% (182 of 301) of adolescents and 52% (156 of 300) of parents. In bivariate analyses, older adolescent age, sexual experience, and less involvement of parents in research processes were associated with higher level of WTP for adolescents; only sexual experience remained in the multivariable analysis. For parents, older adolescent age, perceived adolescent sexual experience, and conversations about sexual health were significant; only conversations remained. Dyadic discordance (44%, 132 of 300) was more likely in dyads in which the parent reported previous research experience, and less likely when parents reported higher family expressiveness. Adolescents (83%, 248 of 299) and parents (88%, 263 of 300) thought that the other would have similar views, influence their decision (adolescents 66%, 199 of 300; parents 75%, 224 of 300), and listen (adolescents 90%, 270 of 300; parents 96%, 287 of 300). There were no relationships between these perceptions and discordance.

Conclusion: Inclusion of adolescents in phase I clinical trials is necessary to ensure that new methods are safe, effective, and acceptable for them. Because these trials currently require parental consent, strategies that manage adolescent-parent discordance and support adolescent independence and parental guidance are critically needed.

Key Words: Adolescent research participation, Topical microbicides, Clinical trials, Sexually transmitted infections

Introduction

One of the 3 ethical principles of the Belmont Report is justice, which requires that there is “fairness in distribution” between the risk or burden of the disease and participation in research.¹ Because of limited success in reducing the epidemic of sexually transmitted infections (STIs) among sexually experienced adolescents,² they should be given the opportunity to participate in clinical trials that are developing new biomedical options for prevention.³ In addition, there are biological and psychological characteristics of younger adolescents that would indicate it might be reasonable to assume that prevention methods or products deemed safe and effective in adults will not necessarily be safe and effective for adolescents.^{4,5}

However, to conduct these trials in adolescents, adolescents must be willing to participate in them. Although there are efforts to allow adolescents to consent without parental permission in certain situations, at the current time, parental permission is the norm because adolescents are considered a “vulnerable population” within the federal regulations.⁶ Thus, it is also critical to understand parent's willingness to let their adolescent participate. In those cases, the adolescent and parent must agree on whether or not to participate. Research has examined adolescent-parent discordance in clinical trials for asthma treatment.^{7,8} However, the reasons underlying the discordance might be different for sensitive topics such as sexual health. Discordance might also differ in the case of prevention trials in healthy individuals because their motivation to participate differs from that of participants who experience a particular disease such as asthma.⁹ Discordance between adolescents and parents presents the possibility that adolescents could be coerced to participate by their parents or to be unable to participate because the parent withholds

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permission. Understanding adolescent's and parent's expectations of how each would respond to the other in terms of collaborating on the decision might be useful in understanding the risk of coercion.

Thus, we sought: (1) to evaluate the relationship between adolescents' and parents' willingness to participate (WTP) in a hypothetical phase I clinical trial and the following factors: demographic characteristics and sexual history, perceptions of parental involvement in research, previous experience with research, parent-adolescent report of relationship and sexual health conversations, and family characteristics; (2) to describe WTP discordance within adolescent-parent dyads, and the relationship of the variables described previously on WTP discordance; and (3) to describe adolescents' and parents' expectations of each other during a decision-making process, and its relationship to WTP discordance.

Materials and Methods

Participants were recruited from adolescent medicine clinics of 2 large medical centers in New York City and through snowball sampling to participate in a longitudinal study on "how teenagers and their parents feel about being in research studies, in particular studies that help teens protect their reproductive health." As part of this study, the adolescents and parents were presented a hypothetical clinical trial examining the safety of a topical microbicide for STI/HIV prevention in adolescents. Adolescents were 14–17 years of age and participated with a parent. All participants spoke either English or Spanish. Institutional review boards of Columbia University Medical Center and Weill Cornell Medical College approved the study, and all participants provided written informed consent/assent. The data presented in this report are from simultaneous individual interviews of adolescents and parents conducted at the baseline study visit.

Interview Content and Measures

WTP

The adolescents were read the description of a typical phase I clinical trial of a microbicide and asked: "If this study were happening today, please rate (on a 6-point Likert scale) your agreement with the statement—I would agree to be in the study." The parents were asked to respond to the statement "I would agree for my son/daughter to be in the study" using the same rating scale. For adolescents and parents, a score of 1–3 reflected disagreement with the statement (strongly, moderately, and mildly) and a score of 4–6 reflected agreement with the statement (mildly, moderately, and strongly). After their answer, the adolescents and parents also were asked to rate using the same 6-level scale, their agreement that the other "would have thoughts similar to mine about my being in the study"; the other's "opinion would influence my decision"; and the other "would listen to what I wanted to do about being in the study."

Sexual History

The interview obtained information about adolescent's sexual histories and parent's perceptions of their

adolescent's sexual experience. Adolescent level of sexual activity was categorized as those who reported no sexual contact beyond kissing and those who reported contact beyond kissing. Parents could answer "I don't know" to questions about their adolescent's sexual activity. Thus, the parent's responses were coded either as reporting their adolescent had not engaged in any sexual activity beyond kissing, reporting that the adolescent had, or reporting that they did not know if their adolescent had engaged in sexual activity beyond kissing.

Perceptions of Parental Involvement in Research

A scale assessing opinions about parental involvement in research was developed in which adolescent and parent participants were asked to respond yes/no to statements about parental involvement in the research process for a teenager the age of the adolescent participant. On the basis of principal component analysis, the items formed 2 subscales.¹⁰ The first was LEARN (parent learning test results or behaviors) and the second was PROCEDURE (parents involved in the procedures of the study).

Parent-Adolescent Report of Relationship and Sexual Health Conversations

Adolescents and parents responded yes/no to whether they had ever discussed 4 relationship topics (ie, making decisions about having sex, dating and romantic relationships, sexual pressure, friends' sexual behaviors) and 4 sexual health topics (ie, condoms, birth control, sexual pressure, protecting against STIs/HIV). For conversations about relationships and conversations about sexual health, the sum of each of the 4 items for the scale was used for purposes of analysis.

Family Environment

Six subscales (cohesion, control, organization, conflict, moral-religious emphasis, expressiveness) of the Family Environment Scale (FES)¹¹ were used.

Statistical Analyses

All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc, Cary, NC). With regard to demographic characteristics, age of the adolescent was dichotomized into 14–15 years of age and 16–17 years of age. Ethnicity was dichotomized into Hispanic vs non-Hispanic.

Ordered logistic regression analyses were used to evaluate the relationship of predictors to the level of WTP for adolescents and parents. For these regression analyses, adolescent reports were used in adolescent models, and parent reports were used in parent models. Significant variables (at $P < .05$) in bivariate analyses were placed into a multivariable model.

To describe WTP discordance within adolescent-parent dyads and investigate the relationship between parent and adolescent predictors and WTP discordance, WTP was dichotomized as willing/unwilling to participate and then adolescent-parent dyads were characterized as concordant or discordant. With regard to concordance, the adolescent-parent dyads could both agree with being likely to

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