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Parents' and Adolescents' Attitudes about Parental Involvement in Clinical Research

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Abstract

Study objective—To understand parent/adolescent attitudes towards parental involvement (PI) during clinical trials and factors related to those attitudes.

Design—As part of a study on willingness to participate in a hypothetical microbicide study, adolescents and their parents were interviewed separately.

Setting—Adolescent medicine clinics in New York City

Participants—There were 301 dyads of adolescents (ages 14 to 17 years; 62% female; 72% Hispanic) and their parents.

Interventions—None

Main outcome measures—The interview included demographics, sexual history, family environment (subscales of the Family Environment Scale (FES)), which was associated with attitudes about parental involvement.

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Results—Factor analysis of the parental involvement scale yielded two factors: LEARN, reflecting gaining knowledge about study test results/behaviors (4 items) and PROCEDURE, reflecting enrollment/permissions (4 items). Adolescents endorsed significantly fewer items on both the LEARN scale and the PROCEDURE scale indicating that adolescents believed in less parental involvement. There was no significant concordance between adolescents and their own parents on the LEARN scale and the PROCEDURE scale. In final multivariate models predicting attitudes, adolescents who were female and had sexual contact beyond kissing, and non-Hispanic parents had lower LEARN scores. Adolescents who were older, had previous research experience, and reported less moral-religious emphasis in their family had lower PROCEDURE scores; there were no significant predictors for parents in the multivariate analyses.

Conclusions—Parents wanted greater involvement in the research process than adolescents. Recruitment/retention may be enhanced by managing these differing expectations.

Keywords

adolescent research participation; parental involvement

INTRODUCTION

Given the rapid psychological and biological changes that occur during adolescence,^{1, 2} findings from clinical trials involving adults may not be directly applicable to adolescents, which results in a need for adolescent-specific studies.³ In addition, the ethical principle of justice as outlined in the Belmont Report⁴ implies that adolescents should have equal opportunity, relative to adults, to participate in research involving conditions and diseases that impact them. Clinical research involving the prevention of sexually transmitted infections (STIs) is a clear instance, where adolescent-specific studies are needed given the high rates of STIs among adolescents.⁵ A tension may exist, however, between the importance of inclusion and the fact that those under 18 years of age are considered a “vulnerable population”,⁶ and in need of protection from coercion or undue influence.⁷

Typically the focus has been on either limiting eligibility to adolescents who are 18 years and older to avoid the need to obtain parental permission or seeking a waiver of parental consent.^{8, 9} However, in many instances, it makes sense to find a way for adolescents to have a sense of agency over their own decision, while benefiting from parental guidance as needed. This balancing process between adolescent autonomy and parental guidance will change as adolescents mature and gain experience.^{10, 11} The specific requirements for parental consent is guided by laws; however, even in situations in which young adults have the legal right to make clinical decisions (e.g., abortion, vaccination), many still involve their parents in their decision making process.^{12, 13}

The act of balancing adolescent autonomy and parental wisdom may be influenced by many factors. There may be an asynchrony in development such that an adolescent may be sexually mature and engaging in high-risk sexual behaviors; however, their cognitive skills may not lead to the best evaluation of risk/benefit. Certainly, there is some evidence that parents and adolescents may differ in how they evaluate risk,^{14–16} as parents are less likely than their adolescent to agree to have the adolescent participate in more than minimal risk

studies.¹⁷ Further, most adolescents by the age of 14 years have cognitive skills similar to those of adults,^{18, 19} and will use their most sophisticated reasoning when approaching a controlled, non-stressful cognitive task.^{20–22} Little is known about the emotional and cognitive demands that a research-decision places on an adolescent, but one may assume it is likely to be a controlled and non-stressful situation. Depending on the topic of the research, parents may respond differently to daughters versus sons. Families (sometimes influenced by race/ethnicity) differ in their approach to adolescent autonomy.²³

Understanding parents' and adolescents' perspectives on appropriate parental involvement will aid in the recruitment and retention of adolescents in clinical trials. Thus, we sought to describe parents' and adolescents' attitudes about parental involvement in the clinical trial experience in the context of a study addressing willingness to participate in a hypothetical microbicide safety study.²⁴ Specifically, we assessed adolescents' and their parents' attitudes about parental knowledge and involvement in the research. We also sought to determine if demographic or family characteristics were related to these attitudes.

MATERIALS AND METHODS

Potential participants were approached in the adolescent medicine clinics of two large medical centers in New York City and through snowball sampling. Adolescents 14–17 years of age and one of their parents or legal guardians were eligible to participate if they spoke English or Spanish, and if both agreed to participate. The study was approved by the Institutional Review Boards of Columbia University Medical Center and Weill Cornell Medical College. All participants provided written informed consent/assent to enroll in a longitudinal study addressing willingness to participate in a hypothetical clinical trial examining the safety of a topical microbicide for sexually transmitted infections/human immunodeficiency virus (STI/HIV) prevention in adolescents. At the baseline study visit, simultaneous individual (adolescent and parent separately) interviews were conducted.

Parents and adolescents were interviewed in English or Spanish by trained research assistants. The interview assessed adolescent and parent demographics, the adolescent's sexual history and parent's perceptions of the adolescent's sexual history. With respect to the adolescent's level of sexual activity, the levels were divided into those adolescents who reported that they had sexual contact beyond kissing and those who did not. The parents were allowed to answer "I don't know" to the questions about sexual activity; thus, the parent responses were divided into those parents who reported that their adolescent had not engaged in any sexual activity beyond kissing, those who reported that the adolescent had, and those who reported that they did not know if their adolescent had engaged in sexual activity beyond kissing. Parents and adolescents completed six subscales (cohesion, control, organization, conflict, moral-religious emphasis, and expression) of the Family Environment Scale (FES).²⁵ Adolescents were asked about prior research participation and parents were asked if they or their adolescent had ever participated in research.

A scale assessing opinions about parental involvement in research was developed based on previous experience conducting research. Participants were asked to respond yes/no to nine items for a teenager their age (or their teenager's age) (Table 1).

Statistical Analyses

All statistical analyses were conducted using SAS 9.4. Demographic variables included adolescent age, which was dichotomized as 14–15 years of age and 16–17 years of age, and ethnicity, which was categorized as Hispanic versus non-Hispanic. For assessing the relationship to adolescents' attitudes about PI, adolescent age, adolescent gender and ethnicity, their report of sexual activity, their perception of the family environment, and previous research participation was used. In the parent models, the adolescent's age and gender was used, parent's ethnicity, report of their adolescent's sexual activity, parent perception of the family environment, and parent report of research participation was used. Principal component analysis with a varimax rotation was used to develop subscales for the 9-item parental involvement scale. Subscale scores were created by summing the items from each factor. In order to test for significant differences between adolescents and parents, a chi-square test was used to compare scores between the group of parents and the group of adolescents. In order to evaluate whether parents and their own adolescents had similar attitudes, Cohen's Kappa coefficient was calculated. Finally, in order to determine if demographic characteristics, adolescent sexual histories, previous research participation and FES subscale scores were related to parent and to adolescent attitudes, bivariate ordinal regressions were done, with those variables that had an alpha level of 0.05 being placed in a multivariate ordinal regression model.

RESULTS

Three hundred and forty-three dyads were enrolled; however, one family withdrew and their data are not included; two parent-adolescent dyads were enrolled twice and only their data from their first visit is included. Of the 340 adolescent-parent dyads, most were recruited from a clinic waiting/exam room ($n = 294$), the remainder through snowball sampling ($n = 46$). The parents were mothers/stepmothers ($n = 303$), fathers/stepfathers ($n = 23$), or other parenting adults (grandparents, aunts) ($n = 14$). There were no differences with regard to adolescent age, gender, or Hispanic ethnicity between those who were recruited in the clinic and those recruited through snowball sampling (all $p > 0.05$). The demographics of the sample are presented in Table 2. The Hispanic participants were from a variety of countries including the Dominican Republic, Mexico, Puerto Rico, Cuba, with the most commonly identified country being the Dominican Republic. With regards to race, 10% of the adolescents were Caucasian, 31% were African-American and 47% described their race as Hispanic. The parent data was similar. Thus, for purposes of analyses, we used Hispanic ethnicity regardless of race. Of the 340 adolescent-parent dyads in the final sample, there were 31 parents with two adolescents and four parents with three adolescents.

Factor Analysis of the Parental Involvement Scale

Principal component analysis was performed on the 9-item parental involvement scale; a varimax rotation was used to determine factors of the parental involvement scale. A two factor solution was forced. The data entered into the factor analysis included the individual responses of 340 adolescents and their parents, thus, the sample size was 674 (six participants left one or more items blank). The item regarding asking details about study participation did not load on either factor and was dropped from further analysis (Table 1).

The first factor, which was labeled “LEARN”, consisted of four items related to learning about the results of testing or behaviors. The factor had a standardized alpha coefficient of 0.80. The second factor, which was labeled “PROCEDURE”, consisted of the items related to enrollment and permissions surrounding the study. This factor had a standardized coefficient alpha of 0.63.

Adolescent and Parental Attitudes

Analyses involving family level variables (FES) include only the first sibling from each family where siblings were enrolled, as family environment can be assumed to be similar across adolescent reports from the same family. This resulted in the exclusion of 39 adolescents; demographic characteristics of the remaining 301 dyads do not differ significantly from the 340 dyads.

Adolescents endorsed fewer items on the LEARN scale ($X^2(4) = 79.98, p < .0001$) and on the PROCEDURE scale ($X^2(4) = 88.34, p < .0001$) than parents indicating that adolescents believed in less parental involvement than parents. For example, on the LEARN scale, 54% of adolescents endorsed all 4 items in contrast to 85% of parents. Similarly on the PROCEDURE scale, 48% of adolescents endorsed all 4 items versus 83% of parents. Adolescents and their parents were not concordant on the LEARN subscale ($\kappa = 0.04$, 95% CI = $-0.03 - 0.10$), nor the PROCEDURE subscale ($\kappa = 0.05$, 95% CI = $-0.03 - 0.12$).

Attitudes about parental knowledge (LEARN)—For adolescents, the results of the bivariate analyses indicated that age, gender, and sexual experience of the adolescent were significantly related to the LEARN score (Table 3). Adolescents who were older, female, and had sexual contact beyond kissing were more likely to believe in less parental knowledge about the findings from research participation. The six subscales of the FES were similarly placed in individual models. The following subscales were significantly related to attitudes about parental knowledge: cohesion, conflict, moral-religious emphasis and organization. The results indicated that adolescents who viewed their families as less cohesive, more conflictual, having less moral-religious emphasis and less organized were more likely to believe in less parental knowledge about the findings from research participation. In the final multivariate regression analysis, only gender (OR 2.5; 95% CL: 1.5 – 4.1) and level of sexual experience remained significant (OR 0.3; 95% CI: 0.2 – 0.5).

For parents, in the bivariate analyses, only Hispanic ethnicity of the parent was significantly related to the LEARN score (Table 4). The results indicated that non-Hispanic parents believed in less parental knowledge. With regard to family characteristics, the moral-religious and organization subscales of the FES were significant. Parents who viewed their families as having less moral-religious emphasis and being less organized were more likely to believe that there should be less parental knowledge. In the final multivariate regression analysis, only parental Hispanic ethnicity 0.43; 95% CL: 0.22 – 0.84) remained significant.

Attitudes about parental involvement in research procedures (PROCEDURE)—In bivariate analyses, adolescent age, sexual experience of the adolescent and previous research participation were significantly related to the PROCEDURE score for adolescents

(Table 3). The results indicated that older adolescents, those who had sexual experience beyond kissing and those with previous research experience were more likely to believe in less parental involvement in the research procedures. For the FES subscales, cohesion, conflict, moral-religious emphasis and organization were significantly related to adolescents' attitudes about parental involvement in research procedures. Adolescents who viewed their families as less cohesive, more conflictual, having less moral-religious emphasis and being less organized were more likely to believe there should be less parental involvement in research procedures. In the final multivariate regression analysis, age (OR .49; 95% CL: 0.3 – 0.8), previous research experience (OR .53; 95% CL: 0.3 – 0.9) and moral-religious emphasis of the FES scale (OR 1.03; 95% CL: 1.0 – 1.05) remained significant.

Among parents, only parent perception of their adolescent's sexual experience was significantly related to the PROCEDURE score (Table 4). Using the perception that the adolescent had sexual contact as the reference group, parents who thought that their adolescent had had sexual contact as compared to those that reported not knowing believed in less parental involvement in research procedures. With regard to family characteristics, none of the FES subscales were related to parental involvement in research procedures.

DISCUSSION

In the context of adolescents and their parents who participated jointly in a study, we found that adolescents and parents had relatively high expectations for parental involvement in clinical trials. Much of this information (e.g. risk behaviors, results of STI testing) is viewed as confidential in the context of routine clinical care and in research studies by clinicians and investigators. In addition, adolescents typically report wanting privacy about many of the concepts measured in the context of daily life.^{26, 27} Thus, it was somewhat surprising that so many adolescents and parents believed parents should be able to learn this information during a research study. Parents and adolescents may feel that information learned in a clinical trial differs from other settings. While it is unlikely that investigators would disclose this information to parents, it is important to understand and manage parental expectations.

Experience also may influence attitudes. For example, those adolescents who had participated in research before believed in having their parents less involved in the procedures of research. This study enrolled a population of adolescents seeking primary care; attitudes about privacy during clinical trials may differ in the setting of biomedical treatment for a chronic condition (e.g., asthma).¹⁵

Overall, parents believed in greater involvement than adolescents and adolescent-parent dyads were not concordant in their beliefs. Given the differences between parents and adolescents, it may be helpful to manage expectations of both through explicit conversations at the start of clinical trial participation about study procedures and the sharing of information. The investigator can help the adolescent-parent dyad develop strategies to manage their expectations.

The adolescents may have been more likely to take a developmental approach since their answers were influenced by their level of sexual experience (which was highly correlated with age), while the parents' responses were not. However, given the cross-sectional nature of the study design, it is possible that parents are focused on their specific adolescent's skill level which would vary for adolescents of the same age and same level of sexual experience.

Context is important for both adolescents and parents. The adolescent females wanted less involvement. Adolescent females (relative to males) may feel that they have more at stake with their parents learning about their behaviors since there are societal differences in the response to adolescent male and female sexuality and risk-taking.²⁸ Hispanic parents wanted more involvement. Hispanic families may differ based on their country of origin and their level of acculturation, but in general, Hispanic families may place more emphasis on parental authority.²⁹ Understanding the role of gender and ethnicity is important in order to ensure that the barriers to participation are reduced and women and minorities do not remain under-represented in clinical studies.^{30, 31}

Particularly for the adolescents, the family environment across Hispanic and non-Hispanic backgrounds was related to attitudes. This is consistent with a study of children and parents deciding about cancer clinical trial participation which found that high parent-child conflict was *not* associated with collaborative decision-making.³² The results also are consistent with a wide-range of studies that show that parenting behaviors (e.g., adolescents' sense of volition, authoritative parenting style) are related to psychosocial competence,³³ although it is likely a bi-directional effect with parents being influenced by their adolescent as well as parents influencing their adolescent.³⁴

These findings are limited by the fact that these were adolescent-parent dyads willing to participate jointly in a study about enrollment in a hypothetical clinical trial that was focused on reproductive health. Although the parental involvement questions did not specifically describe the type of study, the adolescents and parents may have been considering a study on reproductive health. The lack of reference to a specific study weakens the intention-behavior connection, which is always less than perfect, but also provides some information about general perceptions. In addition, there were some measurement issues which require additional research. First, our qualitative experience indicates that many families did not know what 'anemia' was, so it may not have been an effective example of a 'non-sensitive' medical test. Second, as noted "asking questions" did not load on either factor, yet it is a key way that parents learn about the research experience of their adolescents. Previous research has found that lack of questions by parents can indicate a lack of interest in the adolescent's research experiences, while too many questions can lead to adolescents' withholding information.³⁵ More work is needed to understand this aspect of parent-adolescent communication. Finally, this study did not focus on how parents are involved in longitudinal research after initial enrollment,³⁵ which is important for retention.

Ethically and practically, it is imperative that adolescents be included in clinical trials of reproductive health so that new biomedical methods of preventing STIs are safe, effective and acceptable to them given their disease burden. The specific nature of each study should influence appropriate investigator's decisions and plans for parental involvement.

Understanding adolescents' and parents' attitudes toward parental involvement can ensure that adolescents and parents understand what they are consenting to, have a positive experience during the trial, and foster retention. Future research should focus on improving our measurement of these concepts and their application; however, in the meantime, it seems likely that adolescents and parents may bring discordant expectations about parental involvement to research experiences.

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Table 1

Factor Loadings for items of the Parental Involvement Scale.

Factor Name	Item	Factor Loading for Learn	Factor Loading for Procedure
<i>PROCEDURE</i>	Know BEFORE a teenager is asked to be in a study which requires parental permission.	0.10769	0.46591
	Be required to come to the first study appointment with their teenager	0.05141	0.60219
	Give permission for their teenager to be IN a study which requires the teenager to be interviewed or fill out a questionnaire, but there is no medicine involved	0.10993	0.73110
	Give permission for their teenager to be IN a study which is teaching their teenager to make healthy decisions about behavior such as smoking, drinking or sex.	0.17788	0.68601
<i>LEARN</i>	Learn from the study team about their teenagers' behaviors such as smoking, drinking, or sex	0.64760	0.19812
	Learn from the study team about the results of testing done for sexually transmitted infections during the research	0.87122	0.11623
	Learn from the study team about the results of testing done for pregnancy during the research study	0.84949	0.18154
	Learn about the results of other medical tests done during the study, such as anemia	0.65644	0.10765
<i>DROPPED</i>	Ask their teenager about the details of study participation	0.12221	0.38987

For a teenager your (your child's) age, parents should...

Table 2

Sample characteristics of 301 adolescents and parents representing unique families

Adolescent Demographics	%
Age (14–15y)	47
Gender (female)	62
Ethnicity (Hispanic)	72
Lack of Sexual Experience (no experience beyond kissing)	65
Previous Research Participation (yes)	13
Parent Demographics	%
Gender (female)	92
Ethnicity (Hispanic)	71
Perceived Level of Adolescent Sexual Experience	46
No experience beyond kissing	25
Sexual contact beyond kissing	29
Don't know	
Previous Research Participation for either parent or teen (yes)	26

Table 3

Bivariate and Multivariate Analysis of the Association between Adolescent Demographic/ Family Characteristics and Parental Involvement

	Bivariate		Multivariate	
Predictors of LEARN	OR (95% CI)	P	AOR (95%CI)	P
Age	0.41 (0.27 – 0.64)	<0.01	0.72 (0.44 – 1.19)	0.20
Female gender	2.50 (1.55–3.90)	<0.01	2.50 (1.54 – 4.05)	< 0.01
Hispanic ethnicity	0.95 (0.59–1.53)	0.84		
Sexual Experience	0.25 (0.16–0.40)	<0.01	0.30 (0.18 – 0.51)	<0.01
Previous research participation	1.59 (0.86–2.95)	0.14		
FES Cohesion	1.02 (1.01 – 1.04)	<0.01	1.00 (0.98 – 1.02)	0.89
FES Expression	1.01 (0.98 – 1.03)	0.66		
FES Conflict	0.97 (0.95 – 0.99)	<0.01	0.99 (0.97 – 1.01)	0.36
FES Moral-religious emphasis	1.03 (1.01 – 1.05)	0.013	1.02 (0.99 – 1.04)	0.17
FES Organization	1.03 (1.01 – 1.05)	<0.01	1.02 (0.99 – 1.04)	0.18
FES Control	0.99 (0.97 – 1.02)	0.85		
Predictors of PROCEDURE				
Age	0.45 (0.29 – 0.69)	<0.01	0.54 (0.33 – 0.87)	0.01
Female gender	1.26 (0.81 – 1.94)	0.30		
Hispanic ethnicity	0.91 (0.57 – 1.46)	0.70		
Sexual Experience	0.49 (0.32 – 0.76)	<0.01	0.73 (0.44 – 1.21)	0.22
Previous research participation	2.02 (1.09 – 3.75)	0.03	0.53 (0.28–0.99)	0.05
FES Cohesion	1.03 (1.01–1.05)	<0.01	1.00 (0.99 – 1.03)	0.37
FES Expression	1.02 (0.99–1.04)	0.09		
FES Conflict	0.97 (0.95–0.98)	<0.01	0.99 (0.97 – 1.01)	0.29
FES Moral-religious emphasis	1.04 (1.01–1.06)	<0.01	1.04 (1.00 – 1.05)	0.03
FES Organization	1.04 (1.02–1.06)	<0.01	1.02 (0.99 – 1.04)	0.15
FES Control	1.02 (0.99–1.04)	0.12		

Table 4

Bivariate and Multivariate Analysis of the Association between Parent Demographic/Family Characteristics and Parental Involvement

Predictors of LEARN	Bivariate		Multivariate	
	OR (95% CI)	P	AOR (95%CI)	P
Age	0.92 (0.49 – 1.73)	0.80		
Female gender (Adolescent)	0.76 (0.41 – 1.44)	0.40		
Female gender (Parent)	0.54 (0.20–1.45)	0.22		
Hispanic ethnicity	0.40 (0.21–0.75)	<0.01	0.45 (0.23 – 0.88)	0.02
Perceived Adolescent Sexual Experience Yes vs No Yes vs I don't know	1.90 (0.90 – 4.03) 1.39 (0.63 – 3.08)	0.09 0.42		
Previous research participation	1.01 (0.49–2.07)	0.98		
FES Cohesion	1.01 (0.99–1.04)	0.32		
FES Expression	1.00 (0.97–1.04)	0.92		
FES Conflict	0.99 (0.96–1.01)	0.30		
FES Moral-religious emphasis	1.05 (1.01–1.09)	<0.01	1.03 (0.99 – 1.07)	0.11
FES Organization	1.04 (1.02–1.07)	<0.01	1.03 (0.99 – 1.06)	0.07
FES Control	1.01 (0.97–1.05)	0.76		
Predictors of PROCEDURE				
Age	0.94 (0.52–1.72)	0.85		
Female gender (Adolescent)	1.09 (0.59–2.04)	0.78		
Female gender (Parent)	1.45 (0.42 – 5.03)	0.56		
Hispanic ethnicity	0.64 (0.34–1.20)	0.16		
Perceived Adolescent Sexual Experience Yes vs No Yes vs I don't know	1.56 (0.78 – 3.12) 2.33 (1.01–5.37)	0.21 0.05	1.56 (0.78 – 3.12) 2.33 (1.01–5.37)	0.22 0.36
Previous research participation	1.49 (0.78 – 2.84)	0.23		
FES Cohesion	1.00 (0.98–1.03)	0.99		
FES Expression	0.97 (0.94–1.00)	0.08		
FES Conflict	0.98 (0.95–1.00)	0.08		
FES Moral-religious emphasis	1.03 (0.99–1.07)	0.11		
FES Organization	1.03 (1.00 – 1.05)	0.0540		
FES Control	0.99 (0.95–1.02)	0.47		