



Published in final edited form as:

J Pediatr Adolesc Gynecol. 2018 December ; 31(6): 592–596. doi:10.1016/j.jpag.2018.06.001.

Adolescent-Parent Dyadic Retention in an Interview Study and Changes in Willingness to Participate in a Hypothetical Microbicide Safety Study

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Abstract

STUDY OBJECTIVE—The study describes adolescent and parent retention and changes in willingness to participate (WTP) in research among adolescents, parents, and adolescent-parent dyads.

DESIGN AND SETTING—Adolescent-parent dyads were recruited to participate in a longitudinal study to assess research participation attitudes using simultaneous individual interviews of the adolescent and parent with a return visit one year later using the same interview.

PARTICIPANTS—Adolescents (14–17 years old) and their parents.

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The work described in this study was performed at Columbia University Medical Center. The first author, Jenny Francis, now works at the University of Texas Southwestern Medical Center in Dallas, Texas, and the second author, Ariel de Roche, now works at New York University Langone Health.

Conflicts of Interest: There are no conflicts of interests to be declared for any of the authors.

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INTERVENTIONS—None.

MAIN OUTCOME MEASURES—The relationship between participant characteristics and dyad retention was assessed. WTP was measured on a Likert scale and dichotomized (willing/unwilling) in order to assess changes in WTP attitudes over time for adolescents, parents, and dyads.

RESULTS—Eighty-three percent of the 300 dyads were retained. Dyads in which there was successful contact with the parent prior to follow-up were more likely to be retained (OR 4.88; 95% CI: 2.57 – 9.26). For adolescents at baseline, 59% were willing to participate and 55% were willing to participate at follow-up [McNemar's: $S = 0.91(1)$, $p = 0.34$]. For parents at baseline, 51% were willing to participate and 57% were willing to participate at follow-up [McNemar's: $S = 5.12$, $p = 0.02$]. For dyads at baseline, 57% were concordant (in either direction) and 70% of dyads were concordant at follow-up [McNemar's: $S = 10.56$, $p = 0.001$].

CONCLUSIONS—Over one year, parent contact may positively influence successful adolescent retention. Parents become more willing to let their adolescents participate over time, with dyads becoming more concordant about research participation.

Keywords

Adolescent research participation; clinical trials; sexually transmitted infections; topical microbicides; parent communication

INTRODUCTION

Inclusion of adolescents in sexual health biomedical trials is necessary to ensure that new products are safe and effective for them.^{1,2} The sensitivity of sexual health topics for adolescents in research may have an impact on their willingness to participate (WTP) and retention over time.^{3–5} Given the ability of adolescents to seek clinical sexual health services without parental consent,⁶ there is often a desire to allow adolescents to be able to participate in sexual health research on their own. While this may be approved in some instances,⁷ it is not common practice when studies involve more than minimal risk and enroll healthy, low-risk volunteers. Thus, understanding the role of parents in this process is critical.^{8,9}

An additional challenge to recruiting adolescents for trials that require parental permission arises when adolescent-parent dyads are discordant about participation. Researchers must balance respect for an adolescent's emerging capacity for independent decision-making with the needs to secure permission to participate by their parents.¹⁰ Parents provide support and direction for adolescents into their young adult years, and increasing evidence suggests that adolescents may need help with decision-making and behavioral regulation.¹¹ Given the rapid developmental growth during adolescence, changes in sexuality, psychosocial development and physical growth, it is important to know how discordance about participation in research changes over time for adolescents and parents. In addition, a Cochrane Database of Systematic Reviews concluded that “no good evidence is available to examine ways to improve participants returning for follow-up” and suggested that behavioral strategies may warrant further evaluation to improve retention.¹²

By using an adolescent developmental conceptual framework¹³ of how adolescents acquire life/decision-making skills, researchers may be able to provide developmentally-appropriate behavioral support to adolescents as they consider participation in research and commitment to their decision over time for longitudinal studies. The goal of clinical trialists and study coordinators is to ensure that everyone involved in the recruitment of healthy volunteers is comfortable and in agreement with the final decision to participate or not.

Thus, we examined the same adolescents and parents one year later in a longitudinal interview. We previously examined adolescents' (aged 14 to 17 years) and parents' WTP in a hypothetical phase I clinical trial about microbicide safety at baseline and found that 60% of adolescents and 52% of parents were WTP. Of interest, 44% of adolescent-parent dyads were discordant about their WTP at baseline.¹⁴ Dyads in this study were recruited from one location and were predominately Hispanic; thus, the sample focuses on a population with high rates of sexually transmitted infections,^{15,16} yet is often underrepresented in clinical trials,^{17,18} and requires attention to avoid further health disparities.

For this analysis, we sought to describe the following:

- a. Relationship of demographic characteristics to dyad retention in the interview study;
- b. Changes in willingness to participate (WTP) among adolescents and parents;
- c. Changes in discordance about their WTP among adolescent-parent dyads.

This hypothesis-generating study could aid in the recruitment of adolescents into future research studies. It could also inform researchers about adolescents' and parents' attitudes about research participation over time to serve as a tool for supporting parents and adolescents during the research process.

MATERIALS AND METHODS

Adolescent (aged 14–17 years) and parent dyads were recruited in English and/or Spanish to participate in a study assessing their willingness to participate in a hypothetical safety trial of a topical microbicide gel for sexually transmitted infections/human immunodeficiency virus (STIs/HIV) prevention in adolescents. Study procedures^{14,19–22} included simultaneous individual interviews of the adolescent and parent and a return visit one-year later for the same interview at an academic medical center.

The individual interview collected information on demographics, adolescent sexual history, prior research participation, and willingness to participate in a hypothetical sexual health clinical trial as reported in baseline work from this data.¹⁴ During the individual interviews, research coordinators presented an informed consent document that described a hypothetical more than minimal risk randomized controlled-trial. The consent form stated that the purpose of the study was to see if an experimental gel that was being studied for the prevention of STIs/HIV was safe for adolescents. It explained that an experimental or control gel would be assigned to each participant, and the gel would either be applied intravaginally, or topically to the penis. A lengthy review of the procedures, including the

potential risks and benefits of participation, was reviewed. After learning about the hypothetical study, each participant was asked to rank on a 6-point Likert scale his or her willingness to participate (WTP). Participants were specifically asked, “If this study were happening today, please rate your agreement with the statement: I would agree to be in the study,” or if read to a parent, “I would agree for my son/daughter to be in the study.” Response categories ranged from strongly disagree (1) to strongly agree (6).

Participants were each compensated \$50 and a round-trip public transportation card for both the baseline and follow-up visits. This study received approval from the Institutional Review Boards of Columbia University Medical Center (CUMC) and Weill Cornell Medical College (WCMC) and all participants provided written informed assent and consent in either English or Spanish.

Retention Efforts

All participants received cards by postal mail for the adolescents’ birthdays and seasonal holidays (approximately 4–5 a year). Research coordinators began contacting participants by phone to schedule follow-up interviews two months prior to the anniversary of the initial interview. Research coordinators were given guidance to attempt to contact participants up to three times unless the participants indicated a clear lack of interest prior to that attempt. However, research coordinators were not given a limit to the number of times they could continue to reach out to participants who seemed willing to continue participation and were having scheduling or follow-through difficulties. E-mail or postal mail was sent if participants were unable to be reached by phone. Communication with participants was logged on a contact sheet with the date and outcome of the contact (i.e., left voicemail, spoke with participant and scheduled appointment, no answer). The contact sheets were coded for how many times the participants were contacted, whether adolescent contact information was initially obtained, who was contacted (parent, adolescent or both), if other modes of contact were used (email, postal mail), and if the participants cancelled, rescheduled, or did not show to their appointment. With regards to the number of times a participant was contacted, contacts were tallied when there was a change in either the day or the mode of contact.

Participants

Of the 340 dyads at baseline, there were 31 parents who participated with two siblings and four parents with three siblings. For all analyses, we included only the first sibling enrolled, resulting in the exclusion of 39 adolescent-parent dyads and a study sample of 301 dyads. An additional family was excluded from dyadic and parent (but not individual adolescent) analyses because the adolescent returned with a different parent at follow-up. The remaining 300 dyads did not differ significantly on key demographics from the baseline sample of 340 dyads.

Statistical Analysis

All statistical analyses were conducted using SAS 9.4 (SAS Institute Inc, Cary, NC). For demographics, adolescent age at baseline was dichotomized into 14–15-year-olds versus 16–17-year-olds. Adolescent report of their sexual history was dichotomized as those who

reported having no sexual contact beyond kissing and those who did. Adolescent and parent ethnicity was dichotomized into those who identified as being Hispanic/Latino versus those who did not. Adolescent and parent gender was dichotomized as female or male. Parent level of education was dichotomized as those who completed a high school education or higher and those who did not. Finally, adolescent and parent previous research participation (yes or no), and report of each adolescent's willingness to participate and each parent's willingness for their adolescent to participate was assessed using a 6-point Likert scale¹⁴ and dichotomized into agree versus disagree to capture change over time. Dyad discordance was defined by opposing WTP (e.g. adolescent agrees when parent disagrees).

For the first aim (retention), bivariate logistic regressions were used to determine if demographic characteristics (adolescent age, gender, parent ethnicity, parent education), adolescent and parent previous research participation, adolescent and parent individual willingness to participate and baseline dyad discordance were related to dyad retention. Those variables with a p-value of < 0.10 were considered candidates for a multivariable logistic model. The multivariable logistic model was built using stepwise forward selection with an entry and exclusion criteria of 0.05.

For the second aim (changes in individual WTP over time), willingness to participate was divided into those who remained the same (either agreed or disagreed) and those who changed over time. For the third aim (changes in dyad discordance about WTP), descriptive statistics were used to describe discordance and concordance between adolescents and their parents at one year. Dyads were recorded as being concordant at baseline (both adolescent and parent report agree or disagree) and remaining concordant (both agree or both disagree) or becoming discordant (adolescent agrees with parent that disagrees, or adolescent disagrees with parent that agrees) at follow-up. Dyads that were discordant at baseline were similarly recorded as remaining discordant at follow-up or becoming concordant. For both the second and third aim, McNemar's test statistic was used for the adolescents, for the parents and for the dyadic analyses. McNemar's accounts for the fact that the dyads are related (matches pairs of subjects) to detect change in WTP response over time that was not by chance alone. A two-sided significance level of 0.05 was used to determine statistical significance.

RESULTS

The overall adolescent sample at baseline (n = 301) had a mean age of 15.5 (range 14–17) years, 53% were 16–17 years old, 62% were female, 72% were Hispanic/Latino, 65% reported no sexual contact, and 87% had no prior research experience. The overall parent sample at baseline (n = 300) was mostly female (92%) and 71% of parents reported being of Hispanic/Latino ethnicity, 68% of parents completed high school or higher, and 74% had no prior research experience.

Retention After One Year

With regards to adolescent retention (n = 301), 45 adolescents were lost to follow-up, resulting in the retention of 256 adolescents; for parent retention (n = 300), 47 parents were lost to follow-up, resulting in the retention of 253 parents; for dyad retention (n = 300), a

total of 52 dyads were lost to follow-up, resulting in the retention of 248 dyads. There were 40 adolescent-parent dyads where neither member was retained. Other dyads not retained included 7 adolescents who returned without a parent, and 5 parents who returned without an adolescent. See Table 1 for characteristics of those dyads retained versus dyads not retained.

For those dyads who were retained, the median number of contacts was 4 (range = 1 - 21); the median number of contacts was 10 (range = 2 - 43) for those who were not retained. At baseline, adolescent contact information was obtained for 225 (75%) of the adolescents; older adolescents were more likely to have contact information (OR 1.89; 95% CI: 1.11 – 3.21). At follow-up, contact was made with only the parent (63%), with both the adolescent and parent (36%), and with only the adolescent (1%). When comparing parent-only contact versus contact with both the adolescent and the parent, those dyads where only the parent was contacted were more likely to be retained (OR 4.88; 95% CI: 2.57 – 9.26).

In bivariate analyses, adolescent female (OR 2.20; 95% CI: 1.20 – 4.02), younger adolescent age (OR 2.29; 95% CI: 1.21 – 4.33), parental Hispanic/Latino ethnicity (OR 3.06; 95% CI: 1.32 – 7.09), parent's level of education reported as completing high school or higher (OR 3.93; 95% CI: 1.41 – 10.93) and adolescent WTP at baseline (OR 0.51; 95% CI: 0.26–0.99) were all significantly related to dyad retention. The following variables were not significantly related to dyad retention: parent gender, adolescents' or parents' report of previous research experience, and parent WTP or dyad discordance at baseline. All the variables significant in the bivariate analysis except adolescent WTP at baseline remained significant in the final multivariable model (see Table 1).

Changes in WTP After One Year for Adolescents and Parents

Descriptive statistics were used to characterize changes in WTP after one year for the adolescents ($n = 256$) and parents ($n = 251$) who were retained at follow-up. Of the 256 adolescents retained at follow-up: at baseline 59% ($n = 150/256$) were willing to participate and 55% ($n = 142/256$) were willing to participate at follow-up [McNemar's: $S = 0.91$, $p = 0.34$]. Of the 251 parents retained at follow-up who answered the WTP question at both time points (one parent did not answer at baseline and a different parent did not answer at follow-up), 51% ($n = 127/251$) were willing to participate and 57% ($n = 143/251$) were willing to participate at follow-up. Based on a McNemar's test, this represents a significant difference [McNemar's: $S = 5.12$, $p = 0.02$].

Changes in WTP Discordance After One Year for Dyads

For dyadic analyses regarding WTP ($n = 246$ dyads), there was a shift towards concordance: 57% of dyads were concordant (in either direction) at baseline, and at follow-up 70% of dyads were concordant, which also means that fewer dyads (30%) were discordant at follow-up than at baseline (43%). Comparison of discordant versus concordant dyads from baseline to follow-up was statistically significant [McNemar's: $S = 10.56$, $p = 0.001$]. The many possible combinations of directions (discordant or concordant) that the dyad reached at one year are presented in Table 2.

DISCUSSION

Over the course of a year, we were able to retain a high percentage (83%) of adolescent-parent dyads. Perhaps not surprisingly, the dyads with younger adolescents and females were more likely to be retained, suggesting that novel strategies may be needed in studies that focus on older and male adolescents. From a developmental perspective,^{9,23} the goal in research is to honor adolescents' emerging autonomy, although it may be beneficial (and certainly was not a deterrent) to manage retention through partnering with parents. This is particularly the case when parents are already aware of the study or participating themselves, as was the case in this study.

Even though it is assumed that adolescents are personally experiencing rapid developmental changes, it was their parents (not the adolescents themselves) who reported greater willingness to participate over time. Perhaps, parents' perceptions of adolescents' increasing maturity may have had a bigger impact on their decision-making, or parents became more comfortable with the sexual health topic as their adolescent became older. Understanding why individual adolescents or parents were willing to participate alongside a benefit or value was beyond the scope of the current manuscript.

Adolescent-parent concordance is critical regardless of the direction because the final decision to participate or not should be a mutual decision. Both adolescent and parent should be comfortable with the decision and not feel coerced by the other.²⁴ In the context of a clinical trial in which the parent would need to provide permission for the adolescent to participate, our analysis of interviews at baseline shows that for the most part adolescent-parent conflict resolves quickly.²² The results of the current study demonstrate that adolescents and parents become more concordant in their WTP over time. Taken together, these findings, are consistent with developmental research that suggests that most adolescent-parent conflict is over every day mundane issues, and that serious conflict is rare.²⁵ This also suggests that when a dyad is not able to come to a resolution quickly,²² it may be wise to wait and offer them another opportunity at a later time, given the tendency to become concordant over time.

Strengths of this study include the one-year longitudinal follow-up and the high level of dyad retention. Limitations include the "artificial" setting since responses are based on WTP for a hypothetical trial. The lack of actual enrollment into a clinical trial may have altered the participants' responses. This study potentially accrued dyads who may be in less conflict given the fact that they jointly agreed to enroll in this study. Finally, the population in this study is primarily of Hispanic ethnicity; however, Hispanics are often underrepresented in clinical studies, thus this bias should be viewed as a strength and invite further work.

In summary, this study provides a unique glimpse into the retention of adolescents and parents in an interview study over the course of a year, and the changes in attitudes of adolescents, parents and adolescent-parent dyads about research participation. Developmental sensitivity and expertise is required of clinical trialists as they develop recruitment and retention strategies. Study coordinators should manage the complexity of

adolescent-parent dyadic relationships during recruitment and retention by maximizing adolescent autonomy while respecting the role of their parents in providing guidance.

Acknowledgments

Source of Funding: This research was supported by an R01 grant (Grant Number: 5R01HD067287), from the National Institutes of Health, awarded to Susan L. Rosenthal, Ph.D. and the National Center for Advancing Translational Sciences, National Institutes of Health (Grant Number: UL1 TR000040, UL1 TR000457). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

We would like to acknowledge the following research coordinators and post-doctoral fellow who helped with data collection and management: Gabriela Bisono, Noe Chavez, Lauren Dapena Fraiz, Sophia Ebel, Katharine Hargreaves, Lily Fuller Hoffman, Lisa Ipp and Camille Williams, and the clinic staff who helped with the recruitment of families. Findings of the study were presented as a poster presentation at the Society of Adolescent Health and Medicine conference in New Orleans, LA, in March 2017.

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Table 1

Characteristics of Dyads Retained versus Dyads Not Retained

Characteristics	Dyads Retained (n = 248) n, %	Dyads NOT Retained (n = 52) n, %	Bivariate OR (95% CI) p-value	Multivariable OR (95% CI) p-value
Adolescent Age (y)				
14–15 at baseline	125, 50%	16, 31%	OR 2.29 (1.21 – 4.33)	OR 2.37 (1.20 – 4.65)
16–17 at baseline	123, 50%	36, 69%	p = 0.01	p = 0.01
Adolescent Gender				
Female	162, 65%	24, 46%	OR 2.20 (1.20 – 4.02)	OR 2.65 (1.39 – 5.04)
Male	86, 35%	28, 54%	p = 0.01	p = 0.003
Adolescent reports no previous research experience at baseline	213, 86%	49, 94%	OR 2.68 (0.79 – 9.08) p = 0.11	N/A
Adolescent reports willingness to participate at baseline	144, 58%	38, 73%	OR 0.51 (0.26 – 0.99) p = 0.047	N/A
Parent is Hispanic/Latino	168, 68%	45, 86%	OR 3.06 (1.32 – 7.09) p = 0.01	OR 2.87 (1.20 – 6.86) p = 0.02
Parent Gender				
Female	229, 92%	47, 90%	OR 1.28 (0.46 – 3.61)	N/A
Male	19, 8%	5, 10%	p = 0.64	
Parent's Education (completed high school or higher)	178, 72%	27, 52%	OR 3.93 (1.41 – 10.93) p = 0.01	OR 4.26 (1.48 – 12.25) p = 0.01
Parent reports no previous research experience at baseline [^]	184, 74%	36, 71%	OR 0.84 (0.43 – 1.63) p = 0.60	N/A
Parent reports willingness to participate at baseline [^]	123, 50%	32, 62%	OR 0.62 (0.34–1.14) p = 0.13	N/A
Dyad Discordance at Baseline [^]	106, 43%	26, 50%	OR 1.33 (0.73–2.42) p = 0.35	N/A

[^] One parent did not answer question at baseline

Table 2

Dyad's Baseline WTP Agreement Status and Direction of WTP Agreement Status at Follow-up Sorted by Initial Dyad Pairing

Baseline Dyad	n = 246 [^] (100%)	Follow-up Dyad	n = 246 [^] (100%)
Concordant: YES	80 (33%)	Concordant: YES	64 (80%)
		Concordant: NO	2 (3%)
		Discordant: Adol Yes	4 (5%)
		Discordant: Parent Yes	10 (12%)
Concordant: NO	60 (24%)	Concordant: YES	4 (7%)
		Concordant: NO	40 (67%)
		Discordant: Adol Yes	11 (18%)
		Discordant: Parent Yes	5 (8%)
Discordant: Adolescent Yes	63 (26%)	Concordant: YES	17 (27%)
		Concordant: NO	19 (30%)
		Discordant: Adol Yes	20 (32%)
		Discordant: Parent Yes	7 (11%)
Discordant: Parent Yes	43 (17%)	Concordant: YES	15 (35%)
		Concordant: NO	10 (23%)
		Discordant: Adol Yes	1 (2%)
		Discordant: Parent Yes	17 (40%)

WTP = willingness to participate, Adol = adolescent

YES = agrees to participate, NO = disagrees to participation

[^] One parent did not answer at baseline and a different parent did not answer at follow-up