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Adolescents' and Parents' Attitudes Toward Adolescent Clinical Trial Participation: Changes Over One Year

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Introduction

Enrolling adolescents under 18 years of age in early phase clinical trials typically requires adolescent assent and parental permission, as such studies involve more than minimal risk (Santelli et al., 2003). Communication with adolescents and parents about potential enrollment will need to account for their differing perspectives and approaches to clinical trials (Annett, Brody, Scherer, & Perket, 2004; Brody, Annett, Scherer, Perryman, & Cofrin, 2005; Brody, Annett, Scherer, Turner, & Dalen, 2009; Brody, Scherer, Annett, & Pearson-Bish, 2003; Wendler, Abdoler, Wiener, & Grady, 2012) as well as respect adolescents' right to confidentiality (Caskey & Rosenthal, 2005; Flicker & Guta, 2008). Given the complexities of working with adolescents and their parents, there is a tendency to exclude minors from clinical trials (Hoffman et al., 2016; Schenk et al., 2014). However, as adolescence is marked by rapid physical and psychological changes, including adolescents in research is critical to ensure that investigational products are safe and appropriate for their use (Short, Succop, Ugueto, & Rosenthal, 2007; Tanner, Short, Zimet, & Rosenthal, 2009).

These same rapid developmental changes may lead to changes over time in adolescents' and their parents' perspectives on clinical trial participation. Depending on trial size and design factors, screening and enrollment periods typically will extend from a few months to a few years, providing ample time for potential participants to be re-approached. Yet, little is known about whether and how attitudes about clinical trials may evolve over time,

particularly when they are focused on a topic such as sexual health. Attitudes about sexual health trials may be particularly subject to change, given that, for adolescents, new sexual behaviors and attitudes are emerging during this developmental period.

Thus, in this hypothesis-generating study, we sought to examine how adolescents' and parents' thoughts about a clinical trial focused on reproductive health may change over a one-year period of time. We chose to present a hypothetical phase I safety study for a microbicide to prevent sexually transmitted infections (STIs) in order to capture the attitudes of healthy adolescents and their parents about a primary prevention trial for which there is no direct benefit. The information obtained about how adolescents' and parents' attitudes about a trial change over a year may inform the development of strategies to facilitate adolescent enrollment in future clinical trials.

Methods

Participants

Adolescents (14–17 years of age at baseline) and their parent and/or legal guardian were recruited into a longitudinal study requiring participation at baseline and follow up after one year on willingness to participate (WTP) in a hypothetical clinical trial investigating the safety and tolerability of a topical microbicide gel for STI prevention. Participants were recruited from two adolescent medicine clinics in New York City and through snowball sampling, in which enrolled participants referred acquaintances into the study. Criteria for inclusion in the longitudinal study were that adolescents were 14–17 years of age, adolescents and parents spoke English or Spanish, and both adolescent and parent members of the dyad provided informed assent/consent to participate. The study and the participants have been described previously (Catallozzi et al., 2017; Chávez et al., 2016; Francis et al., 2016; Francis et al., 2017; Francis et al., 2018; Rosenthal et al., 2016). The study was approved by the Institutional Review Boards.

Procedures

Trained members of the study team interviewed adolescents and their parents separately in English or Spanish. As part of the interview, participants were read an informed consent form for a hypothetical phase I randomized controlled trial testing the safety of a topical microbicide gel. Key elements of the study (e.g., use of gel for 7 days, sexual abstinence, blood draws, colposcopy for females, and genital photographs for males) and requirements for participation were included, and adolescents and parents were told that the product had been found safe in adult women. WTP for this hypothetical study was measured quantitatively at baseline and one year later using a 6-point Likert scale, with (1) representing strongly disagree and (6) representing strongly agree. Without being reminded of their WTP response from the year before, each participant was asked at the one-year follow-up visit, **“How do you think your thoughts about the study have changed over the past year? How are they the same or different?”** Responses were recorded manually by a research assistant in the language spoken, with Spanish responses translated into English for analysis. The present analysis focuses only on qualitative data in response to the above question.

Analysis

Adolescent and parent responses were grouped into four categories: (1) those who reported that their thoughts had not changed; (2) those who reported that their thoughts had changed; (3) those who reported that they did not know or remember if their thoughts had changed; and (4) those who reported that they assumed their thoughts had not changed but were unsure. Using a chi square analysis, separate contingency tables were constructed for adolescents and parents to describe associations between demographic characteristics and the perception that thoughts had changed (SAS Institute Inc., Version 9.4, Cary, NC, © 2013). In addition, in order to evaluate whether the frequency of perceived changes in thinking varied between adolescents and parents, a McNemar's test was used to adjust for the dyadic relationship.

Among those who stated that their thoughts had not changed, some provided further commentary on their thinking, which included either re-stating how their thinking had remained similar or providing a potential scenario that could lead to their thoughts changing. The responses of those who reported that their thoughts had changed, or provided a scenario in which their thoughts could have changed, were analyzed using framework analysis, in which the research team reviewed the responses and developed a coding system to organize the data into thematic categories (Ritchie & Lewis, 2003). Two members of the research team independently coded each response, and discrepancies in the assignment of initial codes were reviewed by a third member of the research team and resolved through discussion.

It was evident that one could have a change in thinking without a change in WTP. Thus, responses were further coded to reflect whether they clearly indicated a change in WTP, clearly indicated no change in WTP, or were silent on changes in WTP. Given the analytic focus on how thoughts about WTP may change over time qualitatively and the articulated reasons underlying that change, a decision was made to not compare the qualitative responses to the quantitative WTP ratings.

Results

Study Sample

Three hundred and forty-three adolescent-parent dyads were enrolled at baseline. One dyad withdrew from the study after the initial interview and two were enrolled twice. Of the remaining 340 dyads, 39 dyads were removed for the purposes of analysis because they included adolescents who were siblings of a previously enrolled dyad. Thus, there were 301 adolescent-parent dyads that represented unique families (Catallozzi et al., 2017). The adolescents and parents of these 301 dyads who returned for follow up constitute the sample for the present analysis. At follow up, 248 dyads returned, 7 adolescents returned without their parent, and 5 parents returned without their adolescent. An additional adolescent returned with a different parent, so only the adolescent was retained. Thus, the current analysis is comprised of 248 dyads, 256 individual adolescents, and 253 individual parents. Of note, dyads comprised of adolescents who were female or 14–15 years old at baseline were more likely to be retained than those comprised of adolescents who were male or 16–

17 years old at baseline (Francis et al., in press). Willingness to participate at baseline was not associated with dyad retention (Francis et al., in press).

At enrollment, the adolescents were between 14–17 years of age with a mean age of 15.5 years. At follow up, the mean age of the adolescents was 16.5 years, and 24% of the adolescents were 18–19 years of age. The adolescents were mostly female (64%) and Hispanic/Latino (69%). The parents were mostly female (92%) and Hispanic/Latino (68%). Seventy-one percent of parents completed high school or more.

Changes in Thoughts

Of all of the adolescents who returned ($n = 256$), over half (58%) perceived that their thoughts about the study had not changed, approximately one-third (32%) did report a change in their thinking, 6% did not remember if their thoughts had changed, and 3% assumed that their thoughts had not changed but were not certain. Of all of the parents who returned ($n = 253$), most (77%) reported no change in their thinking about the study, 18% stated that their thoughts had changed, and 5% could not remember if their thoughts had changed. No parent reported that they assumed their thoughts had not changed. For the purposes of analysis, adolescents who assumed their thoughts had not changed were combined with adolescents who reported that their thoughts had not changed.

Among adolescents, there were no significant associations between changes in thoughts and Hispanic/Latino ethnicity ($\chi^2 = 0.60$, $p = 0.74$), gender ($\chi^2 = 1.36$, $p = 0.51$), or age at baseline, which was treated categorically ($\chi^2 = 4.16$, $p = 0.12$). Among parents, there were no significant associations between changes in thoughts and the parent's Hispanic/Latino ethnicity ($\chi^2 = 2.00$, $p = 0.37$), adolescent's gender ($\chi^2 = 0.24$, $p = 0.88$), or adolescent's age at baseline ($\chi^2 = 0.71$, $p = 0.70$).

To evaluate whether the frequency of thoughts changing varied between adolescents and parents, the data were further collapsed into two groups: those who perceived that their thoughts had changed and those who perceived that their thoughts had not changed or did not remember. This analysis was limited to the 248 adolescent-parent dyads. A McNemar's test for paired binary data demonstrated a significant difference in thoughts changing between adolescents and parents ($S = 12.96$, $p = 0.0003$); 33% of adolescents reported that their thoughts had changed as compared to 18% of parents.

Changes in WTP

Among adolescents and parents who reported changes in their thinking, 45% of adolescents and 64% of parents also reported a change in their WTP. For example, one mother of a 17-year-old male answered:

“I think last time I strongly disagreed and now I'm [sic] mildly agree. I guess in the beginning my reaction was just like 'no, no, no.' But now reading it over I'm not so adamantly disagreeing because I'm used to the idea. And also, because I know he's sexually active.”

Notably, the majority of both adolescents and parents who reported a change in their WTP conveyed a greater inclination to be involved in the study. Some adolescents (13%) and few

parents (2%) reported a change in thinking while clearly indicating that they did not have a change in WTP. For example, one 16-year-old female stated, *“I think I said I wouldn’t do it because of the pelvic exam. Now I’m worried about something else.”* Many adolescents (42%) and parents (33%) who reported a change in their thinking did not comment on their WTP, such as the 18-year-old female who said, *“I think this study is more important than I thought it was last year.”* It is possible that she thought the study was more important without necessarily being more willing to participate.

Reasons for Change

Participants described changes in their thoughts about the study due to a) a change in their general perception of the study; b) a clearer understanding of the study without new information; c) new knowledge; d) new experiences; e) increased maturity or age of the adolescent; or f) changes in the participant independent of the study. When acknowledging the increased maturity or age of the adolescent, some also described a change in the adolescent-parent dynamic. In some cases, participant responses were assigned more than one code.

Change in perception—Adolescents and parents frequently reported that they simply felt differently about the study. For example, the mother of an 18-year-old female stated, *“last year I was more negative/against the study. Today I’m a little more positive about the study.”* Additionally, an 18-year-old male commented, *“last year I was open to it, but I changed from yes to no because I am not as excited to be one of the first ones to try it.”* In both of these cases, the participants indicated that their perception of the study had changed without an explanation as to what led to that change in perception.

Clearer understanding without new information—Some adolescents and a few parents mentioned that they now understood the study more clearly. Sometimes, the participants did not clarify what led to the improved comprehension, such as the mother of a 16-year-old female who said, *“I understand it more. Before I didn’t understand what they were saying.”* In other cases, both adolescents and parents indicated that hearing the information for a second time changed their understanding; one 15-year-old female stated, *“I think I understand it more now that it’s been re-explained.”* Adolescents, unlike parents, sometimes explicitly indicated that they had paid more attention. For these adolescents, paying greater attention often led to a change in understanding. For example, one 16-year-old male commented, *“before I didn’t pay attention to what it was about, but now I understand more what it’s about.”* Another adolescent, an 18-year-old female, mentioned a situational distraction that impacted her ability to attend to the study, and in turn, her willingness to participate. As she described:

“Last year I didn’t want to do it, I didn’t understand. Last year I wasn’t really listening. I was in a fight with my aunt that day. Now I know what’s going on, I would do it.”

New knowledge—Several adolescents and parents stated that they thought about the study differently because they had obtained new knowledge that they had applied to their decision-making. This new knowledge came from family, school, or other sources. Sometimes, this

information was initially available to the participants but had newly influenced their thinking. With respect to gaining new knowledge, one 15-year-old female stated:

“It changed a lot cause when I first heard I was young and I didn’t know about HIV and I didn’t care. Now in high school I’ve learned about it so I want to get as much help as I can get.”

Additionally, the mother of an 18-year-old male described:

“I would say now I think it’s more important to do because of these kids having sex on the hotel roof - these kids just don’t think because I have no idea what he’s up to.”

New experiences—Both adolescents and parents reported that new experiences influenced their thinking about the study. For the adolescents, new experiences (i.e. sexual activity, contracting a disease or infection, or undergoing tests and procedures) over the past year had allowed them to view the study differently. For example, one 16-year-old female explained:

“It changed just because I got the yeast infection, last year I was just nervous about it, now I have an actual reason.”

Parents also reported that new experiences for either themselves or their adolescent had led to a change in their thoughts. One father of a 17-year-old female, reflecting upon his own experiences, stated, *“I know different things and experiences that’s going on because I’ve participated myself in research.”* Further commenting on the ways in which the sexual experiences of adolescents can affect perceptions of the study, the mother of a 19-year-old female reported, *“they’ve changed in that I didn’t want her to before because she wasn’t sexually active, but now she is.”*

Increased maturity/age—Some adolescents and parents reported viewing the study differently secondary to the adolescent being more mature or older. For example, one 17-year-old male mentioned, *“I guess I’m more hesitant to do it because I realize how badly it could go wrong. Basically I’ve matured more.”*

For both adolescents and parents, this added maturity sometimes included a change in the adolescent-parent dynamic. Reflecting on the maturity of her 15-year-old daughter, one mother mentioned:

“I think the difference is she’s older and I’m more inclined to listen to what she wants to do. If she’s 16 or 17 and she wants to do it, then I know her brain’s a little more developed and she can be making these decisions.”

An adolescent female, who was 18 years of age by the second visit, additionally mentioned:

“Before I wasn’t really open to the idea at all, and my mother’s opinion influenced me. But now I think about it and it’s like this study could help scientists make something important.”

While the mother above viewed a change independent of legal status, occasionally adolescents and parents did specifically mention legal status. For example, one 18-year-old

female stated that her thoughts had changed *“because I’m 18 and I want to start making decisions for myself.”* Additionally, the mother of an 18-year-old male commented upon her thoughts as follows:

“Thoughts are different, because the information now is more open. Also, he is now 18. I would support him. I think it’s something good.”

Change within the participant—A few adolescents and parents commented on a change that had occurred that was independent of the study but that had, in turn, influenced their thoughts about the study. Commenting on a change in his personality, one 17-year-old male reported, *“I feel like I’d be more willing to do it now cause last year I was more shy but now I’m more open to doing things.”* Additionally, the mother of a 16-year-old male commented upon a change in her ability to communicate with her son, stating, *“I have learned more about how to talk to my son and about how to prevent and the risks of sex.”*

Discussion

There has been limited research on how adolescents’ and parents’ thinking about clinical trials changes over time, despite the potential for researchers to provide adolescents with multiple opportunities to participate over the duration of the enrollment period. Participants could be offered multiple opportunities to participate for a variety of reasons—for example, if they newly meet enrollment requirements or no longer meet exclusionary requirements. This study is unique in that it followed both adolescents and their parents over a one-year period. Our results suggest that while most adolescents and parents viewed their thinking about clinical trial participation as relatively stable, a substantial number perceived that their thoughts had changed over the span of a year. More adolescents than parents perceived that their thinking had changed, which is not surprising in the context of a reproductive health trial given the rapid accumulation of experiences and maturation that characterizes adolescence.

The majority of participants whose thoughts changed did not indicate clearly whether this led to a change in WTP, although some participants explicitly stated that their WTP did not change. Among those who did report that their WTP had changed at follow up, the majority of adolescents and parents demonstrated greater (as opposed to lesser) willingness to participate in the study. Whether or not there was a change in WTP, our results suggest that participants may benefit from learning about a study on more than one occasion. The opportunity to hear about the study a second time contributed to improved understanding in both adolescents and parents. Parents reported focusing on information that they had missed the first time, and adolescents appeared vulnerable to distractions. The finding that adolescents appeared more susceptible than parents to the impact of attention is not surprising given that some subsystems of attention are not fully developed until the age of 25 (Diamond, 2006; Rueda, Rothbart, McCandliss, Saccomanno, & Posner, 2005). Additionally, the acquisition of new experiences and knowledge motivated a change in thinking for adolescents and parents alike—particularly when the participants had gained knowledge about STIs or the adolescents had become sexually active over the course of the one-year interval. Of note, nationally, the proportion of adolescents who have had

intercourse nearly doubles from approximately 20% at the age of 15.5 to 40% by the age of 16.5 (Abma & Martinez, 2017).

As is always the case in research with limited or no direct benefit to the participant, it is important to consider the risk of preventative or therapeutic misconception: the failure to appreciate the distinction between research and treatment, which may lead participants to inaccurately attribute therapeutic intent to research procedures (Henderson et al., 2007). Some of the adolescents' responses cited above reflect this concept; for example, one 15-year-old female stated, *"now in high school I've learned about it so I want to get as much help as I can get."* It is possible that this young person now believes that there is potential for direct benefit from study participation. Accordingly, as adolescents mature and acquire new knowledge, is necessary for researchers to continue to reinforce the difference between individual and societal benefit during the informed consent process.

There has been a significant amount of research on the impact of legal status on adolescent participation in clinical trials (Bruce, Berg, & McGuire, 2009; Flicker & Guta, 2008; Moore, Paul, McGuire, & Majumder, 2016; Rosenthal, Morris, Hoffman, & Zimet, in press). Although legal status appeared to shape the thinking of some of our participants, more commonly, they described a maturation process that was independent of the adolescents' status as minors. This maturation process often referenced age but in some cases was related to perceived changes in personality or to changes in the dynamic between adolescents and parents. Accordingly, it appears that adolescents may be more willing to participate in clinical trials and that parents may be willing to grant adolescents more autonomy, simply as a function of increasing age or the passage of time.

This study has several limitations. First, study recruitment was limited to a single geographic location, and the majority of participants identified as Hispanic/Latino. Importantly, however, Hispanic/Latinos have historically been underrepresented in clinical studies (Murthy, Krumboltz, & Gross, 2004); thus, our data may take on particular importance. Second, participants were asked how their thoughts about the hypothetical trial had changed since the last time, but not about how their WTP had changed. While it is therefore difficult to draw conclusions about how changes in thoughts or perceptions about the study influenced participants' WTP, our study did provide a window into their thoughts. Third, our results seemed to suggest that participants should have more than a single opportunity to learn about a study and consider whether to participate; however, we did not determine the optimal time period in which to re-introduce the study. Fourth, we specifically focused on an early phase prevention trial for healthy adolescents. Accordingly, the results of this study may not generalize to the context of intervention or treatment trials. Finally, the participants were asked to consider participation in a hypothetical clinical trial; it is unknown whether participants' responses would have differed if they were asked to consider participation in an actual clinical trial that was open to enrollment.

Best Practices

Our study has important implications for investigators seeking to enroll adolescents in clinical trials. Enrolling adolescents in trials that necessitate adolescent assent and parental

permission requires skilled communication that simultaneously accounts for several factors: a) adolescents' status as a vulnerable population (US Department of Health and Human Services, 45CFR46 Subpart D, 2009); b) differences in adolescents' and parents' approaches to risk and decision-making (Annett et al., 2004; Brody et al., 2005; Brody et al., 2009; Brody et al., 2003; Wendler et al., 2012); and c) the potential for the process of maturation to change the perceptions of some adolescents and parents. The reasons provided by adolescents and parents as to how their thoughts had changed over time suggest that more could be done during the initial informed consent process to ensure attention and accurate comprehension among participants. Thus, upon initial approach, investigators should be sensitive to the context or setting in which communication about the study is occurring. In a clinic waiting room or exam room, participants' susceptibility to distraction and limited attention spans could influence their understanding of the study. In these instances, it may be appropriate to not only check in with participants to determine their level of understanding but also ask the adolescent and/or parent if they would like to return to discuss the study at a different time. Another strategy could involve deliberately asking both adolescents and parents what, if anything, would alter their WTP. This strategy would allow investigators to check participants' understanding and/or potentially identify an appropriate time to re-approach the dyad based on the likelihood that adolescents have matured and/or conditions have changed, while still honoring participants' autonomy in the decision-making process. Importantly, these strategies may facilitate recruitment of adolescents into clinical trials, and in turn ensure successful completion of trials that ultimately will lead to evidence-based advances that protect the health of adolescents.

Research Agenda

As this study was focused on a prevention trial concerning reproductive health, future research should examine how thoughts about participating in other types of prevention trials as well as in treatment studies change over time. Additionally, future studies should be undertaken in different populations, including other racial and ethnic minorities. Since this study was conducted over the course of one year, researchers should also evaluate the extent to which thoughts change over longer or shorter intervals and the optimal manner in which to re-approach adolescents and parents. Re-offering participation to them may present an opportunity to increase enrollment; however, the intent should not be to undermine or disregard their initial decisions. Finally, such investigations should examine how participants perceive being re-approached about participation at a later point in time, as well as the impact of efforts to assure that participants are attending to the information presented in the study.

Educational Implications

The results of this study have key implications for the training of research staff. First, when designing and implementing studies that involve adolescents, it is important for all staff to receive training in adolescent development. Such training should include education about the rapid cognitive changes that occur during adolescence, the evolution of the adolescent-parent dynamic over time, and the new experiences during adolescence that lead to changes in knowledge and attitudes. Second, staff should be sensitized to the possibility that

participants may be distracted during the study and may benefit from repetition of pertinent information or the option to return at a later point. Thus, trainings should include information about how to offer participation while ensuring full comprehension of the study and preventing therapeutic misconception during the informed consent process. Finally, staff should be trained to develop strategies for conveying information that are tailored to adolescents' and parents' individual needs. Enhancing the training of research staff in these ways, particularly for studies that require engagement on the part of both adolescents and parents, may allow researchers to more sensitively and effectively enroll adolescents in relevant clinical trials.

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References

- Abma JC, & Martinez GM (2017). Sexual activity and contraceptive use among teenagers in the United States, 2011–2015. *National Health Statistics Reports*, 104, 1–23.
- Annett RD, Brody JL, Scherer DG, & Perkett EA (2004). Perception of risk associated with asthma research procedures among adolescents, parents, and pediatricians. *Journal of Allergy and Clinical Immunology*, 114, 1138–1145. [PubMed: 15536422]
- Brody JL, Annett RD, Scherer DG, Perryman ML, & Cofrin KM (2005). Comparisons of adolescent and parent willingness to participate in minimal and above-minimal risk pediatric asthma research protocols. *Journal of Adolescent Health*, 37, 229–235. [PubMed: 16109343]
- Brody JL, Annett RD, Scherer DG, Turner C, & Dalen J (2009). Enrolling adolescents in asthma research: Adolescent, parent, and physician influence in the decision-making process. *Journal of Asthma*, 46, 492–497. [PubMed: 19544171]
- Brody JL, Scherer DG, Annett RD, & Pearson-Bish M (2003). Voluntary assent in biomedical research with adolescents: A comparison of parent and adolescent views. *Ethics & Behavior*, 13, 79–95. [PubMed: 14552306]
- Bruce CR, Berg SL, & McGuire AL (2009). Please don't call my mom: Pediatric consent and confidentiality. *Clinical Pediatrics*, 48, 243–246. [PubMed: 19074356]
- Caskey JD, & Rosenthal SL (2005). Conducting research on sensitive topics with adolescents: Ethical and developmental considerations. *Journal of Developmental and Behavioral Pediatrics*, 26, 61–67. [PubMed: 15718886]
- Catallozzi M, de Roche AM, Hu MC, Breitkopf CR, Chang J, Ipp LS, . . . Rosenthal SL (2017). Adolescent and parent willingness to participate in microbicide safety studies. *Journal of Pediatric and Adolescent Gynecology*, 30, 82–87. [PubMed: 27381236]
- Chávez NR, Williams CY, Ipp LS, Catallozzi M, Rosenthal SL, & Breitkopf CR (2016). Altruistic reasoning in adolescent-parent dyads considering participation in a hypothetical sexual health clinical trial for adolescents. *Research Ethics*, 12, 68–79. [PubMed: 27019669]
- Diamond A (2006). The early development of executive functions. In Bialystok E & Craik FIM (Eds.), *Lifespan Cognition: Mechanisms of Change* (pp. 70–95). New York, NY: Oxford University Press.
- Flicker S, & Guta A (2008). Ethical approaches to adolescent participation in sexual health research. *Journal of Adolescent Health*, 42, 3–10. [PubMed: 18155024]
- Francis JK, Hoffman LF, Hu MC, de Roche AM, Catallozzi M, Breitkopf CR, & Rosenthal SL (2016). Adolescents and their parents differ on descriptions of a reproductive health study. *Journal of Pediatric and Adolescent Gynecology*, 29, 240–245. [PubMed: 26409154]

- Francis JKR, Fraiz LD, Catallozzi M, deRoche AM, Mauro C, & Rosenthal SL (2017). Pregnant young women's attitudes about microbicides: The anticipated influence of the grandmother and father of the baby on microbicide use. *Sexual Health*, 14, 581–583. [PubMed: 28514991]
- Francis JKR, Fraiz LD, de Roche AM, Catallozzi M, Radecki Breitkopf C, & Rosenthal SL (2018). Management of adolescent-parent dyads' discordance for willingness to participate in a reproductive health clinical trial. *Journal of Empirical Research on Human Research Ethics*, 13, 42–49. [PubMed: 29226745]
- Francis JKR, de Roche AM, Mauro C, Landers SE, Chang J, Catallozzi M, ... Rosenthal SL (in press). Adolescent-parent dyadic retention in an interview study and changes in willingness to participate in a hypothetical microbicide safety study. *Journal of Pediatric and Adolescent Gynecology*.
- Henderson GE, Churchill LR, Davis AM, Easter MM, Grady C, Joffe S, . . . Zimmer CR (2007). Clinical Trials and Medical Care: Defining the Therapeutic Misconception. *PLoS Medicine*, 4, e324. [PubMed: 18044980]
- Hoffman LF, Francis NK, Catallozzi M, Francis JK, Stanberry LR, & Rosenthal SL (2016). Inclusion of adolescents in clinical trials for sexually transmitted infections: A review of existing registered studies. *Journal of Adolescent Health*, 58, 576–578. [PubMed: 26976148]
- Moore QL, Paul ME, McGuire AL, & Majumder MA (2016). Legal barriers to adolescent participation in research about HIV and other sexually transmitted infections. *American Journal of Public Health*, 106, 40–44. [PubMed: 26562103]
- Murthy VH, Krumholz HM, & Gross CP (2004). Participation in cancer clinical trials: Race-, sex-, and age-based disparities. *Journal of the American Medical Association*, 291, 2720–2726. [PubMed: 15187053]
- Pipher MB (1994). *Reviving Ophelia: Saving the selves of adolescent girls*. New York, NY: Putnam.
- Ritchie J, & Lewis J (2003). *Qualitative research practice: A guide for social science students and researchers*. Thousand Oaks, CA: Sage.
- Rosenthal SL, de Roche AM, Catallozzi M, Breitkopf CR, Ipp LS, Chang J, . . . Hu MC (2016). Parents' and adolescents' attitudes about parental involvement in clinical research. *Journal of Pediatric and Adolescent Gynecology*, 29, 372–377. [PubMed: 26820441]
- Rosenthal SL, Morris MC, Hoffman LF, & Zimet GD (in press). Inclusion of adolescents in STI/HIV biomedical prevention trials: Autonomy, decision-making, and parental involvement. *Clinical Practice in Pediatric Psychology*.
- Rueda MR, Rothbart MK, McCandliss BD, Saccomanno L, & Posner MI (2005). Training, maturation, and genetic influences on the development of executive attention. *Proceedings of the National Academy of Sciences of the United States of America*, 102, 14931–14936. [PubMed: 16192352]
- Santelli JS, Smith Rogers A, Rosenfeld WD, DuRant RH, Dubler N, Morreale M, . . . Society for Adolescent Medicine. (2003). Guidelines for adolescent health research: A position paper of the Society for Adolescent Medicine. *Journal of Adolescent Health*, 33, 396–409. [PubMed: 14596961]
- Schenk KD, Friedland BA, Chau M, Stoner M, Plagianos MG, Skoler-Karpoft S, . . . Ngcozela N (2014). Enrollment of adolescents aged 16–17 years old in microbicide trials: An evidence-based approach. *Journal of Adolescent Health*, 54, 654–662. [PubMed: 24690188]
- Short MB, Mills LC, & Rosenthal SL (2006). When adolescent girls say, "I don't know". *Journal of Pediatric and Adolescent Gynecology*, 19, 267–270. [PubMed: 16873030]
- Short MB, Succop PA, Ugueto AM, & Rosenthal SL (2007). Predictors of using a microbicide-like product among adolescent girls. *Journal of Adolescent Health*, 41, 357–362. [PubMed: 17875461]
- Tanner AE, Short MB, Zimet GD, & Rosenthal SL (2009). Research on adolescents and microbicides: A review. *Journal of Pediatric and Adolescent Gynecology*, 22, 285–291. [PubMed: 19616456]
- US Department of Health and Human Services. (2009). *Code of Federal Regulations* (45 CFR 46 subpart D). Retrieved from <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
- Wendler D, Abdoler E, Wiener L, & Grady C (2012). Views of adolescents and parents on pediatric research without the potential for clinical benefit. *Pediatrics*, 130, 692–699. [PubMed: 22966027]