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Original Studies

Participation of Adolescent Girls in a Study of Sexual Behaviors: Balancing Autonomy and Parental Involvement

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Abstract. *Study Objective:* The process of research with adolescents should balance parental involvement and adolescent autonomy. The attendance of parents and peers at research study visits of girls participating in a 6-month study of topical microbicide acceptability is described, as well as the participants' conversations with their parents.

Methods: Girls, 14 through 21 years, were recruited from previous studies (3%), advertisements (14%), clinics (17%), and recommendations by friends (66%) to participate. Girls under 18 years were required to have parental consent, but parents could provide verbal phone consent as long as a signed consent form was returned before participation.

Results: The 208 participants were 41% African-American, 30% Hispanic, and 29% Caucasian. Girls averaged 18 years of age, and 95 (46%) were under 18. Seventeen percent of parents attended the first visit; only 1 parent attended with a daughter older than 18 years of age. The mothers of older adolescents were less likely to attend the appointment with them. More Caucasian than African-American girls came with a mother. Parental attendance decreased at follow-up visits. Thirty-seven percent of girls brought a peer to the first visit; there were no age or race/ethnic differences. There was no relationship between attending with a parent or peer and talking to a parent about the study. Some adolescents obtained parental consent to participate in the study while keeping their sexual behaviors private.

Conclusions: Parental attendance at study visits may not be marker of parental involvement with the study. Creative ways for balancing concerns about confidentiality, promotion of autonomy, and adult involvement should be considered.

Key Words. Research participation—Adolescent girls—Parents—Communication

Introduction

Adolescents should have the opportunity to participate in and benefit from research that is relevant to their health concerns, including studies on ''sensitive subjects'' such as sexually transmitted infections (STI).[1,2] Inclusion of adolescents in such studies is consistent with the Belmont Report principles of respect for person, justice, and beneficence. Further, girls should have the a part in decision-making, of whether or not to participate in studies and should be protected from exploitation and harm.[3] Yet, because adolescence is the transitional stage from the dependency of childhood to the autonomy of adulthood, adult guidance in decision-making remains important.[4] Parents and health care providers have a responsibility to help adolescents transition to adulthood by providing them opportunities to be autonomous and use their most advanced cognitive skills while making sure that this is done safely. This can be challenging because the maturation process is gradual and within any one adolescent, and across individuals, there may be unevenness across areas of development based on experiences. Decisions as to how to balance parental involvement and adolescent autonomy will impact the practicalities of methods for enhancing adolescents' participation in research. In this manuscript, we describe our experience with parental and peer attendance at study visits and its'

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relationship with parental communication about the study for adolescents participating in a microbicide acceptability study.

Methods

Adolescents (ages 14 through 21 years) were recruited to participate in a 6-month study of experiences of adolescent girls with a topical microbicide surrogate.[5] Topical microbicides are products (gels/creams) which would be used intravaginally to protect against STIs and possibly pregnancy. Microbicides are currently in clinical development but the products used in this study were over the counter vaginal lubricants available in stores (a gel-filled applicator—Replens® Vaginal Moisturizer [Warner Wellcome, Morris Plains, NJ], and a suppository— Lubrin® Insert [Bradley Pharmaceuticals, Fairfield, NJ]).

Participants were recruited from previous studies (3%), advertisements (14%), clinics (17%), and through snowballing (66%). Snowball recruitment (i.e., having friends recommend other friends to the study) was included because a purpose of the primary study was to examine the influence of friends on microbicide attitudes and beliefs. In order to be in the study, the adolescent girls needed to have a history of penile-vaginal sexual intercourse at least once; however, they did not have to plan to have intercourse during the study period.

Those under 18 years were required to have parental consent to participate. Parents were given a brief description of the study with permission sought to talk to their daughter. The study was explained to the adolescents in detail. If the adolescent was under 18 years, this included explaining to the adolescent that although her sexual experience status would not be disclosed to her parents, her parents might assume she was sexually experienced, since the study consent form required her ''to use a vaginal product in the context of romantic relationships'' and that participants would ''strongly be encouraged to use condoms if engaging in sexual activity.''

Participants under 18 were allowed to bring in a witnessed signed consent form if a parent did not accompany them to the first research visit. The method for accomplishing this was that the research coordinator described the study over the phone to the parent. If the research coordinator had any concerns about whether the parent understood the study process, she then had an option of requiring parental attendance. Records were kept of whether the participants attended each of their research visits with a parent figure (''mother'') or a peer, but no records were kept regarding required parental attendance. Nevertheless, this was estimated to have occurred only once or twice across subject recruitment.

Girls had 3 face-to-face interviews at the hospital research center (intake, 3, and 6 months). The interviewer asked whether the adolescent had spoken to friends and to parents about the study. The girls also were called weekly to discuss their sexual experiences and product use over the prior week. At the 3-month visit, they were asked ''Have you talked about the study or the product with your mother or parent figure or has your mother or parent figure asked you about the study?'' If they said yes, they were asked, ''Tell me what you told them regarding the study,'' and if they said no, they were asked, ''Why not?'' For seven girls who missed the 3-month interview, we examined their responses to the same question at the 6-month interview.

Statistical Methods

Quantitative. We ran descriptive statistics on demographic information (age, race/ethnicity), whether subjects had talked to their parents about the study, and whether parents or peers attended each study visit. Further, we examined the extent to which age, race/ethnicity and study discussion with parents influenced parental attendance at each study visit. Race/ethnicity was categorized as African-American, Hispanic, and Non-Hispanic Caucasian/Other. Chi-square analyses were used to assess whether age and race/ethnicity were associated with having a mother come to a study visit. However, since only one girl over the age of 18 had a mother in attendance at any study visit, some analyses were confined to those less than 18 years of age.

Qualitative. To analyze girls' qualitative responses regarding communication with their mothers about study participation,[6] an investigator and a research coordinator independently identified whether responses indicated a belief that her mother thought she was a virgin and if she indicated that she talked to her mother about sexuality. It should be noted that the girls were asked about these two topics specifically; however, several girls spontaneously addressed them when asked about talking with their mother about the study. Discrepancies between the two coders were discussed and resolved by consensus.

Results

Sample

A total of 208 girls were recruited into the study; 41% were African-American, 30% were Hispanic, and 29% were non-Hispanic Caucasian/other. They had a mean age of 18 years, and 95 participants (46%) were under the age of 18. One hundred seventy-six females attended the 3-month visit, and of those, 79 (44%) were less than 18. There were 165 females