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Predictors of Adolescent Participation in Sexually Transmitted Infection Research: Brief Report

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Abstract

We examined the effect of an institutional requirement for parental consent on adolescents' enrollment in a research study involving sexually transmitted infections. Fewer adolescents enrolled when parental consent was required compared with those who enrolled after this requirement was waived (79% vs. 94%, $p = .01$). Of the adolescents, 100% requested confidential test results. We conclude that requiring parental consent decreases participation in STI research.

Keywords

Adolescents; Recruitment; STI; Research bias; Consent

There are ongoing questions regarding the requirement of parental consent for adolescent participation in research related to sexually transmitted infections (STIs). In all states, adolescents may consent to clinical care involving STIs [1]. However many institutional review boards (IRBs) require parental consent for research with adolescents <8 years of age, even when the research involves STIs [2–4]. This requirement raises the concern that adolescents who consent to research may be different from those who refuse, thus limiting the applicability of the results. Previously it was demonstrated that when parental consent was required, 58% of subjects who met initial enrollment criteria refused participation; of those who refused, 23% cited parental barriers as the reason [5]. This resulted in a bias toward recruiting more women ≥18 years of age that was especially significant for white women.

In part because of these results, the institutional requirement for parental consent was waived 3 months after the most recent STI study commenced. This gave us the opportunity to examine the effect of an institutional requirement for parental consent on adolescent women's enrollment in a research study involving STIs.

Methods

This study examines the enrollment process of an institutional review board–approved STI study. We will describe the primary study and the enrollment process separately for clarification.

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Primary study

This cross-sectional sample of sexually active females 14–21 years of age presenting to a teen health center or the emergency department between July 2004 and June 2006 has been described previously [6]. Female adolescents requiring a pelvic examination who presented with STI symptoms or risks for STIs were eligible. Enrolled subjects completed a confidential interview and STI testing. During the interview, each subject was asked whether her parent/guardian was aware of her sexual activity, her STI testing today, and her participation in the research study. During the first 3 months of the study, subject consent or assent was obtained from the adolescent and parental consent was obtained for those <18 years of age. After the first 3 months the IRB granted a waiver of the requirement for parental consent, allowing subsequent consent from all adolescents aged 14 –21 years.

Enrollment process study

For the subset of patients who presented to the pediatric emergency department (PED), a computerized registration system allowed us to assess initial eligibility. This same system was not available in the teen health clinic; thus the enrollment sample is limited to those recruited from the PED.

Simple demographics including age, chief complaint, race, and insurance status were available in the computerized registration system and were used to maintain a de-identified enrollment log. The research assistant invited those who met full enrollment criteria to participate in the study. If the patient refused enrollment, the first reason cited for refusal was recorded. The enrollment log was considered exempt from IRB review because it contained no identifying information.

The primary outcome of interest was study enrollment in the subset of patients recruited from the PED. The proportion of those eligible and enrolled was calculated. Bivariate associations between enrollment and other variables including the parental waiver of consent and demographics were assessed using Chi-square analysis.

Results

Of the 215 subjects who met full eligibility criteria, 197 (92%) agreed to enroll. Nonenrollees did not differ from enrollees by race or by the proportion who were ≥18 years of age. However enrollees were more likely than nonenrollees to report Medicaid as their health insurance (58% vs. 25%, Fisher's exact test $p = .03$). In all, 34 eligible subjects were approached when parental permission was required, and 181 were approached after parental permission was waived. When parental consent was required, fewer eligible females agreed to enroll (27 of 34, 79%) compared with those approached after parental consent was waived (170 of 181, 94%), which was significant at $p = .01$ using Fisher's exact test. The reasons for refusal of enrollment by the 18 subjects included the following: time constraints (n = 2), uninterested (n = 2), parent not aware of sexual activity (n = 3), unavailable parent (n = 2), and other reason, including prior participation or no pelvic examination done on this visit (n = 9).

Of those enrolled, the proportion of individuals who were ≥18 years of age, were black, or had Medicaid did not differ between those recruited before vs. those recruited after the waiver of parental consent. As shown in Table 1, more than 90% of all enrollees reported that a parent was aware of their sexual activity, and 52% acknowledged that a parent was aware of their STI testing. There was no significant difference between those recruited before or after the waiver of parental consent. However subjects enrolled before the waiver of parental consent were more likely to report that a parent was aware of the research study than those enrolled after the

waiver (44% vs. 21%, $p = .009$). Regardless of parental consent or parental awareness, 100% of enrollees requested confidential notification of STI test results.

Discussion

In this convenience sample with a high participation rate, Medicaid status and removing the requirement for parental consent were associated with increased enrollment. Unlike a recent study on STIs recruitment, age ≥18 and black race were not significant in predicting enrollment in this study. [5] These conflicting findings may be caused by the small sample size and high participation rate in a highly selected population of patients who were already undergoing a pelvic examination in the current study. However previous work demonstrated that patient-reported parental barriers accounted for a large number of adolescents refusing enrollment. [5] In this study, we show that removing the institutionally imposed parental consent requirement increases enrollment rates in this population.

Interestingly, even when adolescents report parental awareness of sexual behavior, requiring parental consent appears to decrease participation in STI research. This suggests that adolescents who are comfortable with parental knowledge of their sexual activity still value confidentiality in health care related to sexual issues. In this study, regardless of parental consent, 100% of enrollees requested that STI test results be handled confidentially, confirming that privacy and autonomy are important to adolescent women. Several investigators have demonstrated that an important aspect of accessibility of sexual health care for adolescents is confidentiality [7,8]. Consequently it is not surprising that the lack of confidentiality imposed when parental consent is required is a significant barrier to enrollment in STI-related research.

It is often difficult to recruit a representative sample of subjects for clinical research when constrained by time, money and availability of research personnel. Despite our best efforts to recruit every eligible female in the time available to us, we found that our enrolled sample differed from the eligible sample in being more likely to have Medicaid as their health insurance. We could not fully investigate the many reasons that adolescents may decline to participate, because a full qualitative exploration would have required a separate IRB consent process. Therefore we are limited to reporting the demographics that were available when patients registered for the PED visits.

Despite these limitations, we believe that the institutional requirement of parental consent may bias the sample of adolescents who agree to participate in clinical STI research. Thus the institution that requires parental consent differentially precludes access to the potential benefits of research from a specific at-risk group. In other settings, this would be called discrimination. We hope that our findings will encourage others to explore this topic, and will provide valuable information to IRBs as they review research proposals that include adolescents in relation to STIs and other reproductive health care visits.

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Table 1

Effect of an institutional waiver of parental permission on those enrolled in a sexually transmitted infection (STI) study

	Total N = 197 n (%)	Not waived N = 27 n (%)	Waived N = 170 n (%)	*p* value
Age ≥18 years	68 (34)	12 (44)	56 (33)	.24
Black	165 (83.8)	26 (96)	149 (89.8)	.08
Medicaid	114 (58.8)	18 (67)	96 (57.5)*	.40
Parent aware of sexual activity	175 (90.7)	26 (96)	149 (89.8)	.47
Parent aware of STI testing today	103 (52)	13 (48)	90 (53)	.68
Parent aware of research study	48 (24)	12 (44)	36 (21)	.009
Would like confidential results	197 (100)	27 (100)	170 (100)	1

*Missing/unknown for three subjects.