Case Report

Strategies for Conducting Adolescent Health Research in the Clinical Setting: The Mount Sinai Adolescent Health Center HPV Experience

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A B S T R A C T

Background: Clinical research with adolescents can be challenging due to issues of informed consent, parental involvement, institutional review board requirements, and adolescent psychosocial development. These requirements present a dilemma, particularly in the area of sexual health research, as adolescents are disproportionately affected by sexually transmitted infections such as human papillomavirus (HPV). To successfully conduct adolescent research in the clinical setting, one requires an awareness of state statutes regarding adolescent confidentiality and consent for medical care, and a close partnership with the IRB.
Case Study: In 2007, the Mount Sinai Adolescent Health Center in collaboration with the Albert Einstein College of Medicine developed a longitudinal research study to examine the natural history of oral, cervical, and anal HPV in an adolescent female population engaged in high-risk sexual behaviors. We use this research project as a case study to explore the ethical, methodological, and clinical issues related to conducting adolescent health research.
Summary and Conclusions: Several strategies were identified to promote adolescent study participation, including: (1) building a research team that is motivated to work with adolescents; (2) combining research and patient care visits to avoid duplication of services; and (3) establishing a personalized communication network with participants. Using these methods, adolescent sexual health research can successfully be integrated into the clinical setting. While retaining a prospective cohort of adolescents has its challenges, a persistent and multi-disciplinary approach can help improve recruitment, sustain participation, and acquire critical data that will lead to improved healthcare knowledge applicable to understudied populations of adolescents.
Key Words: Adolescent Research, Human Papillomavirus, Sexual and Reproductive Health, Parental Consent, Institutional Review Boards

Introduction

Clinical research with adolescents can be difficult because they are viewed as a vulnerable population according to the Department of Health and Human Services (DHHS).[1] Adolescent health research is further complicated by issues of informed consent, parental permission and involvement, institutional review board (IRB) approval, and state laws. These issues are accentuated when the clinical research involves sensitive topics such as sexual behaviors and sexually transmitted infections (STI). Because of the aforementioned issues, along with difficulties in the interpretation of federal regulations on adolescent involvement in research, adolescents have often been excluded from participation in clinical trials, public health prevention, and other important research studies. This conflict is unfortunate because there is a critical need to involve adolescents in research to advance our knowledge and understanding of adolescent health.

In 2007, The Mount Sinai Adolescent Health Center (MSAHC) partnered with the Albert Einstein College of Medicine to examine the natural history of human papillomavirus (HPV) infections and effectiveness of the HPV vaccine in sexually active adolescent females. The study underwent ethical review at both parent institutions, and was funded by the National Institute of Allergy and Infectious Diseases. We use the MSAHC HPV research project as a case study to explore the ethical, methodological, and clinical issues related to conducting adolescent health research.

Adolescent Consent Issues

Federal regulations mandate that an individual's decision to participate in research must be based on sufficient information so that the individual can confer an intelligent informed consent. Previous research has shown that by age

Funding for this study was provided by the National Institute of Allergy and Infectious Diseases (R01 grant AI072204). Additional funding was provided in part by the Einstein-Montefiore Center for AIDS funded by the National Institutes of Health (AI51519), and the Einstein Cancer Research Center (P30 CA013330) from the National Cancer Institute. The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.
Dr. Schlecht has served in the past as an advisory board member for Merck and Glaxo-Smith Klein. Dr. Strickler has served in the past as an advisory board member for Glaxo-Smith Klein. The remaining authors do not have commercial or other associations that might pose a conflict of interest.
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1083-3188/$ - see front matter © 2014 North American Society for Pediatric and Adolescent Gynecology. Published by Elsevier Inc.
http://dx.doi.org/10.1016/j.jpag.2013.08.004

14 or 15, adolescents are able to make decisions as well as adult research participants in most circumstances.[2] An adolescent's ability to provide informed consent is closely related to several factors: capacity, previous life experiences, the ability to use formal logic, and emerging cognitive skills and judgment.[3,4,5] It is therefore important to assess the adolescent's developmental stage and to tailor the consent process accordingly.

Parental Role and Legal Concerns in Adolescent Research

One of the potential obstacles faced by adolescent health researchers is navigating parental consent procedures.[6] As a general rule, minors under the age of 18 cannot legally provide consent according to the DHHS,[1] requiring the approval of their parent or guardian. However, several authors have posited that parents cannot ethically provide informed consent for their children since they are not the research subjects themselves and do not personally experience the risks or benefits of the research.[7] As such, federal regulations often use the terms "permission" and "assent," whereby the parent provides permission and the adolescent provides assent for participation.

Mandating parental involvement for research is often difficult and confusing, especially when adolescents can consent to medical care for certain conditions themselves (including sexual and reproductive health, substance abuse, and mental health), without parental consent.[8] Therefore, if under the law a minor can consent to medical treatment or procedures that are also involved in the research, then the DHHS regulations consider the minor to be an "adult" or "mature minor" for purposes of participating in research activities related to that condition.[9,10] In those circumstances, parental permission is not a reasonable requirement. In fact, requiring parental consent for adolescent participation in research may actually cause inadvertent harm and put youth at risk of losing access to health care through increased parental supervision.[11] So, when state statutes give minors the ability to consent for medical care, they are often able to consent to participate in research in that area (obviating concurrent parental permission).

Some minors may be physically, emotionally, or economically threatened by parental involvement in their research participation.[12] This is especially true as it relates to sexual and reproductive health research. Adolescents who are not comfortable discussing sexual health issues with their parents might be excluded from research participation if parental consent was required.[13] Therefore, requiring parental consent for sexual health research may lead to a biased population in that only those teens who are comfortable discussing sensitive issues with their parents will participate.

Mandating parental involvement can also violate the adolescent's right to confidentiality. A number of adolescent health researchers have stipulated that those youth unable to obtain parental consent for research involvement are often the ones most in need of sexual health information and resources.[13] Even when teens report parental awareness of sexual activity, requiring parental consent for participation in sexual behavior research appears to decrease participation in that research.[14] Therefore, most adolescent health researchers advocate for the involvement of parents in adolescent health research to the best of the researchers' ability, while still respecting the needs of the adolescent.[4,13]

Importance of Working with the IRB

Parental consent issues may be further complicated by institutional IRBs. Some IRBs maintain that the capacity to consent to medical care does not necessarily confer the capacity to consent to research.[15] Federal regulations are in place to protect vulnerable populations such as adolescents, but IRBs can grant waivers of parental consent if the following conditions are met: (a) the activity involves no more than minimal risk, (b) the teen would refuse to participate if he/she had to involve their parents, (c) parental permission is not a reasonable requirement to protect the participants, or (d) a patient has suffered parental abuse.[16] Under the US code of federal regulations the definition of minimal risk includes: "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[17] Even though waivers of parental consent can be obtained, some states and municipalities may have laws in place that are more stringent than federal regulations. This emphasizes the point that investigators need to be aware of federal, state, and local regulations, as well as IRB rules when conducting research with adolescents. Parental involvement is not the only consideration for adolescent participation in research. Study investigators also tend to shy away from research with adolescents because of perceived issues with the IRB and the time investment for study approval.[6] Expertise in dealing with adolescents can be lacking or underrepresented on IRBs that are more accustomed to reviewing adult research protocols.

As a clinical site that conducts research with adolescents, the MSAHC has a long-standing relationship with its IRB. Indeed, some of the faculty have been IRB members. For this study, viewing the IRB as a partner in research development helped provide the substance for the research protocols' approval and adoption of amendments. Such collaboration simultaneously helped to improve research participation and safeguard the well-being of participants. Frequent consultations with the IRB, face-to-face meetings and communication during the review process, and directly answering questions in front of the review panel was instrumental and helped facilitate a better understanding of the issues.

The Case Study

The broad objective of the study in question is to examine the burden of oral, cervical, and anal HPV infection in a cohort of sexually active, vaccinated, minority, adolescent females aged 12 to 19 years. Female adolescents who present to the MSAHC for any type of medical visit are given the opportunity to participate. During the medical visit,

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