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

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Abstract

Background—Clinical research with adolescents can be challenging due to issues of informed consent, parental involvement, institutional review board requirements, and adolescent psychosocial development. This presents 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 (MSAHC) 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.

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Conflict of Interest:

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 a commercial or other association that might pose a conflict of interest.

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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.

Keywords

Adolescent Research; Human papillomavirus; Sexual & reproductive health; Parental consent; Institutional Review Boards

Introduction

Clinical research with adolescents can be difficult as 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 (STIs). 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 as 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 HPV infections and effectiveness of the human papillomavirus (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 (NIAID). 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 such that the individual can confer an intelligent informed consent. Previous research has shown that by age 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 DHHS¹ and require 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 the need for 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 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 who are more accustomed to reviewing adult research protocols.

As a clinical site that conducts research with adolescents, the MSAHC has a longstanding 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, research assistants approach patients within the age range of the study in the waiting room. If the adolescent expresses interest in participating, she is screened for eligibility criteria. Interested participants are taken to a private exam room and the consenting process takes place: the purpose, types of data to be collected, frequency of follow up, benefits, and risks of the study are explained. Prior to consenting and to ensure that the adolescents understand the purpose and requirements of participation, they are asked to verbalize their understanding of the research study by answering several questions related to the research process.

Study enrollment began in the fall of 2007. As of January 2012, 1096 adolescents have consented for participation, with enrollment ongoing. Characteristics of the overall MSAHC clinic population and study cohort are shown in Table 1. The MSAHC study population represents a sample of minority adolescents that are at particularly high risk for long-term sequelae of HPV and other STIs acquired in adolescence.

Addressing initial ethical and IRB concerns

At the outset of the study, the HPV vaccine had just been released and there were strong opinions about the vaccine from parents, the public, and policy makers. The study was designed to be conducted with a waiver of parental consent, as earlier studies had been executed at the MSAHC with IRB waivers of parental permission. Initially however, the IRB only granted approval to enroll adolescents 18 and over without parental consent, and minors (less than 18) only with parental consent. This was done with the best of intentions, out of an abundance of caution given the controversial nature of the HPV vaccine at the time. The IRB's position however, was in conflict with MSAHC's policy that reflects New York State Public Health Law which protects adolescents' rights to obtain confidential sexual and reproductive health care without parental consent.⁸

As part of working with the IRB, and given the concerns with conducting sexual health research with younger adolescents, the study followed a phased deployment in recruitment. Eighteen months into enrollment, we submitted another request to the IRB for a waiver of parental consent for minors. This request was supported by presenting clinical vaccination statistics by age, enrollment numbers, legal arguments, and review of the most up to date literature supporting adolescent capacity to consent to participation in research. After much discussion and waiting period, the IRB deemed it safe to enroll minors aged 14–17 years with a waiver of parental consent, while parental consent was still required for participants aged 12 and 13 years. Adolescents between the ages of 14 and 17 did not need parent consent for research study participation, unless they were accompanied by them. Under this IRB approval, if a parent was present at the visit, a good-faith effort to obtain parental consent was made, with the adolescent's verbal assent. If the adolescent presented to the clinic alone, the waiver of parental permission was put into effect and the adolescent consented for the study herself.

However, a large portion of adolescents seeking medical care at the MSAHC come for confidential health care services, and many come without their parents. While we discuss the benefits of young people communicating with their parents and encourage parental participation in the adolescent's medical care, it is not a requirement. All visits are deemed confidential as we make it a priority to discuss sexual and reproductive health, safer sex, and contraception at each visit.

In addition, under the direction of the IRB, and in order to safeguard the participating youth, we established an interdisciplinary committee at the MSAHC to act as advocates for all subjects. The Surrogate Parent Committee consists of MSAHC medical providers and mental health staff who are not involved in the research. If a participant needs assistance in understanding the study details, or wishes to consult someone not involved in the study, a member of the Surrogate Parent Committee is made available during the consent process.

Based on the initial IRB requirements for parental involvement, we were unsuccessful recruiting younger teens. Because we were concerned that requiring parental consent merely because a parent is present abrogates the patient's right to confidentiality and privacy, another amendment was sought to obtain a waiver of parental consent for the entire target

study population. In May 2011, we successfully obtained IRB approval to recruit adolescents between the ages of 12 and 13 with a waiver of parental consent. As a result of the IRB approvals, we have successfully expanded the recruitment of to all adolescents, including those less than 18 years of age. Although the IRB issues were critical for proper subject protection, additional factors as outlined below, greatly facilitated the newly enacted IRB requirements.

Retention strategies that work for adolescents

Since this is a longitudinal study, ensuring the best possible follow-up and minimizing attrition rates is critical. Prior studies have shown that combining clinical and research visits can avoid duplication of service provision and minimize expenses in travel and time.¹⁸ We have attempted to do this whenever possible, empowering adolescents to be responsible and participate altruistically in a research project.

A key to getting participants to return for their follow-up visits is the establishment of confidential and convenient modes of communication. Confidentiality can be compromised by telephone contact at the adolescent's home, so the participants are required to explicitly state how they wish to be contacted and whether the research team can mention who is contacting them. Previous research has found that "the single most important method for maintaining a sample over time...is to collect as many contact names, addresses, and telephone numbers at baseline as possible."¹⁹ It is well known that adolescents are a mobile population, and email addresses and cell phone numbers change quite frequently. Cell phones get lost, numbers change, and plans change with some regularity. Participants are asked to select their preferred methods of communication, be it texting, cell phone, email, or regular mail, and this is respected by the staff. The research team also developed social media profiles on Myspace and Facebook as a way to reach out to research participants and provide general information about HPV. As a result, because of the amount of locator data collected, we are able to contact the patients through a variety of means which helps facilitate follow-up and increase retention.

Previous research has shown that individualized attention and remembering patients on special occasions can also facilitate participation.²⁰ The research team is encouraged to form personal connections with the participants and become involved in the adolescents' lives. Information about key events (such as birthdays or anniversaries) for the adolescent are recorded in the study database, and specific time each day is devoted to phone contacts, mailings, and acknowledging these special occasions for the adolescents. For study participants, the research staff become their personal health navigators. Participants can call the research assistants whenever they have questions or want to schedule a health care visit. In turn, the research staff can facilitate connection with existing services at MSAHC.

Offering convenient physical access and appointment times can also add to patient satisfaction and minimize drop-out rates.¹⁸ The participants are encouraged to contact the research assistants as needed during and between their clinical appointments, which helps facilitate scheduling and coordinating study visits, as well as address the general clinical needs of the participants.

The importance of pilot testing before and being flexible during the study

Prior to starting the protocol, a pilot study was conducted in 2005–2006 with 97 participants. This helped validate the research protocol and identify potential problems prior to conducting the larger study. After the initial feasibility study, the research team sought the advice and opinions from participants, practitioners, and ancillary staff to improve the study design and flow. Involving a multi-disciplinary clinical care team early on in the research process helped align the research and clinical needs as well as improve patient health care delivery, maximize efficiency, and minimize additional time spent at the clinic by participants.²¹ This was also important in minimizing disruption to clinic flow during the study, and satisfying the clinical health care needs of the larger adolescent patient population.

Participants were initially screened, enrolled, and then actually participated in their first research visit on the same day. Previous research has shown that combining these visits can potentially result in loss to follow-up immediately after the initial study visit.²² We also recognized that this strategy may not work for all adolescents. For individuals that are reluctant to participate in research however, separating the enrollment and initial study visits helps ensure commitment to the study, allows ambivalent volunteers to fully consider the decision to participate, and helps confirm locator data (phone number, email, etc.) for participant contact.¹⁹ As such, many participants are recruited during clinical encounters, but scheduled for a first study visit at a later time. As advocated by other researchers, subsequent study visits are then combined with clinic appointments when possible to avoid duplication of service provision and minimize expenses in travel and time.¹⁸ This flexibility in recruitment and follow-up was an important factor in increasing enrollment numbers and retention rates.

Creating a supportive and stimulating research environment

Project staffing is also extremely important to maintain high rates of follow-up in a long-term longitudinal study.²¹ Prior studies have shown that hiring appropriate project staff with the right balance of research, community, and clinical experience helps to ensure professional ethical standards and maintain successful participation.¹¹ We hired dedicated, educated, and motivated research staff, with a personal interest in adolescent health, to help further the research agenda while maintaining clinical integrity and confidentiality. All of the research team members were trained by an expert adolescent medicine physician and taught how to communicate with adolescents, establish empathic and effective relationships, and maintain confidentiality.

Creating an adolescent-friendly environment can also increase participant retention.¹⁸ MSAHC services are delivered by medical and mental health providers who are specifically trained to work with adolescents. Since privacy can be a concern, adolescent confidentiality is respected and preserved as a major characteristic of the center. The center is respectful of individual teens, independent of their financial, educational, emotional or ethnic background. The research team members approach participants in the waiting rooms, but then take them to a confidential space to discuss the research protocol, obtain informed

consent, and complete the questionnaires and instruments. This allows research participants to ask questions and avoid inadvertent disclosure to friends or other patients in the waiting area.

Adolescents value quality health care, caring staff, and personalized attention when participating in research, both during recruitment and follow-up.²³ Initial study visits were conducted by all clinic healthcare providers (both male and female) who were trained by the study investigators. However, these visits took an average of five to ten minutes longer than a regular clinical visit, which sometimes disrupted clinical flow. In response, we recruited a dedicated nurse practitioner to conduct most of the research visits. This provider has an open schedule for research-only visits. Since research participants are seen at least every six months, this provider is also able to establish a therapeutic relationship with the participants and provide personal attention.

As a result of proper staff planning and coordination with the clinic flow, enrollment has gained pace progressively each year. While it required 24 months to obtain the first 100 enrollees, over the subsequent two years with a convergence of changes in the IRB requirements and constructive changes in the study processes and management, we have averaged over 250 new adolescent enrollees per year, including over 300 in the past 12 months.

Same day visits also allow subjects to be immediately available for recruitment and study visits, avoiding missed appointments and no-shows. Expedited visits have also been shown to promote the retention of adult subjects in research.²³ As such, the research team developed a fast-track strategy for research participants. Clinic patients who present without an appointment and consent for research participation are often seen by the research nurse practitioner sooner than they might normally as a patient without an appointment. When offering this option however, great care must be made that such an arrangement does not disadvantage non-research participants. Patients who decline participation still have their medical needs met, and are seen by non-research health care providers as part of the larger walk-in population.

The use of incentives in adolescent research

There is conflicting information as to whether compensation promotes recruitment and retention of research participants.²³ Gift giving can increase positive attitudes about longer clinical trials.²⁰ However, other studies have found that monetary compensation is not a significant factor in an adolescent's decision to participate in research.²³ Moreover, adolescents may be coerced by monetary compensation or gifts.³ Even though we have been successful conducting research without financial compensation in the past, given the overall time commitment and involvement of the HPV study (each study visit is 60–90 minutes in length, and participants have five visits over the course of two years), it was decided that adolescents would be compensated for their participation. For this study, adolescent participants are awarded two movie passes, a \$25 gift card, and two transportation Metrocards for their time and effort. To avoid coercion, participants are informed of the

honoraria in advance, and advised that compensation is not conditional on their level of participation (allowing them to withdraw at any time).

In addition to financial compensation, there are other less tangible but equally important incentives offered. Altruism and health education have been found to be positive reasons for research participation by adolescents.²³ Participants are told about the scientific implications of the study and the potential future benefit to other adolescents. Several adolescent focus groups have expressed the importance of learning about the disease under study and new developments for their specific conditions as a reason for recruitment and retention in research.²⁴ Participants learn more about HPV and the HPV vaccine as a result of research participation, which may help contribute to their overall health. Participants are also thanked for their participation at each visit by all staff, which provides positive reinforcement.

Summary: Clinical Implications and Discussion

Multiple authors have stated that making adolescent health research a priority is important, not only because of the uniqueness of the population, but also because adolescents are not just big children or little adults.²⁵ This research study is an ongoing project demonstrating that adolescent health research can be successfully integrated into the clinical setting. Retaining a cohort in a longitudinal study is challenging, but persistence, training, continual self-evaluation, and a multi-disciplinary approach helps achieve success.

In summary, we suggest consideration of the following viewpoints when conducting research with adolescents:

1. Understand the federal and state laws with regard to the adolescent's right to confidential care and participation in health research.
2. Involve the IRB as a partner in the research process by developing a functional working relationship with the IRB board members.
3. Involve parents in adolescent health research when appropriate, while still respecting the adolescent's autonomy, confidentiality, and private health care needs.
4. Tailor the informed consent process to the developmental and intellectual needs of the adolescent.
5. When conducting adolescent health research in the clinic setting, keep inconveniences and disruptions to a minimum, and avoid compromising normal clinic flow.
6. Provide individualized attention and high-quality health care to maximize enrollment and retention rates.
7. Craft a research team that is comfortable and eager to work with adolescents.
8. Utilize dedicated research-oriented health care provider(s) to conduct research visits and provide continuity of care.

9. Organize a team of providers who are not involved in the research project to serve as advocates for the adolescents.
10. Combine research and clinical health care into one visit (if possible) to streamline the process and avoid duplication.
11. Take advantage of electronic media and adolescent-friendly communication methods.
12. Consider providing compensation for participatory time and effort.

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Table 1

Characteristics of MSAHC population and study cohort at time of initial enrollment

Population characteristics	MSAHC population year prior (N=6966)	HPV study cohort (N=712)
Age	N %	N %
12–13	135 (1.9%)	1 (0.1%)
14–15	516 (7.4%)	56 (7.9%)
16–17	1231 (17.7%)	220 (31.0%)
18–19	1982 (28.5%)	405 (57.1%)
20+	3102 (44.5%)	27 (3.8%)
Race[†]		
African-American	3236 (46.5%)	338 (47.7%)
Ethnicity[†]		
Hispanic	3236 (42.5%)	410 (59.4%)
Sexual history		
Sexually active	5827 (83.6%)	711 (99.8%)
Mean age at 1 st intercourse (in years)	15.3	14.9
History of STI		
Chlamydia	1852 (26.6%)	223 (32.3%)

[†] Race and ethnicity are overlapping