

Adolescent FUV: A Study of Awareness and Sexual Behavior

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A. Study Purpose and Rationale

This project is a sub-study of the PACTS-HOPE cohort study. The PACTS-HOPE cohort was established from a group of pregnant HIV infected women who gave birth from 1986-1994. The HIV infected and exposed children born to these women have been followed throughout childhood in the PACTS-HOPE study.

This sub-study will investigate the awareness about HIV and its transmission in HIV infected and uninfected children as well as their sexual behavior and related factors. As participants in PACTS-HOPE, the infected children who know their status participate in sexual health education. This involves afternoon sessions in groups of either females or males. Though sexual education is taught in the school system, it is hypothesized that the HIV infected children who participate in these sessions will have increased awareness.

With the advent of HAART, children and adolescents who are infected with HIV will be living into adulthood. With this extended survival, information regarding the awareness and behaviors of these teens is needed to develop effective interventions. They need to be aimed at preventing these youth from engaging in behaviors that can spread HIV to others, in addition to secondary prevention to keep patients from contracting resistant strains of HIV. This sub-study will survey cohort participants, aged 10- 16, about several topics. This will include HIV knowledge, sexual thoughts and activities, substance use, adherence, STD history, pregnancy history, and birth control use through the use of questionnaires. The purpose is to determine the effectiveness of the current PACTSHOPE educational intervention.

Ideally, the intervention would be effective enough to make the pre-teens equally informed as the adolescents. It is thought that if the pre-teens have adequate knowledge at an earlier age they will be less likely to engage in unsafe behaviors. If this is not the case then new interventions may need to be added or the current intervention may need revision.

The risk behaviors of these children will also be determined through a set of questionnaires. We will specifically look at condom use as a measure of practicing safe sex. This can be affected by a multitude of associate risk factors such as age, gender, race, substance use, number of sexual partners, age at first coitus, history of STD or pregnancy, HIV status, disclosure status (within the HIV infected group), and sexual education interventions. The purpose is to determine the prevalence of condom use among this cohort. Since the majority of the cohort is aged 10- 11, the number of currently sexually active participants may not be powered for analysis at the conclusion of this study. Therefore follow-up interviews on an annual or biannual basis would be needed in order to analyze the sexual behaviors of these children over a course of four to six years.

B. Study Design and Statistical Analysis

The study will be a case control study of 177 pre-teens and adolescents enrolled in the PACTS-HOPE cohort study. The two arms will be the HIV infected and the HIV uninfected. The uninfected participants will serve as controls since come from similar backgrounds and are matched for place and year of birth as the infected participants. Each subject will be given a HIV knowledge quiz. The potential score ranges from zero to fifteen. This will be used as a continuous variable. There are potentially 177 subjects that could be recruited into the study. If enrollment is estimated at 85% then 150 participants could be included in the analysis. Each group would have about 75 subjects in each. With a

standard deviation of four points and an expected effect of thirty percent the number of subjects needed for 80% power, testing at $P=0.05$ is thirteen using an unpaired t-test. Therefore we will have more than enough subjects to demonstrate an effect of significance if there is one.

When asked if condoms are used during sexual intercourse there are five responses that can be given: always, most of the time, sometimes, almost never/rare, or never, (see Appendix A). We will use a cut off value of 50% (sometimes) or higher to identify a subject as practicing safe sex. Using the chi-square test and estimating that there could be a 50% difference in proportions of condom use, we would need eighteen sexually active children in each group for 80% power, testing at $P=0.05$.

The primary analysis of the study data will be to determine the levels of awareness in the HIV infected versus the HIV uninfected group. We will do multiple logistic regressions for various factors that may affect awareness. These factors include age, grade in school, socioeconomic status, race, gender, parental education level, state of residence, sexual activity, history of an STD and HIV status.

The secondary analysis will involve looking at the amount of condom use between the two groups who are sexually active. We hope to have at least 75% (most of the time) use of condoms. We will do multiple logistic regressions for other associated risk factors such as age, gender, race, substance use, number of sexual partners, age at first coitus, history of STD or pregnancy, HIV status, disclosure status (within the HIV infected group), and participation in PACTS-HOPE educational intervention.

C. Study Procedure

A research assistant that has never met the participant will administer the questionnaires in a single session. The session will last from one to two hours. Participants will be recruited from the PACTS-HOPE cohort sites in New York, New Jersey, Atlanta and Baltimore. Recruitment will be done at the participants normal PACTS-HOPE visits by the interviewer for the PACTS-HOPE study. If interested in participating the PACTS-HOPE interviewer will introduce the parent and child to the research assistant. The assistant will then obtain parental consent and participant assent. Once consented, participants will undergo the interview at a separate visit by the research assistant.

D. Study Drugs

There are no drugs being used in this study.

E. Medical Device

There is no medical device being used in this study.

F. Study Questionnaires

1. HIV Knowledge (see appendix A)
2. Sexual Intent, Behavior, and Risk Questionnaire
3. Self Efficacy Questionnaire
4. Substance Use Questionnaire
5. Adherence Barrier Questionnaire
6. Disease Progression Questionnaire
 - a. Pregnancy History
 - b. STD History
 - c. Birth Control History

G. Study Subjects

All subjects will be required to be participants in the PACTS-HOPE cohort study. Only subjects between the ages of ten and sixteen will qualify for this study.

H. Recruitment of Subjects:

Subjects will be recruited into the study by their PACTS-HOPE interviewer. The parent/primary caregiver will be approached first and if interested the child will be asked about participation in the study.

I. Confidentiality of Study Data

All subjects will be assigned a unique code number for identification to be used on all forms. The study has also applied for a certificate of confidentiality.

J. Potential Conflict of Interest

None of the investigators in this study have any proprietary interest in the results of this study.

K. Location of the Study

The study will be undertaken at each respective PACTS-HOPE cohort site in an outpatient setting.

L. Potential Risks

The main risk involved in the study is unintentional disclosure of HIV status to nondisclosed participants. In order to avoid this, disclosure status will be determined during the parental consent. Therefore, those who are infected, but have not been disclosed to, will receive the same assent and survey as non-infected participants.

M. Potential Benefits

There is no direct benefit to participants of this study. An indirect benefit of the study is the acquisition of information regarding the risk behaviors of perinatally infected adolescents that may lead to new interventions targeted towards HIV infected adolescents.

N. Compensation to the Subjects

Each participant will receive thirty-five dollars in the form of cash and a metro card for transportation, regardless of interview completion. This will be given directly after the session is over.

O. Costs to Subjects

There are no additional costs incurred by the participants.

P. Minors as Research Subjects

All participants are minors therefore parental consent and participant assent is required for each subject.

Appendix A

Knowledge Quiz

Please listen carefully as I read the following statements to you. After each statement is read, please tell me whether you think the statement is TRUE or you think the statement is FALSE.

- | | | |
|--|-------------------------------|--------------------------------|
| 1. Once a person is infected with HIV, he or she is infected for their lifetime | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 2. You can tell by looking at a person that he or she is infected with HIV. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 3. I know that if a person I wanted to have sex with was infected with HIV they would tell me before we had sex. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 4. A person can get HIV from giving blood. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 5. You can get HIV from a toilet seat. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 6. A mother with HIV can give the virus to her baby by breast feeding. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 7. A person can get the HIV virus in one sexual contact. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 8. A shower after sex reduces the risk of getting HIV | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 9. When people don't have sex with more than one partner, they do not have to practice safer sex. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 10. There is no cure for HIV or AIDS. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 11. Having sexual intercourse without a condom increases a person's risk of becoming infected with HIV. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 12. It is okay for two HIV infected persons to have sex together without a condom because they cannot become "re-infected" with HIV. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 13. HIV can be passed from person to person by sharing needles used to inject drugs. | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 14. You can become infected with HIV by having unprotected oral sex | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 15. Having multiple sex partners increases your risk of becoming infected with HIV. | <input type="checkbox"/> True | <input type="checkbox"/> False |

Condom Use Question (within sexual intent/behavior questionnaire)

How often do you use a condom during sexual intercourse

- a. Always (100% of the time)
- b. Almost always (75% of the time)
- c. Sometimes (50% of the time)
- d. Almost never/rarely (25% of the time)
- e. Never (0% of the time)