TRANSFUSION SAFETY STUDY

SUBPROTOCOL

SEXUAL TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) BY RECIPIENTS OF ANTI-HIV-POSITIVE BLOOD

INTRODUCTION

To enhance efforts at preventing transmission of the human immunodeficiency virus (HIV), it is important to identify the mechanisms by which it becomes seeded in segments of the community in which a reservoir does not presently exist. Persons infected as a result of blood transfusion represent a group that until recently has had no reason to identify itself as at risk for HIV infection.[1] As a consequence, unmodified behavior may have resulted in transmission of the virus to others. In this way, even the relatively small number of persons infected as a result of transfusion could represent a disproportionate public health hazard.

In defining any broadening of the HIV reservoir beyond transfusion-transmitted infection, the most informative group seems likely to be the sexual partners of recipients of blood positive for antibodies to HIV (anti-HIV). Several studies have reported heterosexual transmission of HIV from infected individuals to their sexual partners. It has been found that 47 to 71 percent of female partners of patients with AIDS-related complex or AIDS have antibodies to HIV.[2,3,4] Of female sexual partners of men with asymptomatic HIV infection, a small-scale study showed 10 percent to be anti-HIV positive.[5] A study of the sexual partners of congenital hematologic disorder patients with transfusion-acquired HIV infection found that 21 percent were anti-HIV positive.[6] Recently, a national survey found a 10 percent seropositivity rate in tested partners of anti-HIV positive persons with hemophilia.[7]

As part of the Transfusion Safety Study (TSS), it seems appropriate to take advantage of the identification of recipients of anti-HIV positive blood to investigate the efficiency and factors associated with transmission of HIV *by* persons with transfusion-acquired infection.

The advantages of using TSS recruited recipients to assess the risk of heterosexual transmission of HIV are:

1. The date each recipient was transfused with anti-HIV positive blood is known. Therefore the duration of the sexual partners potential exposure to HIV can be estimated with relative accurracy.

2. Recipients include both men and women of all ages, presumably with differences in health status and patterns of behavior. This diversity will allow study of various factors that may influence the risk of heterosexual transmission of HIV.

OBJECTIVES

1. To assess the frequency of transmission of HIV from recipients of anti-HIV-positive blood to their sexual partners.

2. To identify risk factors associated with heterosexual transmission of HIV.

3. To monitor the natural history of HIV infection. (Anti-HIV negative sexual partners of anti-HIV positive persons have the highest risk of seroconversion in our study, allowing for obsevation before and after infection).

4. To evaluate to what extent secondarily infected individuals (i.e. sexual partners) may be exposing others to HIV.

SCIENTIFIC QUESTIONS TO BE ASKED

1. To what extent are sexual partners of persons who receive a unit of anti-HIV-positive blood at risk of developing HIV infection?

2. Are certain types of sexual practices associated with the risk of transmission?

3. Is the risk of male-to-female sexual transmission of HIV different than the risk of female-to-male transmission?

4. Is the risk of transmission of HIV directly related to the frequency of unsafe sexual practices?

5. Does the health or immunologic status of the infected individual and/or the sexual partner affect the risk of transmission?

STUDY POPULATION

Only the primary sexual partners of recipients participating in the Prospective Study of Anti-HIV-Positive Donors and their Recipients (IRB reference #04083) will be eligible. A primary sexual partner is the spouse, spouse equivalent or other regular sexual partner identified by the recipient. This individual must meet the following criteria: 1) Has had vaginal, anal or oral sex with the recipient since the implicated transfusion. 2) Is 18 years of age or older. 3) Is expected to be available for further observation for a period of one to three years.

PROCEDURES

The patient manager will discuss with enrolled recipients the "sub-study" of sexual partners of persons transfused with anti-HIV-positive blood. Recipients will be encouraged to ask their primary sexual partners to participate in the study.

If the recipient agrees, the patient manager will request that the recipient either: (1) Arrange for the sexual partner to get in touch with the patient manager if he/she wishes to participate, or (2) notify the patient manager of the sexual partner's decision about participation.

If no response is received within two (2) weeks, the patient manager will contact the recipient, by telephone or mail, to identify the reason. If the recipient refuses to notify his/her sexual partner, no further action will be taken.

The study will be explained to the sexual partner by the patient manager. After obtaining informed consent, the patient manager will conduct the entry interview, which will contain questions about medical history, present health, and patterns of behavior, including sexual practices and recreational intravenous drug use. The patient manager will then conduct a partial physical examination, including height, weight, temperature, and examination of the mouth, exposed skin, and lymph nodes in the head and neck. If any abnormalities are found, a physician on the study staff will conduct a more complete physical examination, which will include checking for hepatosplenomegaly and a more extensive examination of the skin and lymph nodes, including axillary and inguinal nodes. The patient manager will also draw a sample of blood. The blood collection procedure, including the amount of blood to be drawn, is specified in the manual of operations.

The procedure for handling the completed questionnaires, physical exam records, and blood specimens is described in the manual of operations.

Results of the serologic tests will be reported to subjects, or their physicians if they so desire, as soon as they are available. If the subject is to be informed directly, every effort will be made to do this in person. Guidelines for safe sexual practices will also be discussed.

All subjects entered into the study will be placed into one of three categories based on symptoms, signs on physical exam, and laboratory findings: asymptomatic, AIDS-related findings, or AIDS. These categories are defined in the manual of operations and willbe consistent with CDC criteria. Subjects who are asymptomatic will be followed at six-month intervals. Subjects with AIDS-related findings or AIDS at entry into the study will be followed every three months. Subjects who are asymptomatic at entry but who subsequently present with symptoms will be reclassified and followed at three-month intervals. Symptoms and/or findings related to conditions other than AIDS may also make subjects eligible for special follow-up.

For each sexual partner participating in the study, a schedule of dates for follow-up visits will be kept in the central record. One month before the scheduled visit the patient manager will contact the sexual partner to arrange the time and site for the visit. The follow-up visit should occur within one month of the date scheduled in the record.

Each follow-up visit will include a shorter version of the entry interview, a physical examination, and drawing a sample of blood, as described above.

REFERENCES

1. Centers for Disease Control. Human immunodeficiency virus infection in tranfusion recipients and their family members. MMWR 1987;36:137-140.

2. Centers for Disease Control. Immunodeficiency among female sexual partners of males with acquired immune deficiency syndrome (AIDS) New York. MMWR 1983;31:697-8.

3. Redfield RR, Markham PD, Salahuddin SZ, et al. Frequent transmission of HTLV-III among spouses of patients with AIDS-related complex and AIDS. JAMA 1985;253:1571-3.

4. Fischl MA, Dickenson GA, Scott GB, Klimas N, Fletcher MA, Parks W. Evaluations of heterosexual partners, children, and household contacts of adults with AIDS. JAMA 1987;257:640-4.

5. Kreiss JK, Kitchen LW, Prince HE, Kasper CK, Essex M. Antibody to human T-lymphotropic virus type III in wives of hemophiliacs: evidence for heterosexual transmission. Ann Intern Med 1985;102:623-6.

6. Operskalski E. Transmission of human immmunodeficiency virus infection to household contacts of persons with congenital hematolgic disorders. Blood 1986:68;131a.

7. Centers for Disease Control. HIV infection and pregnancies in sexual partners of HIV-seropositive hemophilic men - United States. MMWR 1987;36:593-595.