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# AIDS EDUCATION AND THE PREVENTION OF TRANSFUSION-TRANSMITTED HIV INFECTION IN THE UNITED STATES

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## INTRODUCTION

Beginning in 1982—when AIDS was first suspected to be a blood-borne disease—and continuing until the present time, education for blood donors has been a principal public health strategy for preventing transfusion-transmitted HIV infections in the United States. Initially, the U. S. Public Health Service (USPHS) used epidemiological data obtained from studies of unusual opportunistic illnesses in male homosexuals, intravenous drug users and hemophiliacs to formulate preliminary surveillance definitions for "risk groups" for AIDS. These definitions were disseminated as educational messages via the Department of Health and Human Services (HHS), as well as by the USPHS Interagency AIDS Task Force, which included the Center for Disease Control (CDC), Food and Drug Administration (FDA), and National Institutes of Health (NIH). As the regulatory agency of the USPHS, the FDA disseminated regulatory communications about AIDS and transfusion-transmitted HIV infection for implementation by FDA-licensed blood collection sites. National organizations representing blood collectors, namely, the American Association of Blood Banks (AABB), American Red Cross (ARC), and the Council of Community Blood Centers (CCBC) promulgated these educational messages to constituent blood centers and blood banks. The following chapter presents a chronology of the development of these various education programs, their rationale, and their evolution as new scientific information became available. The unique interactions of the federal regulatory agency (FDA), the blood collection organizations (AABB, ARC, CCBC) and the public reflect norms of the American culture during the early years of the AIDS epidemic in the United States.

## AIDS EDUCATION BEFORE THE HIV ANTIBODY TEST (1982–5)

In December, 1982, the first report of a case of "possible transfusion-transmitted AIDS" was published in the CDC's *Morbidity and Mortality Weekly Report* (*MMWR*), add-

*AIDS Education*, edited by Schenker et al.
Plenum Press, New York, 1996

ing to the growing concern that AIDS was being spread by blood transfusions.[1] Despite vigorous efforts, no infectious agent had been isolated from AIDS patients and no laboratory test consistently detected a serological marker that could be used to identify persons suspected of transmitting AIDS. In the absence of a laboratory test to screen potential blood donors, an educational program was initiated to inform potential blood donors about AIDS and to request persons at increased risk of AIDS to refrain from donating blood. On January 13, 1983, the AABB, ARC and CCBC issued a Joint Statement calling on "blood banks and transfusion services [to] further extend educational campaigns to physicians to balance the decision to use each blood component against the risks of transfusion", and on blood collectors to make "reasonable attempts to limit blood donation from individuals or groups that may have an unacceptably high risk of AIDS."[2]

On March 24, 1983, the FDA promulgated the first federal regulation establishing requirements for blood donor AIDS education. FDA required blood collectors to establish education programs for all potential blood donors and, in addition, to include an educational component as part of the donor screening process:

> Educational programs should be instituted to inform persons at increased risk of AIDS that until the AIDS problem is resolved or definitive tests become available, they should refrain from blood donation because of the potential risk to recipients of their blood. As presently defined this group includes: persons with symptoms and signs suggestive of AIDS, sexually active homosexual or bisexual men with multiple partners, Haitian entrants to the United States, present or past abusers of intravenous drugs, and sexual partners of individuals at increased risk of AIDS. Educational programs should include the individual donor as part of the donor screening procedure.[3]

FDA also called on blood services to establish educational programs for nurses and other personnel working at blood collection sites to ensure uniform donor screening standards nationwide.[3]

Shortly thereafter, these FDA requirements were implemented by the blood collectors in the United States. It should be apparent in retrospect—as it was apparent in 1983–5—that voluntary exclusion of blood donations from persons with *symptomatic* AIDS addressed only the "tip of the iceberg" and additional measures, including a specific laboratory screening test, were needed to exclude potentially infective *asymptomatic* carriers. This concept—educating people about AIDS and requesting persons in risk groups for AIDS to refrain from donating blood—remains a key strategy for preventing transfusion-transmitted HIV infection in the United States. While the introduction of the HIV antibody test in 1985 has had a major impact on blood transfusion safety, this laboratory test is not 100% effective and, therefore, donor education remains the key factor in reducing transfusion-transmitted HIV infections.

## IMPACT OF THE HIV ANTIBODY TEST ON AIDS EDUCATION FOR BLOOD DONORS

In March 1985, FDA issued the first license to a manufacturer of an enzyme immunoassay (EIA) for antibody to human T-lymphotropic virus, type III (HTLV-III). The name of the virus (and, thus, test kits) was changed subsequently to the human immunodeficiency virus (HIV). Within a few weeks after the test kit's license was issued, blood collectors in the United States were testing donated blood for HIV antibody and discarding blood units that tested "repeatedly reactive" (provisionally positive).

Widespread implementation of the HIV antibody test by blood services in the United States required a new educational message. Since the HIV antibody test would be available without charge to potential blood donors, there was concern that some people who were at risk of AIDS would use blood donation as a means to obtain a free and, presumably, confidential test for HIV antibody. Since the HIV antibody test was not 100% effective, people who were at risk for HIV infection and donated blood might spread HIV after testing negative ("falsely negative" test results). Their donations would *decrease*, rather than *increase*, the safety of blood transfusions. To avert this so-called "magnet effect", Red Cross required all blood centers to ensure that free testing for HIV antibody would be available elsewhere in the community before the blood center could begin routine testing for HIV antibody. In many communities, Red Cross Blood Services offered free testing services themselves because timely implementation at such proposed alternative sites was not happening. Educational programs were initiated nationwide urging people who were at risk for AIDS not to use blood donation as a means of determining their HIV antibody status.

During the first six months of testing for HIV antibody, medical directors in Red Cross regional blood centers interviewed blood donors whose EIA test results were repeatedly reactive for HIV antibody. The purpose of these confidential interviews was to identify the donors' risk behaviors for HIV infection and to determine why the Red Cross predonation educational materials did not result in their self-deferral. There were two important outcomes from these early follow up interviews with HIV-seropositive blood donors. First, there was a remarkable correlation between the risk groups identified among the HIV-seropositive deferred blood donors and the risk groups for AIDS that had been previously identified by the USPHS, confirming the accuracy (specificity) of the HIV antibody test in an operational setting. For both groups, more than 90% of persons could be categorized as sexually active male homosexuals or bisexual men with multiple sex partners, present or past abusers of intravenous drugs, or Haitian entrants into the United States. Persons with hemophilia accounted for approximately six percent of AIDS patients in the United States at that time, but none were blood donors. As soon as the results of these interviews were available and recognized to validate the accuracy of the HIV antibody test in actual donor operations, Red Cross and other blood collectors began notifying blood donors about HIV-seropositive EIA results and counseling them about the health implications.

The second important outcome of these interviews was early feedback that educational messages defining risk for HIV in terms of "risk groups," rather than "risk behaviors," contributed to misinterpretations by some donors. Several HIV-seropositive male donors admitted that they had had sex with other men, but they explained that they did not self-defer as blood donors because they did not identify themselves as male homosexuals. To simplify the educational message, HIV risk groups were redefined in terms of risk behaviors (see below).

## AIDS EDUCATION FOR BLOOD DONORS AFTER IMPLEMENTATION OF THE HIV ANTIBODY TEST (1986–96)

By late Spring 1985. all donated blood in the United States was being tested for HIV antibody. The HIV antibody test was quickly recognized to be essentially 100% effective (sensitive) for detecting persons who had an HIV infection for at least six months, that is, for the time required to develop a sufficiently high titer of HIV antibody to be detectable by the (first generation) EIA. With the HIV antibody test in place, the risk to transfusion recipients shifted to donors whose HIV infections were too recent to be detected by the antibody test, that is, donors whose blood was collected within the 6-week-to-6-month seronegative win-

dow period. To address this change, educational messages were modified and risk was redefined in terms of "risk behaviors". Red Cross' predonation pamphlet was updated and listed the following revised categories for donor self-deferral:[4]

- Any man who has had sex with another man since 1977, even if only once;
- Any person who has ever used illegal drugs by needle;
- Any native of Haiti, sub-Saharan Africa, or an island close to sub-Saharan Africa who has entered the United States since 1977;
- Anyone with AIDS or one of its signs or symptoms;
- Anyone with a history of a confirmed positive test for antibodies to the AIDS virus;
- Any hemophiliac who has received clotting factor concentrate since 1977;
- Any sex partner (since 1977) of any of the persons described in categories above;
- Any person who has engaged in prostitution at any time since 1977; and
- Any male who has had contact with a female prostitute, and any female who has had contact with a male prostitute in the 6 months prior to donation.

## HIV SEROEPIDEMIOLOGY: THE BASIS FOR AIDS EDUCATION MESSAGES

Presently, in the United States AIDS, educational messages are developed using the results of HIV seroepedemiological studies conducted in specific at-risk populations. The pertinent studies are too numerous to list, but the following three examples illustrate how HIV/AIDS educational messages are formulated.

### AIDS Education for Potential Recipients of Blood Transfusions

The most frequently asked question by potential recipients of a blood transfusion is, "What is the chance that I'll develop AIDS from a blood transfusion?" No precise answer to this question is possible. However, several seroepidemiological studies have been conducted in the United States using the HIV antibody test to provide the information needed to make a reasonable estimate. The most recent study was conducted by USPHS/CDC investigators who analyzed 4,119,095 blood donations in 19 Red Cross regions.[5] There were 318 HIV seropositive donations (7.7 per 100,000). They determined that 1 in every 360,000 donations was made during the seronegative window period, projecting to 1 undetected HIV-infective blood unit in every 450,000—600,000 units. From these data, educational messages have been formulated and, presently, potential recipients of blood transfusions in the United States are informed that the chance is approximately 1 in 500,000 that each unit of blood will be capable of transmitting an HIV infection.

### AIDS Education for Heterosexual Blood Donors

To monitor the spread of HIV in heterosexuals, investigators from the CDC and certain municipal health departments conducted a seroepidemiological study testing anonymous blood samples from persons attending clinics for sexually transmitted diseases (STDs).[6] For 552,665 specimens tested, the overall seroprevalence was 33 percent, with a geographic range of 5–52 percent. The results of the study "suggest that racial and ethnic disparate are becoming greater among heterosexual men and women, as well as gay and bisexual men."[6]

While HIV prevalence appeared to decrease among white men and women—including white homosexual men—it was remaining stable among African-Americans. The investigators noted that "the results reflect a shift in the HIV epidemic as it becomes increasingly characterized by infected heterosexuals and intravenous drug users, especially within minority populations."[6] These findings provide a basis for updating AIDS educational messages for potential blood donors with increasing emphasis on educating specific minority populations.

## AIDS Education for College-Age Blood Donors

To increase the information available on HIV infection among college students in the United States, the American College Health Association conducted a serosurvey in 1989–90 of 20,380 students at 10 large state universities and 25 randomly selected colleges. The results were reported in the September 1995 issue of *CDC HIV/AIDS Prevention*. There were 39 HIV-seropositive students (prevalence 0.19). More importantly, however, only 11 of the 39 infected students (28%) were aware of their infection at the time blood samples were obtained. These new data provided resulted in increased efforts for offering confidential HIV counseling, testing and prevention programs for college students. Such programs are important because bloodmobiles on college campuses are a significant source for blood in many communities in the United States. The lesson of this study was that educating donors to self-defer from blood donation will not work when donors do not perceive themselves to be at-risk. Large scale testing of young adults may be needed to help them recognize the shifting demographics of the HIV epidemic.

# CURRENT BLOOD DONOR QUESTIONNAIRES AND QUALIFICATIONS

The current questionnaire and qualification for blood donors in the United States is the product of 13 years of continuous modifications based on results of interviews with HIV-seropositive donors, seroepedemiologic studies and national consensus conferences. The current Red Cross predonation educational message is as follows:

*Do not give blood if you have-*

- Had hepatitis on or after age 11. Some individuals with this liver disease cannot give blood.
- Had malaria or have taken drugs to prevent malaria in the past 3 years.
- Been treated for syphilis or gonorrhea in the last 12 months.
- AIDS or one of its symptoms, including:
  - Unexplained weight loss (10 pounds or more in less than 12 months).
  - Night sweats.
  - Blue or purple spots on or under the skin.
  - Long-lasting white spots or unusual sores in your mouth.
  - Lumps in your neck, armpits, or groin, lasting over a month.
  - Diarrhea lasting over a month.
  - Persistent cough and shortness of breath.
  - Fever higher than 99°F lasting more than 10 days.
- Done something that might mean your blood is infected with HIV-1 or -2, the viruses that cause AIDS.

*You are at risk of AIDS if you have-*

- Taken ("shot up") illegal drugs by needle, even once.
- Taken clotting factor concentrates for a bleeding disorder such as hemophilia.
- Tested positive for any AIDS virus or antibody.
- Been given money or drugs for sex, since 1977.
- Had a sexual partner who puts you at risk of AIDS. This means-
  - You have had sex within the last 12 months with someone who is at risk of AIDS (described above).
  - *For men:* Since 1977, has sex *even once* with another man. Within the last 12 months, had sex with a female prostitute.
  - *For women:* Within the last 12 months, had sex with a male or female prostitute *or* had a male sexual partner who had sex with another man *even once* since 1977.

## SUMMARY

For AIDS education messages to be effective they must be simple and readily understandable by intended recipients. This task is best accomplished by separating the various messages so they can be written in language that is specific for the intended audience, namely, male homosexuals, heterosexuals, intravenous drug users, and potential blood donors. In the United States, educational messages for blood donors have been formulated by the USPHS since 1983 as uniform, nationwide and, in certain situations, federally-regulated components of the blood donor screening process. Although the HIV antibody test has been highly effective in reducing the incidence of transfusion-transmitted AIDS, the persistence of a vulnerable seronegative window period requires continuous donor education to inform persons at risk for AIDS/HIV that they must not donate blood. To ensure the accuracy and timeliness of these educational messages, they are continuously updated using results of specific HIV seroepedemicological surveys in the United States.

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