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MORBIDITY AND MORTALITY WEEKLY REPORT

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Provisional Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome

In March 1983, the U.S. Public Health Service issued inter-agency recommendations on the prevention of acquired immunodeficiency syndrome (AIDS) (*1*). Included was the recommendation that members of groups at increased risk for AIDS should refrain from donating plasma and/or blood. That recommendation was made to decrease the risk of AIDS associated with the administration of blood or blood products, which accounts for about 2% of all reported AIDS cases in the United States.

Evidence has shown that a newly recognized retrovirus is the cause of AIDS. Although this virus has been given several names, including human T-lymphotropic virus type III (HTLV-III) (*2*), lymphadenopathy-associated virus (LAV) (*3*), and AIDS-associated retrovirus (ARV) (*4*), it is referred to as HTLV-III in this discussion. Tests to detect antibody to HTLV-III will be licensed and commercially available in the United States in the near future to screen blood and plasma for laboratory evidence of infection with the virus. The antibody tests are modifications of the enzyme-linked immunosorbent assay (ELISA), which uses antigens derived from whole disrupted HTLV-III (*5*).

There is considerable experience with the ELISA test in research laboratories, but much additional information will be gathered following its widespread application. In the early phases of testing, a number of false-positive tests may be encountered. Adjustments in interpretation are anticipated as more is learned about the performance of the test in an individual laboratory and about the specific proportion of falsely positive or falsely negative tests in the screening setting where the test is used.

The present recommendations concern the use of these tests to screen blood and plasma collected for transfusion or manufactured into other products. They are intended to supplement, rather than replace, the U.S. Food and Drug Administration's recently revised recommendations to blood and plasma collection facilities and the earlier inter-agency recommendations (*1*). Additional public health applications of these tests in the understanding and control of AIDS will be described in a subsequent report.

BACKGROUND

Antibody Detection Studies

The ELISA test has been used in many research programs for detecting antibodies to HTLV-III in patients with AIDS and with AIDS-related conditions. In different studies, HTLV-III antibody was found to range from 68% to 100% of patients with AIDS, and in 84%-100% of persons with related conditions, such as unexplained generalized lymphadenopathy (*5-7*). Serologic surveys have yielded variable seropositivity rates in groups at increased risk for AIDS: 22%-65% of homosexual men (*8-11*), 87% of intravenous-drug abusers admitted to a detoxification program in New York City (*12*), 56%-72% of persons with hemophilia A (*13,14*), and 35% of women who were sexual partners of men with AIDS (*15*). In contrast to

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the above groups, HTLV-III antibody has been detected in fewer than 1% of persons with no known risks for AIDS (*4-10*).

The time needed to develop a positive antibody test following infection is not known. Data regarding the interval between infection with HTLV-III and seroconversion are limited. A nurse who sustained a needle-stick injury while caring for an AIDS patient developed antibody between 4 and 7 weeks following exposure (*16*). Additionally, a recent study described several asymptomatic individuals infected with HTLV-III for more than 6 months in the absence of detectable antibody (*17,18*). Nonetheless, currently available ELISA tests can be expected to identify most persons with HTLV-III infection.

Virus Isolation Studies

HTLV-III has been isolated from blood, semen, and saliva and has been recovered from many individuals in the presence of antibody (*19,20*). HTLV-III has been isolated from the blood of 85% or more of seropositive individuals with AIDS (*21*), lymphadenopathy, or other AIDS-associated conditions (*2*) and from three of four mothers of infants with AIDS (*2*). The virus has also been isolated from asymptomatic seropositive homosexual men and hemophiliacs, and has been recovered from 95% of seropositive high-risk blood donors who had been implicated in the transmission of AIDS through transfusion (*21*). The recovery of HTLV-III from these high-risk donors 2 or more years after their initial donation provides evidence that viremia may persist for years in both asymptomatic and symptomatic individuals. HTLV-III has also been isolated from some asymptomatic seronegative persons, but this is the exception (*17*).

Modes of Transmission

Epidemiologic data suggest that the virus has been transmitted through intimate sexual contact; sharing contaminated needles; transfusion of whole blood, blood cellular components, plasma; or clotting factor concentrates that have not been heat treated; or from infected mother to child before, at, or shortly after the time of birth. No other products prepared from blood (e.g., immunoglobulin, albumin, plasma protein fraction, hepatitis B vaccine) have been implicated, nor have cases been documented to occur through such common exposures as sharing meals, sneezing or coughing, or other casual contact.

Natural History of Infection

Information about the course of infection with HTLV-III is incomplete, but the majority of infected adults will not acquire clinically apparent AIDS in the first few years after infection. In some studies 5%-19% of seropositive homosexual men developed AIDS within 2-5 years after a previously collected serum sample was retrospectively tested and found to be seropositive. An additional 25% developed generalized lymphadenopathy, oral candidiasis, or other AIDS-associated conditions within the same interval (*11,22*). The long-term prognosis for most persons infected with HTLV-III is unknown.

SCREENING BLOOD AND PLASMA

Initial Testing

Persons accepted as donors should be informed that their blood or plasma will be tested for HTLV-III antibody. Persons not wishing to have their blood or plasma tested must refrain from donation. Donors should be told that they will be notified if their test is positive and that they may be placed on the collection facility's donor deferral list, as is currently practiced with other infectious diseases, and should be informed of the identities of additional deferral lists to which the positive donors may be added.

All blood or plasma should be tested for HTLV-III antibody by ELISA. Any blood or plasma that is positive on initial testing must not be transfused or manufactured into other products capable of transmitting infectious agents.

When the ELISA is used to screen populations in whom the prevalence of HTLV-III infections is low, the proportion of positive results that are falsely positive will be high. Therefore,

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the ELISA should be repeated on all seropositive specimens before the donor is notified. If the repeat ELISA test is negative, the specimen should be tested by another test.

Other Testing

Other tests have included immunofluorescence and radioimmunoprecipitation assays, but the most extensive experience has been with the Western blot technique (22), in which antibodies can be detected to HTLV-III proteins of specific molecular weights. Based on available data, the Western blot should be considered positive for antibody to HTLV-III if band p24 or gp41 is present (alone or in combination with other bands).

Notification of Donors

If the repeat ELISA test is positive or if other tests are positive, it is the responsibility of the collection facility to ensure that the donor is notified. The information should be given to the donor by an individual especially aware of the sensitivities involved. At present, the proportion of these seropositive donors who have been infected with HTLV-III is not known. It is, therefore, important to emphasize to the donor that the positive result is a preliminary finding that may not represent true infection. To determine the significance of a positive test, the donor should be referred to a physician for evaluation. The information should be given to the donor in a manner to ensure confidentiality of the results and of the donor's identify.

Maintaining Confidentiality

Physicians, laboratory and nursing personnel, and others should recognize the importance of maintaining confidentiality of positive test results. Disclosure of this information for purposes other than medical or public health could lead to serious consequences for the individual. Screening procedures should be designed with safeguards to protect against unauthorized disclosure. Donors should be given a clear explanation of how information about them will be handled. Facilities should consider developing contingency plans in the event that disclosure is sought through legal process. If donor deferral lists are kept, it is necessary to maintain confidentiality of such lists. Whenever appropriate, as an additional safeguard, donor deferral lists should be general, without indication of the reason for inclusion.

Medical Evaluation

The evaluation might include ELISA testing of a follow-up serum specimen and Western blot testing, if the specimen is positive. Persons who continue to show serologic evidence of HTLV-III infection should be questioned about possible exposure to the virus or possible risk factors for AIDS in the individual or his/her sexual contacts and examined for signs of AIDS or related conditions, such as lymphadenopathy, oral candidiasis, Kaposi's sarcoma, and unexplained weight loss. Additional laboratory studies might include tests for other sexually transmitted diseases, tests of immune function, and where available, tests for the presence of the virus, such as viral culture. Testing for antibodies to HTLV-III in the individual's sexual contacts may also be useful in establishing whether the test results truly represent infection.

RECOMMENDATIONS FOR THE INDIVIDUAL

An individual judged most likely to have an HTLV-III infection should be provided the following information and advice:

1. The prognosis for an individual infected with HTLV-III over the long term is not known. However, data available from studies conducted among homosexual men indicate that most persons will remain infected.
2. Although asymptomatic, these individuals may transmit HTLV-III to others. Regular medical evaluation and follow-up is advised, especially for individuals who develop signs or symptoms suggestive of AIDS.
3. Refrain from donating blood, plasma, body organs, other tissue, or sperm.
4. There is a risk of infecting others by sexual intercourse, sharing of needles, and possibly, exposure of others to saliva through oral-genital contact or intimate kissing. The

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efficacy of condoms in preventing infection with HTLV-III is unproven, but the consistent use of them may reduce transmission.

5. Toothbrushes, razors, or other implements that could become contaminated with blood should not be shared.
6. Women with a seropositive test, or women whose sexual partner is seropositive, are themselves at increased risk of acquiring AIDS. If they become pregnant, their offspring are also at increased risk of acquiring AIDS.
7. After accidents resulting in bleeding, contaminated surfaces should be cleaned with household bleach freshly diluted 1:10 in water.
8. Devices that have punctured the skin, such as hypodermic and acupuncture needles, should be steam sterilized by autoclave before reuse or safely discarded. Whenever possible, disposable needles and equipment should be used.
9. When seeking medical or dental care for intercurrent illness, these persons should inform those responsible for their care of their positive antibody status so that appropriate evaluation can be undertaken and precautions taken to prevent transmission to others.
10. Testing for HTLV-III antibody should be offered to persons who may have been infected as a result of their contact with seropositive individuals (e.g., sexual partners, persons with whom needles have been shared, infants born to seropositive mothers).

Revised recommendations will be published as additional information becomes available and additional experience is gained with this test.

Reported by Centers for Disease Control; Food and Drug Administration; Alcohol, Drug Abuse, and Mental Health Administration; National Institutes of Health; Health Resources and Services Administration.

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Poliomyelitis — Finland

As of January 9, 1985, four cases of paralytic and one case of nonparalytic poliomyelitis had been diagnosed and confirmed during the previous 2 months from various parts of Finland, including the vicinities of Helsinki and Turku. The outbreak apparently began in late October 1984; when a 6-year-old boy developed aseptic meningitis; type 3 poliovirus was isolated from his stool. In mid-November, paralytic poliomyelitis occurred in a 17-year-old male who had previously received five doses of inactivated poliomyelitis vaccine (IPV). Subsequently, three other cases of paralytic poliomyelitis were diagnosed from mid-November to mid-December. One patient, a 12-year-old boy, had previously received five doses of IPV; one, a 31-year-old pregnant woman, was unvaccinated; and one, a 33-year-old man with Hodgkin's disease, was incompletely immunized. Poliovirus type 3 was isolated from stool specimens of all four individuals with paralytic disease; these isolates have been characterized as "not vaccine-like" by the method of van Wezel (*1*). Poliovirus type 3 has also been isolated from approximately 15% of 700 stool samples or throat swabs from children without clinical illness, most of whom were residents of communities with cases.

Since 1960, routine vaccination against poliomyelitis using IPV has been performed in Finland. Before this outbreak, paralytic poliomyelitis was last reported in Finland in 1964. Sewage surveys conducted from 1971-1981 had failed to detect any poliovirus. Epidemiologic investigations are currently being conducted. All children 6 months to 18 years old have been given an additional dose of IPV. Vaccination of the entire population with oral poliomyelitis vaccine (OPV) is to begin soon.

Reported by National Board of Health, Government of Finland; Div of Immunization, Center for Prevention Svcs, CDC.

Editorial Note: In developed countries, such as Japan, Australia, New Zealand, Canada, and the countries of industrialized Europe, the risk of acquiring poliomyelitis is usually no greater than in the United States. In contrast, all developing countries should generally be considered endemic for poliomyelitis. Proof of poliomyelitis immunization is not required for international travel. However, the Immunization Practices Advisory Committee (ACIP) recommends that travelers to countries where poliomyelitis is occurring—which now includes Finland—be immunized. Schedules for primary immunization against poliomyelitis require three or more doses. In general, OPV is the vaccine of choice for persons under 18 years of age. Unimmunized adults (18 years and older) should receive at least two doses of IPV, 4 or more weeks apart, and preferably a complete primary series, before traveling; if an individual's travel plans