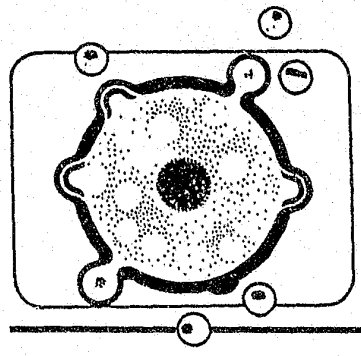

Acquired Immunodeficiency Syndrome

# AIDS

# Recommendations and Guidelines

## November 1982 - December 1987



Centers for Disease Control
Atlanta, Georgia 30333

PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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# TABLE OF CONTENTS

## IV. PATIENTS WITH SPECIAL DISEASE CONDITIONS (CONTINUED)



## V. DONORS OF BODY FLUIDS AND TISSUES



## VI. VACCINES



## VII. MATERNAL AND CHILD HEALTH



## VIII. WORLD HEALTH ORGANIZATION GUIDELINES

# I. GENERAL RECOMMENDATIONS & GUIDELINES

1983 March 4;32:101-03

## Prevention of Acquired Immune Deficiency Syndrome (AIDS): Report of Inter-Agency Recommendations

Since June 1981, over 1,200 cases of acquired immune deficiency syndrome (AIDS) have been reported to CDC from 34 states, the District of Columbia, and 15 countries. Reported cases of AIDS include persons with Kaposi's sarcoma who are under age 60 years and/or persons with life-threatening opportunistic infections with no known underlying cause for immune deficiency. Over 450 persons have died from AIDS, and the case-fatality rate exceeds 60% for cases first diagnosed over 1 year previously (*1,2*). Reports have gradually increased in number. An average of one case per day was reported during 1981, compared with three to four daily in late 1982 and early 1983. Current epidemiologic evidence identifies several groups in the United States at increased risk for developing AIDS (*3-7*). Most cases have been reported among homosexual men with multiple sexual partners, abusers of intravenous (IV) drugs, and Haitians, especially those who have entered the country within the past few years. However, each group contains many persons who probably have little risk of acquiring AIDS. Recently, 11 cases of unexplained, life-threatening opportunistic infections and cellular immune deficiency have been diagnosed in patients with hemophilia. Available data suggest that the severe disorder of immune regulation underlying AIDS is caused by a transmissible agent.

A national case-control study and an investigation of a cluster of cases among homosexual men in California indicate that AIDS may be sexually transmitted among homosexual or bisexual men (*8,9*). AIDS cases were recently reported among women who were steady sexual partners of men with AIDS or of men in high-risk groups, suggesting the possibility of heterosexual transmission (*10*). Recent reports of unexplained cellular immunodeficiencies and opportunistic infections in infants born to mothers from groups at high risk for AIDS have raised concerns about in utero or perinatal transmission of AIDS (*11*). Very little is known about risk factors for Haitians with AIDS.

The distribution of AIDS cases parallels that of hepatitis B virus infection, which is transmitted sexually and parenterally. Blood products or blood appear responsible for AIDS among hemophilia patients who require clotting factor replacement. The likelihood of blood transmission is supported by the occurrence of AIDS among IV drug abusers. Many drug abusers share contaminated needles, exposing themselves to blood-borne agents, such as hepatitis B virus. Recently, an infant developed severe immune deficiency and an opportunistic infection several months after receiving a transfusion of platelets derived from the blood of a man subsequently found to have AIDS (*12*). The possibility of acquiring AIDS through blood components or blood is further suggested by several cases in persons with no known risk factors who have received blood products or blood within 3 years of AIDS diagnosis (*2*). These cases are currently under investigation.

No AIDS cases have been documented among health care or laboratory personnel caring for AIDS patients or processing laboratory specimens. To date, no person-to-person transmission has been identified other than through intimate contact or blood transfusion.

Several factors indicate that individuals at risk for transmitting AIDS may be difficult to identify. A New York City study showed that a significant proportion of homosexual men who were asymptomatic or who had nonspecific symptoms or signs (such as generalized lymphadenopathy) had altered immune functions demonstrated by in vitro tests (*2,13,14*). Similar findings have been reported among patients with hemophilia (*2,15,16*). Although the significance of these immunologic alterations is not yet clear, their occurrence in at least two groups at high risk for AIDS suggests that the pool of persons potentially capable of transmitting an AIDS agent may be considerably larger than the presently known number of AIDS cases. Furthermore, the California cluster investigation and other epidemiologic findings sug-

gest a "latent period" of several months to 2 years between exposure and recognizable clinical illness and imply that transmissibility may precede recognizable illness. Thus, careful histories and physical examinations alone will not identify all persons capable of transmitting AIDS but should be useful in identifying persons with definite AIDS diagnoses or related symptoms, such as generalized lymphadenopathy, unexplained weight loss, and thrush. Since only a small percentage of members of high-risk groups actually has AIDS, a laboratory test is clearly needed to identify those with AIDS or those at highest risk of acquiring AIDS. For the above reasons, persons who may be considered at increased risk of AIDS include those with symptoms and signs suggestive of AIDS; sexual partners of AIDS patients; sexually active homosexual or bisexual men with multiple partners; Haitian entrants to the United States; present or past abusers of IV drugs; patients with hemophilia, and sexual partners of individuals at increased risk for AIDS.

Statements on prevention and control of AIDS have been issued by the National Gay Task Force, the National Hemophilia Foundation, the American Red Cross, the American Association of Blood Banks, the Council of Community Blood Centers, the American Association of Physicians for Human Rights, and others. These groups agree that steps should be implemented to reduce the potential risk of transmitting AIDS through blood products, but differ in the methods proposed to accomplish this goal. Public health agencies, community organizations, and medical organizations and groups share the responsibility to rapidly disseminate information on AIDS and recommended precautions.

Although the cause of AIDS remains unknown, the Public Health Service recommends the following actions:

1. Sexual contact should be avoided with persons known or suspected to have AIDS. Members of high risk groups should be aware that multiple sexual partners increase the probability of developing AIDS.
2. As a temporary measure, members of groups at increased risk for AIDS should refrain from donating plasma and/or blood. This recommendation includes all individuals belonging to such groups, even though many individuals are at little risk of AIDS. Centers collecting plasma and/or blood should inform potential donors of this recommendation. The Food and Drug Administration (FDA) is preparing new recommendations for manufacturers of plasma derivatives and for establishments collecting plasma or blood. This is an interim measure to protect recipients of blood products and blood until specific laboratory tests are available.
3. Studies should be conducted to evaluate screening procedures for their effectiveness in identifying and excluding plasma and blood with a high probability of transmitting AIDS. These procedures should include specific laboratory tests as well as careful histories and physical examinations.
4. Physicians should adhere strictly to medical indications for transfusions, and autologous blood transfusions are encouraged.
5. Work should continue toward development of safer blood products for use by hemophilia patients.

The National Hemophilia Foundation has made specific recommendations for management of patients with hemophilia (*17*).

The interim recommendation requesting that high-risk persons refrain from donating plasma and/or blood is especially important for donors whose plasma is recovered from plasmapheresis centers or other sources and pooled to make products that are not inactivated and may transmit infections, such as hepatitis B. The clear intent of this recommendation is to eliminate plasma and blood potentially containing the putative AIDS agent from the supply. Since no specific test is known to detect AIDS at an early stage in a potential donor, the recommendation to discourage donation must encompass all members of groups at increased risk for AIDS, even though it includes many individuals who may be at little risk of transmitting AIDS.

As long as the cause remains unknown, the ability to understand the natural history of AIDS and to undertake preventive measures is somewhat compromised. However, the above recommendations are prudent measures that should reduce the risk of acquiring and transmitting AIDS.

*Reported by the Centers for Disease Control, the Food and Drug Administration, and the National Institutes of Health.*

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# Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus in the Workplace

## Summary:

The information and recommendations contained in this document have been developed with particular emphasis on health-care workers and others in related occupations in which exposure might occur to blood from persons infected with HTLV-III/LAV, the "AIDS virus." Because of public concern about the purported risk of transmission of HTLV-III/LAV by persons providing personal services and those preparing and serving food and beverages, this document also addresses personal-service and food-service workers. Finally, it addresses "other workers"—persons in settings, such as offices, schools, factories, and construction sites, where there is no known risk of AIDS virus transmission.

Because AIDS is a bloodborne, sexually transmitted disease that is not spread by casual contact, this document does *not* recommend routine HTLV-III/LAV antibody screening for the groups addressed. Because AIDS is not transmitted through preparation or serving of food and beverages, these recommendations state that food-service workers known to be infected with AIDS should not be restricted from work unless they have another infection or illness for which such restriction would be warranted.

This document contains detailed recommendations for precautions appropriate to prevent transmission of all bloodborne infectious diseases to people exposed—in the course of their duties—to blood from persons who may be infected with HTLV-III/LAV. They emphasize that health-care workers should take all possible precautions to prevent needlestick injury. The recommendations are based on the well-documented modes of HTLV-III/LAV transmission and incorporate a "worst case" scenario, the hepatitis B model of transmission. Because the hepatitis B virus is also bloodborne and is both hardier and more infectious than HTLV-III/LAV, recommendations that would prevent transmission of hepatitis B will also prevent transmission of AIDS.

Formulation of specific recommendations for health-care workers who perform invasive procedures is in progress

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Persons at increased risk of acquiring infection with human T-lymphotropic virus type III lymphadenopathy-associated virus (HTLV-III/LAV), the virus that causes acquired immunodeficiency syndrome (AIDS), include homosexual and bisexual men, intravenous (IV) drug abusers, persons transfused with contaminated blood or blood products, heterosexual contacts of persons with HTLV-III/LAV infection, and children born to infected mothers. HTLV-III/LAV is transmitted through sexual contact, parenteral exposure to infected blood or blood components, and perinatal transmission from mother to neonate. HTLV-III/LAV has been isolated from blood, semen, saliva, tears, breast milk, and urine and is likely to be isolated from some other body fluids, secretions, and excretions, but epidemiologic evidence has implicated only blood and semen in transmission. Studies of nonsexual household contacts of AIDS patients indicate that casual contact with saliva and tears does not result in transmission of infection. Spread of infection to household contacts of infected persons has not been detected when the household contacts have not been sex partners or have not been infants of infected mothers. The kind of nonsexual person-to-person contact that generally occurs among workers and clients or consumers in the workplace does not pose a risk for transmission of HTLV-III/LAV.

As in the development of any such recommendations, the paramount consideration is the protection of the public's health. The following recommendations have been developed for all workers, particularly workers in occupations in which exposure might occur to blood from individuals infected with HTLV-III/LAV. These recommendations reinforce and supplement the specific recommendations that were published earlier for clinical and laboratory staffs (*1*) and for dental-care personnel and persons performing necropsies and morticians' services (*2*). Because of public concern about the purported risk of transmission of HTLV-III/LAV by persons providing personal services and by food and beverages, these recommendations contain infor-

mation and recommendations for personal-service and food-service workers. Finally, these recommendations address workplaces in general where there is no known risk of transmission of HTLV-III/LAV (e.g., offices, schools, factories, construction sites). Formulation of specific recommendations for health-care workers (HCWs) who perform invasive procedures (e.g., surgeons, dentists) is in progress. Separate recommendations are also being developed to prevent HTLV-III/LAV transmission in prisons, other correctional facilities, and institutions housing individuals who may exhibit uncontrollable behavior (e.g., custodial institutions) and in the perinatal setting. In addition, separate recommendations have already been developed for children in schools and day-care centers (*3*).

HTLV-III/LAV-infected individuals include those with AIDS (*4*); those diagnosed by their physician(s) as having other illnesses due to infection with HTLV-III/LAV; and those who have virologic or serologic evidence of infection with HTLV-III/LAV but who are not ill.

These recommendations are based on the well-documented modes of HTLV-III/LAV transmission identified in epidemiologic studies and on comparison with the hepatitis B experience. Other recommendations are based on the hepatitis B model of transmission.

## COMPARISON WITH THE HEPATITIS B VIRUS EXPERIENCE

The epidemiology of HTLV-III/LAV infection is similar to that of hepatitis B virus (HBV) infection, and much that has been learned over the last 15 years related to the risk of acquiring hepatitis B in the workplace can be applied to understanding the risk of HTLV-III/LAV transmission in the health-care and other occupational settings. Both viruses are transmitted through sexual contact, parenteral exposure to contaminated blood or blood products, and perinatal transmission from infected mothers to their offspring. Thus, some of the same major groups at high risk for HBV infection (e.g., homosexual men, IV drug abusers, persons with hemophilia, infants born to infected mothers) are also the groups at highest risk for HTLV-III/LAV infection. Neither HBV nor HTLV-III/LAV has been shown to be transmitted by casual contact in the workplace, contaminated food or water, or airborne or fecal-oral routes (*5*).

HBV infection is an occupational risk for HCWs, but this risk is related to degree of contact with blood or contaminated needles. HCWs who do not have contact with blood or needles contaminated with blood are not at risk for acquiring HBV infection in the workplace (*6-8*).

In the health-care setting, HBV transmission has not been documented between hospitalized patients, except in hemodialysis units, where blood contamination of the environment has been extensive or where HBV-positive blood from one patient has been transferred to another patient through contamination of instruments. Evidence of HBV transmission from HCWs to patients has been rare and limited to situations in which the HCWs exhibited high concentrations of virus in their blood (at least 100,000,000 infectious virus particles per ml of serum), and the HCWs sustained a puncture wound while performing traumatic procedures on patients or had exudative or weeping lesions that allowed virus to contaminate instruments or open wounds of patients (*9-11*).

Current evidence indicates that, despite epidemiologic similarities of HBV and HTLV-III/LAV infection, the risk for HBV transmission in health-care settings far exceeds that for HTLV-III LAV transmission. The risk of acquiring HBV infection following a needlestick from an HBV carrier ranges from 6% to 30% (*12,13*), far in excess of the risk of HTLV-III/LAV infection following a needlestick involving a source patient infected with HTLV-III/LAV, which is less than 1%. In addition, all HCWs who have been shown to transmit HBV infection in health-care settings have belonged to the subset of chronic HBV carriers who, when tested, have exhibited evidence of exceptionally high concentrations of virus (at least 100,000,000 infectious virus particles per ml) in their blood. Chronic carriers who have substantially lower concentrations of virus in their blood have not been implicated in transmission in the health-care setting (*9-11,14*). The HBV model thus represents a "worst case" condition in regard to transmission in health-care and other related settings. Therefore, recommendations for the control of HBV infection should, if followed, also effectively prevent spread of HTLV-III/LAV. Whether additional measures are indicated for those HCWs who perform invasive procedures will be addressed in the recommendations currently being developed.

Routine screening of all patients or HCWs for evidence of HBV infection has never been recommended. Control of HBV transmission in the health-care setting has emphasized the implementation of recommendations for the appropriate handling of blood, other body fluids, and items soiled with blood or other body fluids.

## TRANSMISSION FROM PATIENTS TO HEALTH-CARE WORKERS

HCWs include, but are not limited to, nurses, physicians, dentists and other dental workers, optometrists, podiatrists, chiropractors, laboratory and blood bank technologists and technicians, phlebotomists, dialysis personnel, paramedics, emergency medical technicians, medical examiners, morticians, housekeepers, laundry workers, and others whose work involves contact with patients, their blood or other body fluids, or corpses.

Recommendations for HCWs emphasize precautions appropriate for preventing transmission of bloodborne infectious diseases, including HTLV-III/LAV and HBV infections. Thus, these precautions should be enforced routinely, as should other standard infection-control precautions, regardless of whether HCWs or patients are known to be infected with HTLV-III/LAV or HBV. In addition to being informed of these precautions, all HCWs, including students and housestaff, should be educated regarding the epidemiology, modes of transmission, and prevention of HTLV-III LAV infection.

**Risk of HCWs acquiring HTLV-III/LAV in the workplace.** Using the HBV model, the highest risk for transmission of HTLV-III/LAV in the workplace would involve parenteral exposure to a needle or other sharp instrument contaminated with blood of an infected patient. The risk to HCWs of acquiring HTLV-III LAV infection in the workplace has been evaluated in several studies. In five separate studies, a total of 1,498 HCWs have been tested for antibody to HTLV-III LAV. In these studies, 666 (44.5%) of the HCWs had direct parenteral (needlestick or cut) or mucous membrane exposure to patients with AIDS or HTLV-III/LAV infection. Most of these exposures were to blood rather than to other body fluids. None of the HCWs whose initial serologic tests were negative developed subsequent evidence of HTLV-III/LAV infection following their exposures. Twenty-six HCWs in these five studies were seropositive when first tested; all but three of these persons belonged to groups recognized to be at increased risk for AIDS (*15*). Since one was tested anonymously, epidemiologic information was available on only two of these three seropositive HCWs. Although these two HCWs were reported as probable occupationally related HTLV-III LAV infection (*15,16*), neither had a preexposure nor an early postexposure serum sample available to help determine the onset of infection. One case reported from England describes a nurse who seroconverted following an accidental parenteral exposure to a needle contaminated with blood from an AIDS patient (*17*).

In spite of the extremely low risk of transmission of HTLV-III LAV infection, even when needlestick injuries occur, more emphasis must be given to precautions targeted to prevent needlestick injuries in HCWs caring for any patient, since such injuries continue to occur even during the care of patients who are known to be infected with HTLV-III/LAV.

**Precautions to prevent acquisition of HTLV-III/LAV infection by HCWs in the workplace.** These precautions represent prudent practices that apply to preventing transmission of HTLV-III/LAV and other bloodborne infections and should be used routinely (*18*).

1. Sharp items (needles, scalpel blades, and other sharp instruments) should be considered as potentially infective and be handled with extraordinary care to prevent accidental injuries.
2. Disposable syringes and needles, scalpel blades, and other sharp items should be placed into puncture-resistant containers located as close as practical to the area in which they were used. To prevent needlestick injuries, needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand.
3. When the possibility of exposure to blood or other body fluids exists, routinely recommended precautions should be followed. The anticipated exposure may require gloves alone, as in handling items soiled with blood or equipment contaminated with blood or other body fluids, or may also require gowns, masks, and eye-coverings when performing procedures involving more extensive contact with blood or potentially infective body fluids, as in some dental or endoscopic procedures or postmortem examinations. Hands should be washed thoroughly and immediately if they accidentally become contaminated with blood.
4. To minimize the need for emergency mouth-to-mouth resuscitation, mouth pieces, resuscitation bags, or other ventilation devices should be strategically located and available for use in areas where the need for resuscitation is predictable.

5. Pregnant HCWs are not known to be at greater risk of contracting HTLV-III/LAV infections than HCWs who are not pregnant; however, if a HCW develops HTLV-III/LAV infection during pregnancy, the infant is at increased risk of infection resulting from perinatal transmission. Because of this risk, pregnant HCWs should be especially familiar with precautions for the preventing HTLV-III/LAV transmission (*19*).

**Precautions for HCWs during home care of persons infected with HTLV-III/LAV.** Persons infected with HTLV-III/LAV can be safely cared for in home environments. Studies of family members of patients infected with HTLV-III/LAV have found no evidence of HTLV-III/LAV transmission to adults who were not sexual contacts of the infected patients or to children who were not at risk for perinatal transmission (*3*). HCWs providing home care face the same risk of transmission of infection as HCWs in hospitals and other health-care settings, especially if there are needlesticks or other parenteral or mucous membrane exposures to blood or other body fluids.

When providing health-care service in the home to persons infected with HTLV-III/LAV, measures similar to those used in hospitals are appropriate. As in the hospital, needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand. Needles and other sharp items should be placed into puncture-resistant containers and disposed of in accordance with local regulations for solid waste. Blood and other body fluids can be flushed down the toilet. Other items for disposal that are contaminated with blood or other body fluids that cannot be flushed down the toilet should be wrapped securely in a plastic bag that is impervious and sturdy (not easily penetrated). It should be placed in a second bag before being discarded in a manner consistent with local regulations for solid waste disposal. Spills of blood or other body fluids should be cleaned with soap and water or a household detergent. As in the hospital, individuals cleaning up such spills should wear disposable gloves. A disinfectant solution or a freshly prepared solution of sodium hypochlorite (household bleach, see below) should be used to wipe the area after cleaning.

**Precautions for providers of prehospital emergency health care.** Providers of prehospital emergency health care include the following: paramedics, emergency medical technicians, law enforcement personnel, firefighters, lifeguards, and others whose job might require them to provide first-response medical care. The risk of transmission of infection, including HTLV-III/LAV infection, from infected persons to providers of prehospital emergency health care should be no higher than that for HCWs providing emergency care in the hospital if appropriate precautions are taken to prevent exposure to blood or other body fluids.

Providers of prehospital emergency health care should follow the precautions outlined above for other HCWs. No transmission of HBV infection during mouth-to-mouth resuscitation has been documented. However, because of the theoretical risk of salivary transmission of HTLV-III/LAV during mouth-to-mouth resuscitation, special attention should be given to the use of disposable airway equipment or resuscitation bags and the wearing of gloves when in contact with blood or other body fluids. Resuscitation equipment and devices known or suspected to be contaminated with blood or other body fluids should be used once and disposed of or be thoroughly cleaned and disinfected after each use.

**Management of parenteral and mucous membrane exposures of HCWs.** If a HCW has a parenteral (e.g., needlestick or cut) or mucous membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids, the source patient should be assessed clinically and epidemiologically to determine the likelihood of HTLV-III/LAV infection. If the assessment suggests that infection may exist, the patient should be informed of the incident and requested to consent to serologic testing for evidence of HTLV-III/LAV infection. If the source patient has AIDS or other evidence of HTLV-III/LAV infection, declines testing, or has a positive test, the HCW should be evaluated clinically and serologically for evidence of HTLV-III/LAV infection as soon as possible after the exposure, and, if seronegative, retested after 6 weeks and on a periodic basis thereafter (e.g., 3, 6, and 12 months following exposure) to determine if transmission has occurred. During this follow-up period, especially the first 6-12 weeks, when most infected persons are expected to seroconvert, exposed HCWs should receive counseling about the risk of infection and follow U.S. Public Health Service (PHS) recommendations for preventing transmission of AIDS (*20,21*). If the source patient is seronegative and has no other evidence of HTLV-III/LAV infection, no further follow-up of the HCW is neces-

sary. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposure and the likelihood that the source patient was infected.

**Serologic testing of patients.** Routine serologic testing of all patients for antibody to HTLV-III/LAV is not recommended to prevent transmission of HTLV-III/LAV infection in the workplace. Results of such testing are unlikely to further reduce the risk of transmission, which, even with documented needlesticks, is already extremely low. Furthermore, the risk of needlestick and other parenteral exposures could be reduced by emphasizing and more consistently implementing routinely recommended infection-control precautions (e.g., not recapping needles). Moreover, results of routine serologic testing would not be available for emergency cases and patients with short lengths of stay, and additional tests to determine whether a positive test was a true or false positive would be required in populations with a low prevalence of infection. However, this recommendation is based only on considerations of occupational risks and should not be construed as a recommendation against other uses of the serologic test, such as for diagnosis or to facilitate medical management of patients. Since the experience with infected patients varies substantially among hospitals (75% of all AIDS cases have been reported by only 280 of the more than 6,000 acute-care hospitals in the United States), some hospitals in certain geographic areas may deem it appropriate to initiate serologic testing of patients.

## TRANSMISSION FROM HEALTH-CARE WORKERS TO PATIENTS

**Risk of transmission of HTLV-III/LAV infection from HCWs to patients.** Although there is no evidence that HCWs infected with HTLV-III/LAV have transmitted infection to patients, a risk of transmission of HTLV-III/LAV infection from HCWs to patients would exist in situations where there is both (1) a high degree of trauma to the patient that would provide a portal of entry for the virus (e.g., during invasive procedures) and (2) access of blood or serous fluid from the infected HCW to the open tissue of a patient, as could occur if the HCW sustains a needlestick or scalpel injury during an invasive procedure. HCWs known to be infected with HTLV-III/LAV who do not perform invasive procedures need not be restricted from work unless they have evidence of other infection or illness for which any HCW should be restricted. Whether additional restrictions are indicated for HCWs who perform invasive procedures is currently being considered.

**Precautions to prevent transmission of HTLV-III/LAV infection from HCWs to patients.** These precautions apply to all HCWs, regardless of whether they perform invasive procedures. (1) All HCWs should wear gloves for direct contact with mucous membranes or nonintact skin of all patients and (2) HCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.

**Management of parenteral and mucous membrane exposures of patients.** If a patient has a parenteral or mucous membrane exposure to blood or other body fluids of a HCW, the patient should be informed of the incident and the same procedure outlined above for exposures of HCWs to patients should be followed for both the source HCW and the potentially exposed patient. Management of this type of exposure will be addressed in more detail in the recommendations for HCWs who perform invasive procedures.

**Serologic testing of HCWs.** Routine serologic testing of HCWs who do not perform invasive procedures (including providers of home and prehospital emergency care) is not recommended to prevent transmission of HTLV-III LAV infection. The risk of transmission is extremely low and can be further minimized when routinely recommended infection-control precautions are followed. However, serologic testing should be available to HCWs who may wish to know their HTLV-III/LAV infection status. Whether indications exist for serologic testing of HCWs who perform invasive procedures is currently being considered.

**Risk of occupational acquisition of other infectious diseases by HCWs infected with HTLV-III/LAV.** HCWs who are known to be infected with HTLV-III/LAV and who have defective immune systems are at increased risk of acquiring or experiencing serious complications of other infectious diseases. Of particular concern is the risk of severe infection following exposure to patients with infectious diseases that are easily transmitted if appropriate precau-

tions are not taken (e.g., tuberculosis). HCWs infected with HTLV-III/LAV should be counseled about the potential risk associated with taking care of patients with transmissible infections and should continue to follow existing recommendations for infection control to minimize their risk of exposure to other infectious agents (*18,19*). The HCWs' personal physician(s), in conjunction with their institutions' personnel health services or medical directors, should determine on an individual basis whether the infected HCWs can adequately and safely perform patient-care duties and suggest changes in work assignments, if indicated. In making this determination, recommendations of the Immunization Practices Advisory Committee and institutional policies concerning requirements for vaccinating HCWs with live-virus vaccines should also be considered.

## STERILIZATION, DISINFECTION, HOUSEKEEPING, AND WASTE DISPOSAL TO PREVENT TRANSMISSION OF HTLV-III/LAV

Sterilization and disinfection procedures currently recommended for use (*22,23*) in health-care and dental facilities are adequate to sterilize or disinfect instruments, devices, or other items contaminated with the blood or other body fluids from individuals infected with HTLV-III/LAV. Instruments or other nondisposable items that enter normally sterile tissue or the vascular system or through which blood flows should be sterilized before reuse. Surgical instruments used on all patients should be decontaminated after use rather than just rinsed with water. Decontamination can be accomplished by machine or by hand cleaning by trained personnel wearing appropriate protective attire (*24*) and using appropriate chemical germicides. Instruments or other nondisposable items that touch intact mucous membranes should receive high-level disinfection.

Several liquid chemical germicides commonly used in laboratories and health-care facilities have been shown to kill HTLV-III/LAV at concentrations much lower than are used in practice (*25*). When decontaminating instruments or medical devices, chemical germicides that are registered with and approved by the U.S. Environmental Protection Agency (EPA) as "sterilants" can be used either for sterilization or for high-level disinfection depending on contact time; germicides that are approved for use as "hospital disinfectants" and are mycobactericidal when used at appropriate dilutions can also be used for high-level disinfection of devices and instruments. Germicides that are mycobactericidal are preferred because mycobacteria represent one of the most resistant groups of microorganisms; therefore, germicides that are effective against mycobacteria are also effective against other bacterial and viral pathogens. When chemical germicides are used, instruments or devices to be sterilized or disinfected should be thoroughly cleaned before exposure to the germicide, and the manufacturer's instructions for use of the germicide should be followed.

Laundry and dishwashing cycles commonly used in hospitals are adequate to decontaminate linens, dishes, glassware, and utensils. When cleaning environmental surfaces, housekeeping procedures commonly used in hospitals are adequate; surfaces exposed to blood and body fluids should be cleaned with a detergent followed by decontamination using an EPA-approved hospital disinfectant that is mycobactericidal. Individuals cleaning up such spills should wear disposable gloves. Information on specific label claims of commercial germicides can be obtained by writing to the Disinfectants Branch, Office of Pesticides, Environmental Protection Agency, 401 M Street, S.W., Washington, D.C., 20460.

In addition to hospital disinfectants, a freshly prepared solution of sodium hypochlorite (household bleach) is an inexpensive and very effective germicide (*25*). Concentrations ranging from 5,000 ppm (a 1:10 dilution of household bleach) to 500 ppm (a 1:100 dilution) sodium hypochlorite are effective, depending on the amount of organic material (e.g., blood, mucus, etc.) present on the surface to be cleaned and disinfected.

Sharp items should be considered as potentially infective and should be handled and disposed of with extraordinary care to prevent accidental injuries. Other potentially infective waste should be contained and transported in clearly identified impervious plastic bags. If the outside of the bag is contaminated with blood or other body fluids, a second outer bag should be used. Recommended practices for disposal of infective waste (*23*) are adequate for disposal of waste contaminated by HTLV-III/LAV. Blood and other body fluids may be carefully poured down a drain connected to a sanitary sewer.

## CONSIDERATIONS RELEVANT TO OTHER WORKERS

**Personal-service workers (PSWs).** PSWs are defined as individuals whose occupations involve close personal contact with clients (e.g., hairdressers, barbers, estheticians, cosmetologists, manicurists, pedicurists, massage therapists). PSWs whose services (tattooing, ear piercing, acupuncture, etc.) require needles or other instruments that penetrate the skin should follow precautions indicated for HCWs. Although there is no evidence of transmission of HTLV-III/LAV from clients to PSWs, from PSWs to clients, or between clients of PSWs, a risk of transmission would exist from PSWs to clients and vice versa in situations where there is both (1) trauma to one of the individuals that would provide a portal of entry for the virus and (2) access of blood or serous fluid from one infected person to the open tissue of the other, as could occur if either sustained a cut. A risk of transmission from client to client exists when instruments contaminated with blood are not sterilized or disinfected between clients. However, HBV transmission has been documented only rarely in acupuncture, ear piercing, and tattoo establishments and never in other personal-service settings, indicating that any risk for HTLV-III/LAV transmission in personal-service settings must be extremely low.

All PSWs should be educated about transmission of bloodborne infections, including HTLV-III/LAV and HBV. Such education should emphasize principles of good hygiene, antisepsis, and disinfection. This education can be accomplished by national or state professional organizations, with assistance from state and local health departments, using lectures at meetings or self-instructional materials. Licensure requirements should include evidence of such education. Instruments that are intended to penetrate the skin (e.g., tattooing and acupuncture needles, ear piercing devices) should be used once and disposed of or be thoroughly cleaned and sterilized after each use using procedures recommended for use in health-care institutions. Instruments not intended to penetrate the skin but which may become contaminated with blood (e.g., razors), should be used for only one client and be disposed of or thoroughly cleaned and disinfected after use using procedures recommended for use in health-care institutions. Any PSW with exudative lesions or weeping dermatitis, regardless of HTLV-III/LAV infection status, should refrain from direct contact with clients until the condition resolves. PSWs known to be infected with HTLV-III/LAV need not be restricted from work unless they have evidence of other infections or illnesses for which any PSW should also be restricted.

Routine serologic testing of PSWs for antibody to HTLV-III/LAV is not recommended to prevent transmission from PSWs to clients.

**Food-service workers (FSWs).** FSWs are defined as individuals whose occupations involve the preparation or serving of food or beverages (e.g., cooks, caterers, servers, waiters, bartenders, airline attendants). All epidemiologic and laboratory evidence indicates that bloodborne and sexually transmitted infections are not transmitted during the preparation or serving of food or beverages, and no instances of HBV or HTLV-III/LAV transmission have been documented in this setting.

All FSWs should follow recommended standards and practices of good personal hygiene and food sanitation (*26*). All FSWs should exercise care to avoid injury to hands when preparing food. Should such an injury occur, both aesthetic and sanitary considerations would dictate that food contaminated with blood be discarded. FSWs known to be infected with HTLV-III/LAV need not be restricted from work unless they have evidence of other infection or illness for which any FSW should also be restricted.

Routine serologic testing of FSWs for antibody to HTLV-III/LAV is not recommended to prevent disease transmission from FSWs to consumers.

**Other workers sharing the same work environment.** No known risk of transmission to co-workers, clients, or consumers exists from HTLV-III/LAV-infected workers in other settings (e.g., offices, schools, factories, construction sites). This infection is spread by sexual contact with infected persons, injection of contaminated blood or blood products, and by perinatal transmission. Workers known to be infected with HTLV-III/LAV should not be restricted from work solely based on this finding. Moreover, they should not be restricted from using telephones, office equipment, toilets, showers, eating facilities, and water fountains. Equipment contaminated with blood or other body fluids of any worker, regardless of HTLV-III/LAV infection status, should be cleaned with soap and water or a detergent. A disinfectant solution or a fresh solution of sodium hypochlorite (household bleach, see above) should be used to wipe the area after cleaning.

## OTHER ISSUES IN THE WORKPLACE

The information and recommendations contained in this document do not address all the potential issues that may have to be considered when making specific employment decisions for persons with HTLV-III/LAV infection. The diagnosis of HTLV-III/LAV infection may evoke unwarranted fear and suspicion in some co-workers. Other issues that may be considered include the need for confidentiality, applicable federal, state, or local laws governing occupational safety and health, civil rights of employees, workers' compensation laws, provisions of collective bargaining agreements, confidentiality of medical records, informed consent, employee and patient privacy rights, and employee right-to-know statutes.

## DEVELOPMENT OF THESE RECOMMENDATIONS

The information and recommendations contained in these recommendations were developed and compiled by CDC and other PHS agencies in consultation with individuals representing various organizations. The following organizations were represented: Association of State and Territorial Health Officials, Conference of State and Territorial Epidemiologists, Association of State and Territorial Public Health Laboratory Directors, National Association of County Health Officials, American Hospital Association, United States Conference of Local Health Officers, Association for Practitioners in Infection Control, Society of Hospital Epidemiologists of America, American Dental Association, American Medical Association, American Nurses' Association, American Association of Medical Colleges, American Association of Dental Schools, National Institutes of Health, Food and Drug Administration, Food Research Institute, National Restaurant Association, National Hairdressers and Cosmetologists Association, National Gay Task Force, National Funeral Directors and Morticians Association, American Association of Physicians for Human Rights, and National Association of Emergency Medical Technicians. The consultants also included a labor union representative, an attorney, a corporate medical director, and a pathologist. However, these recommendations may not reflect the views of individual consultants or the organizations they represented.

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# Additional Recommendations to Reduce Sexual and Drug Abuse-Related Transmission of Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus

## BACKGROUND

Human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the virus that causes acquired immunodeficiency syndrome (AIDS), is transmitted through sexual contact, parenteral exposure to infected blood or blood components, and perinatally from mother to fetus or neonate. In the United States, over 73% of adult AIDS patients are homosexual or bisexual men; 11% of these males also had a history of intravenous (IV) drug abuse. Seventeen percent of all adult AIDS patients were heterosexual men or women who abused IV drugs (*1,2*). The prevalence of HTLV-III LAV antibody is high in certain risk groups in the United States (*3,4*).

Since a large proportion of seropositive asymptomatic persons have been shown to be viremic (*5*), all seropositive individuals, whether symptomatic or not, must be presumed capable of transmitting this infection. A repeatedly reactive serologic test for HTLV-III/LAV has important medical, as well as public health, implications for the individual and his/her health-care provider. The purpose of these recommendations is to suggest ways to facilitate identification of seropositive asymptomatic persons, both for medical evaluation and for counseling to prevent transmission.

Previous U.S. Public Health Service recommendations pertaining to sexual, IV drug abuse, and perinatal transmission of HTLV-III/LAV have been published (*6-8*). Reduction of sexual and IV transmission of HTLV-III LAV should be enhanced by using available serologic tests to give asymptomatic, infected individuals in high-risk groups the opportunity to know their status so they can take appropriate steps to prevent the further transmission of this virus.

Since the objective of these additional recommendations is to help interrupt transmission by encouraging testing and counseling among persons in high-risk groups, careful attention must be paid to maintaining confidentiality and to protecting records from any unauthorized disclosure. The ability of health departments to assure confidentiality—and the public confidence in that ability—are crucial to efforts to increase the number of persons requesting such testing and counseling. Without appropriate confidentiality protection, anonymous testing should be considered. Persons tested anonymously would still be offered medical evaluation and counseling.

## PERSONS AT INCREASED RISK OF HTLV-III/LAV INFECTION

Persons at increased risk of HTLV-III/LAV infection include: (1) homosexual and bisexual men; (2) present or past IV drug abusers; (3) persons with clinical or laboratory evidence of infection, such as those with signs or symptoms compatible with AIDS or AIDS-related complex (ARC); (4) persons born in countries where heterosexual transmission is thought to play a major role*; (5) male or female prostitutes and their sex partners; (6) sex partners of infected persons or persons at increased risk; (7) all persons with hemophilia who have received clotting-factor products; and (8) newborn infants of high-risk or infected mothers.

## RECOMMENDATIONS

1. Community health education programs should be aimed at members of high-risk groups to: (a) increase knowledge of AIDS; (b) facilitate behavioral changes to reduce risks of HTLV-III LAV infection; and (c) encourage voluntary testing and counseling.
2. Counseling and voluntary serologic testing for HTLV-III/LAV should be routinely offered to all persons at increased risk when they present to health-care settings. Such facilities include, but are not limited to, sexually transmitted disease clinics, clinics for treating parenteral drug abusers, and clinics for examining prostitutes.
   a. Persons with a repeatedly reactive test result (see section on Test Interpretation) should receive a thorough medical evaluation, which may include history, physical examination, and appropriate laboratory studies.
   b. High-risk persons with a negative test result should be counseled to reduce their risk of becoming infected by:
      (1) Reducing the number of sex partners. A stable, mutually monogamous relationship with an uninfected person eliminates any new risk of sexually transmitted HTLV-III LAV infection.

*e.g., Haiti, Central African countries.

(2) Protecting themselves during sexual activity with any possibly infected person by taking appropriate precautions to prevent contact with the person's blood, semen, urine, feces, saliva, cervical secretions, or vaginal secretions. Although the efficacy of condoms in preventing infections with HTLV-III/LAV is still under study, consistent use of condoms should reduce transmission of HTLV-III/LAV by preventing exposure to semen and infected lymphocytes (*9,10*).

(3) For IV drug abusers, enrolling or continuing in programs to eliminate abuse of IV substances. Needles, other apparatus, and drugs must never be shared.

c. Infected persons should be counseled to prevent the further transmission of HTLV-III/LAV by:

(1) Informing prospective sex partners of his/her infection with HTLV-III/LAV, so they can take appropriate precautions. Clearly, abstention from sexual activity with another person is one option that would eliminate any risk of sexually transmitted HTLV-III/LAV infection.

(2) Protecting a partner during any sexual activity by taking appropriate precautions to prevent that individual from coming into contact with the infected person's blood, semen, urine, feces, saliva, cervical secretions, or vaginal secretions. Although the efficacy of using condoms to prevent infections with HTLV-III/LAV is still under study, consistent use of condoms should reduce transmission of HTLV-III/LAV by preventing exposure to semen and infected lymphocytes (*9,10*).

(3) Informing previous sex partners and any persons with whom needles were shared of their potential exposure to HTLV-III/LAV and encouraging them to seek counseling/testing.

(4) For IV drug abusers, enrolling or continuing in programs to eliminate abuse of IV substances. Needles, other apparatus, and drugs must never be shared.

(5) Not sharing toothbrushes, razors, or other items that could become contaminated with blood.

(6) Refraining from donating blood, plasma, body organs, other tissue, or semen.

(7) Avoiding pregnancy until more is known about the risks of transmitting HTLV-III/LAV from mother to fetus or newborn (*8*).

(8) Cleaning and disinfecting surfaces on which blood or other body fluids have spilled, in accordance with previous recommendations (*2*).

(9) Informing physicians, dentists, and other appropriate health professionals of his/her antibody status when seeking medical care so that the patient can be appropriately evaluated.

3. Infected patients should be encouraged to refer sex partners or persons with whom they have shared needles to their health-care provider for evaluation and/or testing. If patients prefer, trained health department professionals should be made available to assist in notifying their partners and counseling them regarding evaluation and/or testing.
4. Persons with a negative test result should be counseled regarding their need for continued evaluation to monitor their infection status if they continue high-risk behavior (*8*).
5. State and local health officials should evaluate the implications of requiring the reporting of repeatedly reactive HTLV-III LAV antibody test results to the state health department.
6. State or local action is appropriate on public health grounds to regulate or close establishments where there is evidence that they facilitate high-risk behaviors, such as anonymous sexual contacts and or intercourse with multiple partners or IV drug abuse (e.g., bathhouses, houses of prostitution, "shooting galleries").

**TEST INTERPRETATION**

Commercially available tests to detect antibody to HTLV-III/LAV are enzyme-linked immunosorbant assays (ELISAs) using antigens derived from disrupted HTLV-III/LAV. When the ELISA is reactive on initial testing, it is standard procedure to repeat the test on the same specimen. Repeatedly reactive tests are highly sensitive and specific for HTLV-III/LAV antibody. However, since falsely positive tests occur, and the implications of a positive test are serious, additional more specific tests (e.g., Western blot, immunofluorescent assay, etc.) are recommended following repeatedly reactive ELISA results, especially in low-prevalence populations. If additional more specific test results are not readily available, persons in high-risk groups with strong repeatedly reactive ELISA results can be counseled before any additional test results are received regarding their probable infection status, their need for medical follow-up, and ways to reduce further transmission of HTLV-III/LAV.

## OTHER CONSIDERATIONS

State or local policies governing informing and counseling sex partners and those who share needles with persons who are HTLV-III/LAV-antibody positive will vary, depending on state and local statutes that authorize such actions. Accomplishing the objective of interrupting transmission by encouraging testing and counseling among persons in high-risk groups will depend heavily on health officials paying careful attention to maintaining confidentiality and protecting records from unauthorized disclosure.

The public health effectiveness of various approaches to counseling, sex-partner referral, and laboratory testing will require careful monitoring. The feasibility and efficacy of each of these measures should be evaluated by state and local health departments to best utilize available resources.

*Developed by Center for Prevention Svcs and Center for Infectious Diseases, CDC, in consultation with persons from numerous other organizations and groups.*

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## Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS

These guidelines are the outgrowth of the 1986 recommendations published in the *MMWR* (*1*); the report on the February 24-25, 1987, Conference on Counseling and Testing (*2*); and a series of meetings with representatives from the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, the National Association of County Health Officials, the United States Conference of Local Health Officers, and the National Association of State Alcohol and Drug Abuse Directors.

Human immunodeficiency virus (HIV), the causative agent of acquired immunodeficiency syndrome (AIDS) and related clinical manifestations, has been shown to be spread by sexual contact; by parenteral exposure to blood (most often through intravenous [IV] drug abuse) and, rarely, by other exposures to blood; and from an infected woman to her fetus or infant.

Persons exposed to HIV usually develop detectable levels of antibody against the virus within 6-12 weeks of infection. The presence of antibody indicates current infection, though many infected persons may have minimal or no clinical evidence of disease for years. Counseling and testing persons who are infected or at risk for acquiring HIV infection is an important component of prevention strategy (*1*). Most of the estimated 1.0 to 1.5 million infected persons in the United States are unaware that they are infected with HIV. The primary public health purposes of counseling and testing are to help uninfected individuals initiate and sustain behavioral changes that reduce their risk of becoming infected and to assist infected individuals in avoiding infecting others.

Along with the potential personal, medical, and public health benefits of testing for HIV antibody, public health agencies must be concerned about actions that will discourage the use of counseling and testing facilities, most notably the unauthorized disclosure of personal information and the possibility of inappropriate discrimination.

Priorities for public health counseling and testing should be based upon providing ready access to persons who are most likely to be infected or who practice high-risk behaviors, thereby helping to reduce further spread of infection. There are other considerations for determining testing priorities, including the likely effectiveness of preventing the spread of infection among persons who would not otherwise realize that they are at risk. Knowledge of the prevalence of HIV infection in different populations is useful in determining the most efficient and effective locations providing such services. For example, programs that offer counseling and testing to homosexual men, IV-drug abusers, persons with hemophilia, sexual and/or needle-sharing partners of these persons, and patients of sexually transmitted disease clinics may be most effective since persons in these groups are at high risk for infection. After counseling and testing are effectively implemented in settings of high and moderate prevalence, consideration should be given to establishing programs in settings of lower prevalence.

### Interpretation of HIV-Antibody Test Results

A test for HIV antibody is considered positive when a sequence of tests, starting with a repeatedly reactive enzyme immunoassay (EIA) and including an additional, more specific assay, such as a Western blot, are consistently reactive.

The *sensitivity* of the currently licensed EIA tests is 99% or greater when performed under optimal laboratory conditions. Given this performance, the probability of a false-negative test result is remote, except during the first weeks after infection, before antibody is detectable.

The *specificity* of the currently licensed EIA tests is approximately 99% when repeatedly reactive tests are considered. Repeat testing of specimens initially reactive by EIA is required to reduce the likelihood of false-positive test results due to laboratory error. To further increase the specificity of the testing process, laboratories must use a supplemental test—most often the Western blot test—to validate repeatedly reactive EIA results. The sensitivity of the licensed Western blot test is comparable to that of the EIA, and it is highly specific when strict criteria are used for interpretation. Under ideal circumstances, the probability that a testing sequence will be falsely positive in a population with a low rate of infection ranges from less than 1 in 100,000 (Minnesota Department of Health, unpublished data) to an estimated 5 in 100,000 (*3,4*). Laboratories using different Western blot reagents or other tests or using less stringent interpretive criteria may experience higher rates of false-positive results.

Laboratories should carefully guard against human errors, which are likely to be the most common source of false-positive test results. All laboratories should anticipate the need for assuring quality performance of tests for HIV antibody by training personnel, establishing quality controls, and participating in performance evaluation systems. Health department laboratories should facilitate the quality assurance of the performance of laboratories in their jurisdiction.

**Guidelines for Counseling and Testing for HIV Antibody**

These guidelines are based on public health considerations for HIV testing, including the principles of counseling before and after testing, confidentiality of personal information, and the understanding that a person may decline to be tested without being denied health care or other services, except where testing is required by law (*5*). Counseling before testing may not be practical when screening for HIV antibody is required. This is true for donors of blood, organs, and tissue; prisoners; and immigrants for whom testing is a Federal requirement as well as for persons admitted to state correctional institutions in states that require testing. When there is no counseling before testing, persons should be informed that testing for HIV antibody will be performed, that individual results will be kept confidential to the extent permitted by law, and that appropriate counseling will be offered. Individual counseling of those who are either HIV-antibody positive or at continuing risk for HIV infection is critical for reducing further transmission and for ensuring timely medical care.

Specific recommendations follow:

1. *Persons who may have sexually transmitted disease.* All persons seeking treatment for a sexually transmitted disease, in all health-care settings including the offices of private physicians, should be routinely* counseled and tested for HIV antibody.
2. *IV-drug abusers.* All persons seeking treatment for IV-drug abuse or having a history of IV-drug abuse should be routinely counseled and tested for HIV antibody. Medical professionals in all health-care settings, including prison clinics, should seek a history of IV-drug abuse from patients and should be aware of its implications for HIV infection. In

*"Routine counseling and testing" is defined as a policy to provide these services to all clients after informing them that testing will be done. Except where testing is required by law, individuals have the right to decline to be tested without being denied health care or other services.

addition, state and local health policy makers should address the following issues:

- Treatment programs for IV-drug abusers should be sufficiently available to allow persons seeking assistance to enter promptly and be encouraged to alter the behavior that places them and others at risk for HIV infection.
- Outreach programs for IV-drug abusers should be undertaken to increase their knowledge of AIDS and of ways to prevent HIV infection, to encourage them to obtain counseling and testing for HIV antibody, and to persuade them to be treated for substance abuse.

3. *Persons who consider themselves at risk.* All persons who consider themselves at risk for HIV infection should be counseled and offered testing for HIV antibody.

4. *Women of childbearing age.* All women of childbearing age with identifiable risks for HIV infection should be routinely counseled and tested for HIV antibody, regardless of the health-care setting. Each encounter between a health-care provider and a woman at risk and/or her sexual partners is an opportunity to reach them with information and education about AIDS and prevention of HIV infection. Women are at risk for HIV infection if they:
   - Have used IV drugs.
   - Have engaged in prostitution.
   - Have had sexual partners who are infected or are at risk for infection because they are bisexual or are IV-drug abusers or hemophiliacs.
   - Are living in communities or were born in countries where there is a known or suspected high prevalence of infection among women.
   - Received a transfusion before blood was being screened for HIV antibody but after HIV infection occurred in the United States (e.g., between 1978 and 1985).

   Educating and testing these women before they become pregnant allows them to avoid pregnancy and subsequent intrauterine perinatal infection of their infants (30%-50% of the infants born to HIV-infected women will also be infected).

   All pregnant women at risk for HIV infection should be routinely counseled and tested for HIV antibody. Identifying pregnant women with HIV infection as early in pregnancy as possible is important for ensuring appropriate medical care for these women; for planning medical care for their infants; and for providing counseling on family planning, future pregnancies, and the risk of sexual transmission of HIV to others.

   All women who seek family planning services and who are at risk for HIV infection should be routinely counseled about AIDS and HIV infection and tested for HIV antibody. Decisions about the need for counseling and testing programs in a community should be based on the best available estimates of the prevalence of HIV infection and the demographic variables of infection.

5. *Persons planning marriage.* All persons considering marriage should be given information about AIDS, HIV infection, and the availability of counseling and testing for HIV antibody. Decisions about instituting routine or mandatory premarital testing for HIV antibody should take into account the prevalence of HIV infection in the area and/or population group as well as other factors and should be based upon the likely

cost-effectiveness of such testing in preventing further spread of infection. Premarital testing in an area with a prevalence of HIV infection as low as 0.1% may be justified if reaching an infected person through testing can prevent subsequent transmission to the spouse or prevent pregnancy in a woman who is infected.

6. *Persons undergoing medical evaluation or treatment.* Testing for HIV antibody is a useful diagnostic tool for evaluating patients with selected clinical signs and symptoms such as generalized lymphadenopathy; unexplained dementia; chronic, unexplained fever or diarrhea; unexplained weight loss; or diseases such as tuberculosis as well as sexually transmitted diseases, generalized herpes, and chronic candidiasis.

   Since persons infected with both HIV and the tubercle bacillus are at high risk for severe clinical tuberculosis, all patients with tuberculosis should be routinely counseled and tested for HIV antibody (*6*). Guidelines for managing patients with both HIV and tuberculous infection have been published (*7*).

   The risk of HIV infection from transfusions of blood or blood components from 1978-1985 was greatest for persons receiving large numbers of units of blood collected from areas with high incidences of AIDS. Persons who have this increased risk should be counseled about the potential risk of HIV infection and should be offered antibody testing (*8*).
7. *Persons admitted to hospitals.* Hospitals, in conjunction with state and local health departments, should periodically determine the prevalence of HIV infections in the age groups at highest risk for infection. Consideration should be given to routine testing in those age groups deemed to have a high prevalence of HIV infection.
8. *Persons in correctional systems.* Correctional systems should study the best means of implementing programs for counseling inmates about HIV infection and for testing them for such infection at admission and discharge from the system. In particular, they should examine the usefulness of these programs in preventing further transmission of HIV infection and the impact of the testing programs on both the inmates and the correctional system (*9*). Federal prisons have been instructed to test all prisoners when they enter and leave the prison system.
9. *Prostitutes.* Male and female prostitutes should be counseled and tested and made aware of the risks of HIV infection to themselves and others. Particularly prostitutes who are HIV-antibody positive should be instructed to discontinue the practice of prostitution. Local or state jurisdictions should adopt procedures to assure that these instructions are followed.

**Partner Notification/Contact Tracing**

Sexual partners and those who share needles with HIV-infected persons are at risk for HIV infection and should be routinely counseled and tested for HIV antibody. Persons who are HIV-antibody positive should be instructed in how to notify their partners and to refer them for counseling and testing. If they are unwilling to notify their partners or if it cannot be assured that their partners will seek counseling, physicians or health department personnel should use confidential procedures to assure that the partners are notified.

## Confidentiality and Antidiscrimination Considerations

The ability of health departments, hospitals, and other health-care providers and institutions to assure confidentiality of patient information and the public's confidence in that ability are crucial to efforts to increase the number of persons being counseled and tested for HIV infection. Moreover, to assure broad participation in the counseling and testing programs, it is of equal or greater importance that the public perceive that persons found to be positive will not be subject to inappropriate discrimination.

Every reasonable effort should be made to improve confidentiality of test results. The confidentiality of related records can be improved by a careful review of actual record-keeping practices and by assessing the degree to which these records can be protected under applicable state laws. State laws should be examined and strengthened when found necessary. Because of the wide scope of "need-to-know" situations, because of the possibility of inappropriate disclosures, and because of established authorization procedures for releasing records, it is recognized that there is no perfect solution to confidentiality problems in all situations. Whether disclosures of HIV-testing information are deliberate, inadvertent, or simply unavoidable, public health policy needs to carefully consider ways to reduce the harmful impact of such disclosures.

Public health prevention policy to reduce the transmission of HIV infection can be furthered by an expanded program of counseling and testing for HIV antibody, but the extent to which these programs are successful depends on the level of participation. Persons are more likely to participate in counseling and testing programs if they believe that they will not experience negative consequences in areas such as employment, school admission, housing, and medical services should they test positive. There is no known medical reason to avoid an infected person in these and ordinary social situations since the cumulative evidence is strong that HIV infection is not spread through casual contact. It is essential to the success of counseling and testing programs that persons who are tested for HIV are not subjected to inappropriate discrimination.

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# Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome

*Reported by*
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## INTRODUCTION

The following revised case definition for surveillance of acquired immunodeficiency syndrome (AIDS) was developed by CDC in collaboration with public health and clinical specialists. The Council of State and Territorial Epidemiologists (CSTE) has officially recommended adoption of the revised definition for national reporting of AIDS. The objectives of the revision are a) to track more effectively the severe disabling morbidity associated with infection with human immunodeficiency virus (HIV) (including HIV-1 and HIV-2); b) to simplify reporting of AIDS cases; c) to increase the sensitivity and specificity of the definition through greater diagnostic application of laboratory evidence for HIV infection; and d) to be consistent with current diagnostic practice, which in some cases includes presumptive, i.e., without confirmatory laboratory evidence, diagnosis of AIDS-indicative diseases (e.g., *Pneumocystis carinii* pneumonia, Kaposi's sarcoma).

The definition is organized into three sections that depend on the status of laboratory evidence of HIV infection (e.g., HIV antibody) (Figure 1). The major proposed changes apply to patients with laboratory evidence for HIV infection: a) inclusion of HIV encephalopathy, HIV wasting syndrome, and a broader range of specific AIDS-indicative diseases (Section II.A); b) inclusion of AIDS patients whose indicator diseases are diagnosed presumptively (Section II.B); and c) elimination of exclusions due to other causes of immunodeficiency (Section I.A).

Application of the definition for children differs from that for adults in two ways. First, multiple or recurrent serious bacterial infections and lymphoid interstitial pneumonia/pulmonary lymphoid hyperplasia are accepted as indicative of AIDS among children but not among adults. Second, for children<15 months of age whose mothers are thought to have had HIV infection during the child's perinatal period, the laboratory criteria for HIV infection are more stringent, since the presence of HIV antibody in the child is, by itself, insufficient evidence for HIV infection because of the persistence of passively acquired maternal antibodies < 15 months after birth.

The new definition is effective immediately. State and local health departments are requested to apply the new definition henceforth to patients reported to them. The initiation of the actual reporting of cases that meet the new definition is targeted for September 1, 1987, when modified computer software and report forms should be in place to accommodate the changes. CSTE has recommended retrospective application of the revised definition to patients already reported to health departments. The new definition follows:

# 1987 REVISION OF CASE DEFINITION FOR AIDS FOR SURVEILLANCE PURPOSES

For national reporting, a case of AIDS is defined as an illness characterized by one or more of the following "indicator" diseases, depending on the status of laboratory evidence of HIV infection, as shown below.

## I. Without Laboratory Evidence Regarding HIV Infection

If laboratory tests for HIV were not performed or gave inconclusive results (*See* Appendix I) and the patient had no other cause of immunodeficiency listed in Section I.A below, then any disease listed in Section I.B indicates AIDS if it was diagnosed by a definitive method (*See* Appendix II).

**A. Causes of immunodeficiency that disqualify diseases as indicators of AIDS in the absence of laboratory evidence for HIV infection**

1. high-dose or long-term systemic corticosteroid therapy or other immunosuppressive/cytotoxic therapy ≤3 months before the onset of the indicator disease
2. any of the following diseases diagnosed ≤3 months after diagnosis of the indicator disease: Hodgkin's disease, non-Hodgkin's lymphoma (other than primary brain lymphoma), lymphocytic leukemia, multiple myeloma, any other cancer of lymphoreticular or histiocytic tissue, or angioimmunoblastic lymphadenopathy
3. a genetic (congenital) immunodeficiency syndrome or an acquired immunodeficiency syndrome atypical of HIV infection, such as one involving hypogammaglobulinemia

**B. Indicator diseases diagnosed definitively (*See* Appendix II)**

1. candidiasis of the esophagus, trachea, bronchi, or lungs
2. cryptococcosis, extrapulmonary
3. cryptosporidiosis with diarrhea persisting >1 month
4. cytomegalovirus disease of an organ other than liver, spleen, or lymph nodes in a patient >1 month of age
5. herpes simplex virus infection causing a mucocutaneous ulcer that persists longer than 1 month; or bronchitis, pneumonitis, or esophagitis for any duration affecting a patient >1 month of age
6. Kaposi's sarcoma affecting a patient < 60 years of age
7. lymphoma of the brain (primary) affecting a patient < 60 years of age
8. lymphoid interstitial pneumonia and/or pulmonary lymphoid hyperplasia (LIP/PLH complex) affecting a child <13 years of age
9. *Mycobacterium avium* complex or *M. kansasii* disease, disseminated (at a site other than or in addition to lungs, skin, or cervical or hilar lymph nodes)
10. *Pneumocystis carinii* pneumonia
11. progressive multifocal leukoencephalopathy
12. toxoplasmosis of the brain affecting a patient >1 month of age

## II. With Laboratory Evidence for HIV Infection

*Regardless of the presence of other causes of immunodeficiency (I.A),* in the presence of laboratory evidence for HIV infection (*See* Appendix I), any disease listed above (I.B) or below (II.A or II.B) indicates a diagnosis of AIDS.

**A. Indicator diseases diagnosed definitively (*See* Appendix II)**

1. bacterial infections, multiple or recurrent (any combination of at least two within a 2-year period), of the following types affecting a child < 13 years of age:
   septicemia, pneumonia, meningitis, bone or joint infection, or abscess of an internal organ or body cavity (excluding otitis media or superficial skin or mucosal abscesses), caused by *Haemophilus*, *Streptococcus* (including pneumococcus), or other pyogenic bacteria
2. coccidioidomycosis, disseminated (at a site other than or in addition to lungs or cervical or hilar lymph nodes)
3. HIV encephalopathy (also called "HIV dementia," "AIDS dementia," or "subacute encephalitis due to HIV") (*See* Appendix II for description)
4. histoplasmosis, disseminated (at a site other than or in addition to lungs or cervical or hilar lymph nodes)
5. isosporiasis with diarrhea persisting >1 month
6. Kaposi's sarcoma at any age
7. lymphoma of the brain (primary) at any age
8. other non-Hodgkin's lymphoma of B-cell or unknown immunologic phenotype and the following histologic types:
   a. small noncleaved lymphoma (either Burkitt or non-Burkitt type) (*See* Appendix IV for equivalent terms and numeric codes used in the *International Classification of Diseases*, Ninth Revision, Clinical Modification)
   b. immunoblastic sarcoma (equivalent to any of the following, although not necessarily all in combination: immunoblastic lymphoma, large-cell lymphoma, diffuse histiocytic lymphoma, diffuse undifferentiated lymphoma, or high-grade lymphoma) (*See* Appendix IV for equivalent terms and numeric codes used in the *International Classification of Diseases*, Ninth Revision, Clinical Modification)

   **Note:** Lymphomas are not included here if they are of T-cell immunologic phenotype or their histologic type is not described or is described as "lymphocytic," "lymphoblastic," "small cleaved," or "plasmacytoid lymphocytic"
9. any mycobacterial disease caused by mycobacteria other than *M. tuberculosis*, disseminated (at a site other than or in addition to lungs, skin, or cervical or hilar lymph nodes)
10. disease caused by *M. tuberculosis*, extrapulmonary (involving at least one site outside the lungs, regardless of whether there is concurrent pulmonary involvement)
11. *Salmonella* (nontyphoid) septicemia, recurrent
12. HIV wasting syndrome (emaciation, "slim disease") (*See* Appendix II for description)

**B. Indicator diseases diagnosed presumptively (by a method other than those in Appendix II)**

**Note:** Given the seriousness of diseases indicative of AIDS, it is generally important to diagnose them definitively, especially when therapy that would be used may have serious side effects or when definitive diagnosis is needed

for eligibility for antiretroviral therapy. Nonetheless, in some situations, a patient's condition will not permit the performance of definitive tests. In other situations, accepted clinical practice may be to diagnose presumptively based on the presence of characteristic clinical and laboratory abnormalities. Guidelines for presumptive diagnoses are suggested in Appendix III.

1. candidiasis of the esophagus
2. cytomegalovirus retinitis with loss of vision
3. Kaposi's sarcoma
4. lymphoid interstitial pneumonia and/or pulmonary lymphoid hyperplasia (LIP/PLH complex) affecting a child <13 years of age
5. mycobacterial disease (acid-fast bacilli with species not identified by culture), disseminated (involving at least one site other than or in addition to lungs, skin, or cervical or hilar lymph nodes)
6. *Pneumocystis carinii* pneumonia
7. toxoplasmosis of the brain affecting a patient >1 month of age

### III. With Laboratory Evidence Against HIV Infection

With laboratory test results negative for HIV infection (*See* Appendix I), a diagnosis of AIDS for surveillance purposes is ruled out *unless*:

A. all the other causes of immunodeficiency listed above in Section I.A are excluded; **AND**

B. the patient has had either:
   1. *Pneumocystis carinii* pneumonia diagnosed by a definitive method (*See* Appendix II); **OR**
   2. a. any of the other diseases indicative of AIDS listed above in Section I.B diagnosed by a definitive method (*See* Appendix II); **AND**
      b. a T-helper/inducer (CD4) lymphocyte count <400/mm$^3$.

## COMMENTARY

The surveillance of severe disease associated with HIV infection remains an essential, though not the only, indicator of the course of the HIV epidemic. The number of AIDS cases and the relative distribution of cases by demographic, geographic, and behavioral risk variables are the oldest indices of the epidemic, which began in 1981 and for which data are available retrospectively back to 1978. The original surveillance case definition, based on then-available knowledge, provided useful epidemiologic data on severe HIV disease (*1*). To ensure a reasonable predictive value for underlying immunodeficiency caused by what was then an unknown agent, the indicators of AIDS in the old case definition were restricted to particular opportunistic diseases diagnosed by reliable methods in patients without specific known causes of immunodeficiency. After HIV was discovered to be the cause of AIDS, however, and highly sensitive and specific HIV-antibody tests became available, the spectrum of manifestations of HIV infection became better defined, and classification systems for HIV infection were developed (*2-5*). It became apparent that some progressive, seriously disabling, and even fatal conditions (e.g., encephalopathy, wasting syndrome) affecting a substantial number of HIV-infected patients were not subject to epidemiologic surveillance, as they were not included in the AIDS

case definition. For reporting purposes, the revision adds to the definition most of those severe non-infectious, non-cancerous HIV-associated conditions that are categorized in the CDC clinical classification systems for HIV infection among adults and children (*4,5*).

Another limitation of the old definition was that AIDS-indicative diseases are diagnosed presumptively (i.e., without confirmation by methods required by the old definition) in 10%-15% of patients diagnosed with such diseases; thus, an appreciable proportion of AIDS cases were missed for reporting purposes (*6,7*). This proportion may be increasing, which would compromise the old case definition's usefulness as a tool for monitoring trends. The revised case definition permits the reporting of these clinically diagnosed cases as long as there is laboratory evidence of HIV infection.

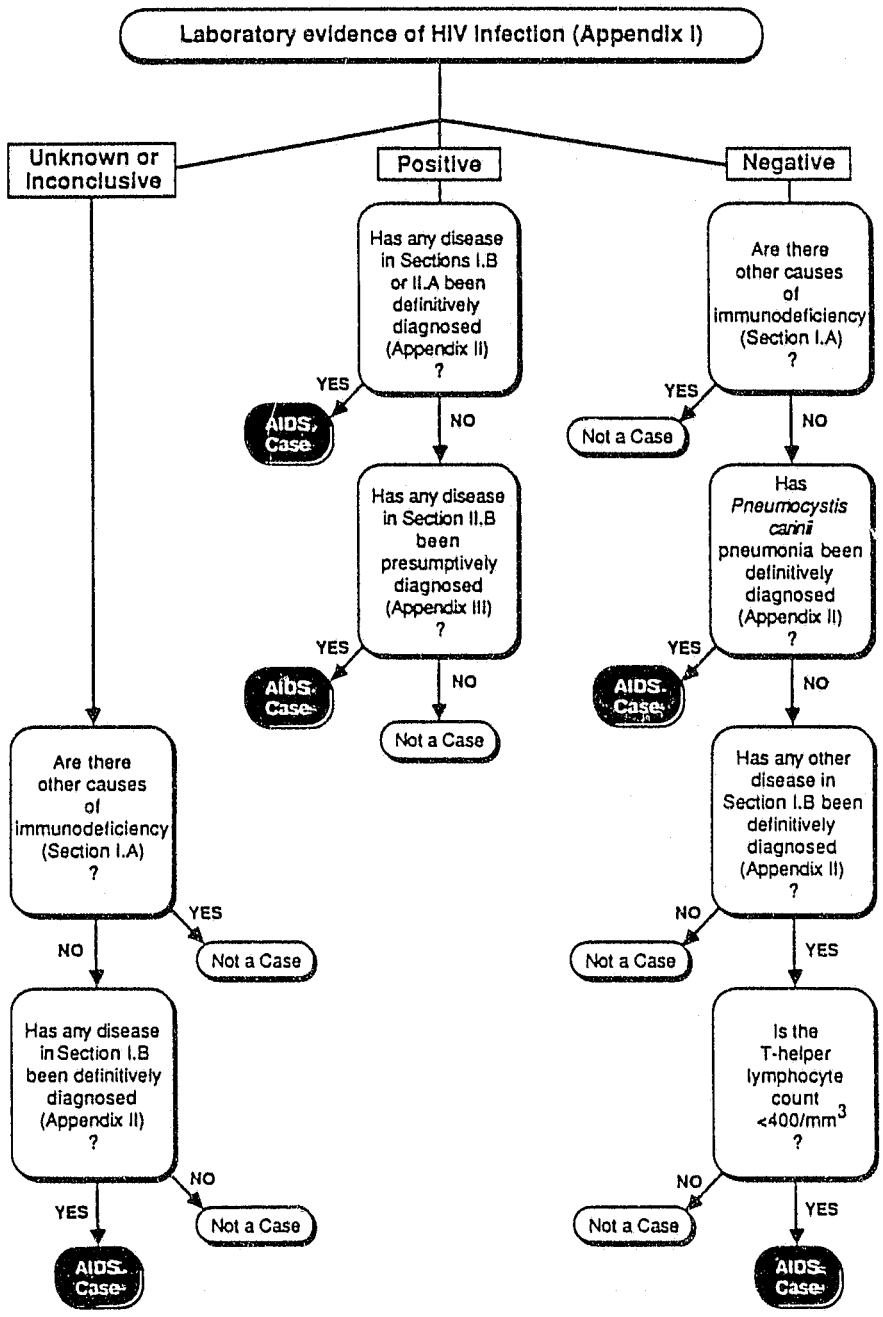
The effectiveness of the revision will depend on how extensively HIV-antibody tests are used. Approximately one third of AIDS patients in the United States have been from New York City and San Francisco, where, since 1985, < 7% have been reported with HIV-antibody test results, compared with > 60% in other areas. The impact of the revision on the reported numbers of AIDS cases will also depend on the proportion of AIDS patients in whom indicator diseases are diagnosed presumptively rather than definitively. The use of presumptive diagnostic criteria varies geographically, being more common in certain rural areas and in urban areas with many indigent AIDS patients.

To avoid confusion about what should be reported to health departments, the term "AIDS" should refer only to conditions meeting the surveillance definition. This definition is intended only to provide consistent statistical data for public health purposes. Clinicians will not rely on this definition alone to diagnose serious disease caused by HIV infection in individual patients because there may be additional information that would lead to a more accurate diagnosis. For example, patients who are not reportable under the definition because they have either a negative HIV-antibody test or, in the presence of HIV antibody, an opportunistic disease not listed in the definition as an indicator of AIDS nonetheless may be diagnosed as having serious HIV disease on consideration of other clinical or laboratory characteristics of HIV infection or a history of exposure to HIV.

Conversely, the AIDS surveillance definition may rarely misclassify other patients as having serious HIV disease if they have no HIV-antibody test but have an AIDS-indicative disease with a background incidence unrelated to HIV infection, such as cryptococcal meningitis.

The diagnostic criteria accepted by the AIDS surveillance case definition should not be interpreted as the standard of good medical practice. Presumptive diagnoses are accepted in the definition because not to count them would be to ignore substantial morbidity resulting from HIV infection. Likewise, the definition accepts a reactive screening test for HIV antibody without confirmation by a supplemental test because a repeatedly reactive screening test result, in combination with an indicator disease, is highly indicative of true HIV disease. For national surveillance purposes, the tiny proportion of possibly false-positive screening tests in persons with AIDS-indicative diseases is of little consequence. For the individual patient, however, a correct diagnosis is critically important. The use of supplemental tests is, therefore, strongly endorsed. An increase in the diagnostic use of HIV-antibody tests could improve both the quality of medical care and the function of the new case definition, as well as assist in providing counselling to prevent transmission of HIV.

FIGURE I. Flow diagram for revised CDC case definition of AIDS, September 1, 1987



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*Use of trade names is for identification only and does not constitute endorsement by the Public Health Service or the U.S. Department of Health and Human Services.*

# APPENDIX I

## Laboratory Evidence For or Against HIV Infection

1. **For Infection:**
   When a patient has disease consistent with AIDS:
   a. a serum specimen from a patient ≥15 months of age, or from a child <15 months of age whose mother is not thought to have had HIV infection during the child's perinatal period, that is repeatedly reactive for HIV antibody by a screening test (e.g., enzyme-linked immunosorbent assay [ELISA]), as long as subsequent HIV-antibody tests (e.g., Western blot, immunofluorescence assay), if done, are positive; **OR**
   b. a serum specimen from a child < 15 months of age, whose mother is thought to have had HIV infection during the child's perinatal period, that is repeatedly reactive for HIV antibody by a screening test (e.g., ELISA), plus increased serum immunoglobulin levels and at least one of the following abnormal immunologic test results: reduced absolute lymphocyte count, depressed CD4 (T-helper) lymphocyte count, or decreased CD4/CD8 (helper/suppressor) ratio, as long as subsequent antibody tests (e.g., Western blot, immunofluorescence assay), if done, are positive; **OR**
   c. a positive test for HIV serum antigen; **OR**
   d. a positive HIV culture confirmed by both reverse transcriptase detection and a specific HIV-antigen test or in situ hybridization using a nucleic acid probe; **OR**
   e. a positive result on any other highly specific test for HIV (e.g., nucleic acid probe of peripheral blood lymphocytes).

2. **Against Infection:**
   A nonreactive screening test for serum antibody to HIV (e.g., ELISA) without a reactive or positive result on any other test for HIV infection (e.g., antibody, antigen, culture), if done.

3. **Inconclusive (Neither For nor Against Infection):**
   a. a repeatedly reactive screening test for serum antibody to HIV (e.g., ELISA) followed by a negative or inconclusive supplemental test (e.g., Western blot, immunofluorescence assay) without a positive HIV culture or serum antigen test, if done; **OR**
   b. a serum specimen from a child < 15 months of age, whose mother is thought to have had HIV infection during the child's perinatal period, that is repeatedly reactive for HIV antibody by a screening test, even if positive by a supplemental test, without additional evidence for immunodeficiency as described above (in 1.b) and without a positive HIV culture or serum antigen test, if done.

# APPENDIX II

## Definitive Diagnostic Methods for Diseases Indicative of AIDS

| Diseases | Definitive Diagnostic Methods |
|---|---|
| cryptosporidiosis<br>cytomegalovirus<br>isosporiasis<br>Kaposi's sarcoma<br>lymphoma<br>lymphoid pneumonia or hyperplasia<br>*Pneumocystis carinii* pneumonia<br>progressive multifocal leukoencephalopathy<br>toxoplasmosis | microscopy (histology or cytology). |
| candidiasis | gross inspection by endoscopy or autopsy or by microscopy (histology or cytology) on a specimen obtained directly from the tissues affected (including scrapings from the mucosal surface), not from a culture. |
| coccidioidomycosis<br>cryptococcosis<br>herpes simplex virus<br>histoplasmosis | microscopy (histology or cytology), culture, or detection of antigen in a specimen obtained directly from the tissues affected or a fluid from those tissues. |
| tuberculosis<br>other mycobacteriosis<br>salmonellosis<br>other bacterial infection | culture. |
| HIV encephalopathy* (dementia) | clinical findings of disabling cognitive and/or motor dysfunction interfering with occupation or activities of daily living, or loss of behavioral developmental milestones affecting a child, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection that could explain the findings. Methods to rule out such concurrent illnesses and conditions must include cerebrospinal fluid examination and either brain imaging (computed tomography or magnetic resonance) or autopsy. |
| HIV wasting syndrome* | findings of profound involuntary weight loss >10% of baseline body weight plus either chronic diarrhea (at least two loose stools per day for ≥ 30 days) or chronic weakness and documented fever (for ≥ 30 days, intermittent or constant) in the absence of a concurrent illness or condition other than HIV infection that could explain the findings (e.g., cancer, tuberculosis, cryptosporidiosis, or other specific enteritis). |

*For HIV encephalopathy and HIV wasting syndrome, the methods of diagnosis described here are not truly definitive, but are sufficiently rigorous for surveillance purposes.

# APPENDIX III

## Suggested Guidelines for Presumptive Diagnosis of Diseases Indicative of AIDS

| Diseases | Presumptive Diagnostic Criteria |
|---|---|
| candidiasis of esophagus | a. recent onset of retrosternal pain on swallowing; **AND**<br>b. oral candidiasis diagnosed by the gross appearance of white patches or plaques on an erythematous base or by the microscopic appearance of fungal mycelial filaments in an uncultured specimen scraped from the oral mucosa. |
| cytomegalovirus retinitis | a characteristic appearance on serial ophthalmoscopic examinations (e.g., discrete patches of retinal whitening with distinct borders, spreading in a centrifugal manner, following blood vessels, progressing over several months, frequently associated with retinal vasculitis, hemorrhage, and necrosis). Resolution of active disease leaves retinal scarring and atrophy with retinal pigment epithelial mottling. |
| mycobacteriosis | microscopy of a specimen from stool or normally sterile body fluids or tissue from a site other than lungs, skin, or cervical or hilar lymph nodes, showing acid-fast bacilli of a species not identified by culture. |
| Kaposi's sarcoma | a characteristic gross appearance of an erythematous or violaceous plaque-like lesion on skin or mucous membrane.<br>(**Note:** Presumptive diagnosis of Kaposi's sarcoma should not be made by clinicians who have seen few cases of it.) |
| lymphoid interstitial pneumonia | bilateral reticulonodular interstitial pulmonary infiltrates present on chest X ray for ≥2 months with no pathogen identified and no response to antibiotic treatment. |
| *Pneumocystis carinii* pneumonia | a. a history of dyspnea on exertion or nonproductive cough of recent onset (within the past 3 months); **AND**<br>b. chest X-ray evidence of diffuse bilateral interstitial infiltrates or gallium scan evidence of diffuse bilateral pulmonary disease; **AND**<br>c. arterial blood gas analysis showing an arterial $pO_2$ of <70 mm Hg or a low respiratory diffusing capacity (<80% of predicted values) or an increase in the alveolar-arterial oxygen tension gradient; **AND**<br>d. no evidence of a bacterial pneumonia. |
| toxoplasmosis of the brain | a. recent onset of a focal neurologic abnormality consistent with intracranial disease or a reduced level of consciousness; **AND**<br>b. brain imaging evidence of a lesion having a mass effect (on computed tomography or nuclear magnetic resonance) or the radiographic appearance of which is enhanced by injection of contrast medium; **AND**<br>c. serum antibody to toxoplasmosis or successful response to therapy for toxoplasmosis. |

# APPENDIX IV

## Equivalent Terms and International Classification of Disease (ICD) Codes for AIDS-Indicative Lymphomas

The following terms and codes describe lymphomas indicative of AIDS in patients with antibody evidence for HIV infection (Section II.A.8 of the AIDS case definition). Many of these terms are obsolete or equivalent to one another.

### ICD-9-CM (1978)

| Codes | Terms |
|---|---|
| 200.0 | **Reticulosarcoma**<br>lymphoma (malignant): histiocytic (diffuse) reticulum cell sarcoma: pleomorphic cell type or not otherwise specified |
| 200.2 | **Burkitt's tumor or lymphoma**<br>malignant lymphoma, Burkitt's type |

### ICD-O (Oncologic Histologic Types 1976)

| Codes | Terms |
|---|---|
| 9600/3 | **Malignant lymphoma, undifferentiated cell type**<br>non-Burkitt's or not otherwise specified |
| 9601/3 | **Malignant lymphoma, stem cell type**<br>stem cell lymphoma |
| 9612/3 | **Malignant lymphoma, immunoblastic type**<br>immunoblastic sarcoma, immunoblastic lymphoma, or immunoblastic lymphosarcoma |
| 9632/3 | **Malignant lymphoma, centroblastic type**<br>diffuse or not otherwise specified, or germinoblastic sarcoma: diffuse or not otherwise specified |
| 9633/3 | **Malignant lymphoma, follicular center cell, non-cleaved**<br>diffuse or not otherwise specified |
| 9640/3 | **Reticulosarcoma, not otherwise specified**<br>malignant lymphoma, histiocytic: diffuse or not otherwise specified reticulum cell sarcoma, not otherwise specified malignant lymphoma, reticulum cell type |
| 9641/3 | **Reticulosarcoma, pleomorphic cell type**<br>malignant lymphoma, histiocytic, pleomorphic cell type reticulum cell sarcoma, pleomorphic cell type |
| 9750/3 | **Burkitt's lymphoma or Burkitt's tumor**<br>malignant lymphoma, undifferentiated, Burkitt's type malignant lymphoma, lymphoblastic, Burkitt's type |

# II. HEALTH-CARE WORKERS AND LABORATORY PERSONNEL

1982 November 5;31:577–80

## Acquired Immune Deficiency Syndrome (AIDS): Precautions for Clinical and Laboratory Staffs

The etiology of the underlying immune deficiencies seen in AIDS cases is unknown. One hypothesis consistent with current observations is that a transmissible agent may be involved. If so, transmission of the agent would appear most commonly to require intimate, direct contact involving mucosal surfaces, such as sexual contact among homosexual males, or through parenteral spread, such as occurs among intravenous drug abusers and possibly hemophilia patients using Factor VIII products. Airborne spread and interpersonal spread through casual contact do not seem likely. These patterns resemble the distribution of disease and modes of spread of hepatitis B virus, and hepatitis B virus infections occur very frequently among AIDS cases.

There is presently no evidence of AIDS transmission to hospital personnel from contact with affected patients or clinical specimens. Because of concern about a possible transmissible agent, however, interim suggestions are appropriate to guide patient-care and laboratory personnel, including those whose work involves experimental animals. At present, it appears prudent for hospital personnel to use the same precautions when caring for patients with AIDS as those used for patients with hepatitis B virus infection, in which blood and body fluids likely to have been contaminated with blood are considered infective. Specifically, patient-care and laboratory personnel should take precautions to avoid direct contact of skin and mucous membranes with blood, blood products, excretions, secretions, and tissues of persons judged likely to have AIDS. The following precautions do not specifically address outpatient care, dental care, surgery, necropsy, or hemodialysis of AIDS patients. In general, procedures appropriate for patients known to be infected with hepatitis B virus are advised, and blood and organs of AIDS patients should not be donated.

The precautions that follow are advised for persons and specimens from persons with: opportunistic infections that are not associated with underlying immunosuppressive disease or therapy; Kaposi's sarcoma (patients under 60 years of age); chronic generalized lymphadenopathy, unexplained weight loss and/or prolonged unexplained fever in persons who belong to groups with apparently increased risks of AIDS (homosexual males, intravenous drug abusers, Haitian entrants, hemophiliacs); and possible AIDS (hospitalized for evaluation). Hospitals and laboratories should adapt the following suggested precautions to their individual circumstances; these recommendations are not meant to restrict hospitals from implementing additional precautions.

A. The following precautions are advised in providing care to AIDS patients:

1. Extraordinary care must be taken to avoid accidental wounds from sharp instruments contaminated with potentially infectious material and to avoid contact of open skin lesions with material from AIDS patients.
2. Gloves should be worn when handling blood specimens, blood-soiled items, body fluids, excretions, and secretions, as well as surfaces, materials, and objects exposed to them.
3. Gowns should be worn when clothing may be soiled with body fluids, blood, secretions, or excretions.
4. Hands should be washed after removing gowns and gloves and before leaving the rooms of known or suspected AIDS patients. Hands should also be washed thoroughly and immediately if they become contaminated with blood.
5. Blood and other specimens should be labeled prominently with a special warning, such as "Blood Precautions" or "AIDS Precautions." If the outside of the specimen container is visibly contaminated with blood, it should be cleaned with a disinfectant (such as a 1:10 dilution of 5.25% sodium hypochlorite [household bleach] with water). All blood specimens should be placed in a second container, such as an impervious bag, for transport. The container or bag should be examined carefully for leaks or cracks.

6. Blood spills should be cleaned up promptly with a disinfectant solution, such as sodium hypochlorite (see above).
7. Articles soiled with blood should be placed in an impervious bag prominently labeled "AIDS Precautions" or "Blood Precautions" before being sent for reprocessing or disposal. Alternatively, such contaminated items may be placed in plastic bags of a particular color designated solely for disposal of infectious wastes by the hospital. Disposable items should be incinerated or disposed of in accord with the hospital's policies for disposal of infectious wastes. Reusable items should be reprocessed in accord with hospital policies for hepatitis B virus-contaminated items. Lensed instruments should be sterilized after use on AIDS patients.
8. Needles should not be bent after use, but should be promptly placed in a puncture-resistant container used solely for such disposal. Needles should not be reinserted into their original sheaths before being discarded into the container, since this is a common cause of needle injury.
9. Disposable syringes and needles are preferred. Only needle-locking syringes or one-piece needle-syringe units should be used to aspirate fluids from patients, so that collected fluid can be safely discharged through the needle, if desired. If reusable syringes are employed, they should be decontaminated before reprocessing.
10. A private room is indicated for patients who are too ill to use good hygiene, such as those with profuse diarrhea, fecal incontinence, or altered behavior secondary to central nervous system infections.

Precautions appropriate for particular infections that concurrently occur in AIDS patients should be added to the above, if needed.

B. The following precautions are advised for persons performing laboratory tests or studies on clinical specimens or other potentially infectious materials (such as inoculated tissue cultures, embryonated eggs, animal tissues, etc.) from known or suspected AIDS cases:

1. Mechanical pipetting devices should be used for the manipulation of all liquids in the laboratory. Mouth pipetting should not be allowed.
2. Needles and syringes should be handled as stipulated in Section A (above).
3. Laboratory coats, gowns, or uniforms should be worn while working with potentially infectious materials and should be discarded appropriately before leaving the laboratory.
4. Gloves should be worn to avoid skin contact with blood, specimens containing blood, blood-soiled items, body fluids, excretions, and secretions, as well as surfaces, materials, and objects exposed to them.
5. All procedures and manipulations of potentially infectious material should be performed carefully to minimize the creation of droplets and aerosols.
6. Biological safety cabinets (Class I or II) and other primary containment devices (e.g., centrifuge safety cups) are advised whenever procedures are conducted that have a high potential for creating aerosols or infectious droplets. These include centrifuging, blending, sonicating, vigorous mixing, and harvesting infected tissues from animals or embryonated eggs. Fluorescent activated cell sorters generate droplets that could potentially result in infectious aerosols. Translucent plastic shielding between the droplet-collecting area and the equipment operator should be used to reduce the presently uncertain magnitude of this risk. Primary containment devices are also used in handling materials that might contain concentrated infectious agents or organisms in greater quantities than expected in clinical specimens.
7. Laboratory work surfaces should be decontaminated with a disinfectant, such as sodium hypochlorite solution (see A5 above), following any spill of potentially infectious material and at the completion of work activities.
8. All potentially contaminated materials used in laboratory tests should be decontaminated, preferably by autoclaving, before disposal or reprocessing.
9. All personnel should wash their hands following completion of laboratory activities, removal of protective clothing, and before leaving the laboratory.

C. The following additional precautions are advised for studies involving experimental animals inoculated with tissues or other potentially infectious materials from individuals with known or suspected AIDS.

1. Laboratory coats, gowns, or uniforms should be worn by personnel entering rooms housing inoculated animals. Certain nonhuman primates, such as chimpanzees, are prone to throw excreta and to spit at attendants; personnel attending inoculated animals should wear molded surgical masks and goggles or other equipment sufficient to prevent potentially infective droplets from reaching the mucosal surfaces of their mouths, nares, and eyes. In addition, when handled, other animals may disturb excreta in their bedding. Therefore, the above precautions should be taken when handling them.
2. Personnel should wear gloves for all activities involving direct contact with experimental animals and their bedding and cages. Such manipulations should be performed carefully to minimize the creation of aerosols and droplets.
3. Necropsy of experimental animals should be conducted by personnel wearing gowns and gloves. If procedures generating aerosols are performed, masks and goggles should be worn.
4. Extraordinary care must be taken to avoid accidental sticks or cuts with sharp instruments contaminated with body fluids or tissues of experimental animals inoculated with material from AIDS patients.
5. Animal cages should be decontaminated, preferably by autoclaving, before they are cleaned and washed.
6. Only needle-locking syringes or one-piece needle-syringe units should be used to inject potentially infectious fluids into experimental animals.

The above precautions are intended to apply to both clinical and research laboratories. Biological safety cabinets and other safety equipment may not be generally available in clinical laboratories. Assistance should be sought from a microbiology laboratory, as needed, to assure containment facilities are adequate to permit laboratory tests to be conducted safely.

*Reported by Hospital Infections Program, Div of Viral Diseases, Div of Host Factors, Div of Hepatitis and Viral Enteritis, AIDS Activity, Center for Infectious Diseases, Office of Biosafety, CDC; Div of Safety, National Institutes of Health.*

# Acquired Immunodeficiency Syndrome (AIDS): Precautions for Health-Care Workers and Allied Professionals

Acquired immunodeficiency syndrome (AIDS) was first recognized in 1981. The epidemiology of AIDS is consistent with the hypothesis that it is caused by a transmissible infectious agent (*1-3*). AIDS appears to be transmitted by intimate sexual contact or by percutaneous inoculation of blood or blood products. There has been no evidence of transmission by casual contact or airborne spread, nor have there been cases of AIDS in health-care or laboratory personnel that can be definitely ascribed to specific occupational exposures (*4*).

CDC has published recommended precautions for clinical and laboratory personnel who work with AIDS patients (*5*). Precautions for these and allied professionals are designed to minimize the risk of mucosal or parenteral exposure to potentially infective materials. Such exposure can occur during direct patient care or while working with clinical or laboratory specimens and from inadvertent or unknowing exposure to equipment, such as needles, contaminated with potentially infective materials. Caution should be exercised in handling secretions or excretions, particularly blood and body fluids, from the following: (1) patients who meet the existing surveillance definition of AIDS (*1*); (2) patients with chronic, generalized lymphadenopathy, unexplained weight loss, and/or prolonged unexplained fever when the patient's history suggests an epidemiologic risk for AIDS (*1,2*); and (3) all hospitalized patients with possible AIDS.

These principles for preventing AIDS transmission also need to be adopted by allied professionals not specifically addressed in the previous publications but whose work may bring them into contact with potentially infective material from patients with the illnesses described in the above three groups.

The following precautions are recommended for those who provide dental care, perform postmortem examinations, and perform work as morticians when working with persons with histories of illnesses described in the above three groups:

**DENTAL-CARE PERSONNEL**

1. Personnel should wear gloves, masks, and protective eyewear when performing dental or oral surgical procedures.
2. Instruments used in the mouths of patients should be sterilized after use (*5-9*).

**PERSONS PERFORMING NECROPSIES OR PROVIDING MORTICIANS' SERVICES**

1. As part of immediate postmortem care, deceased persons should be identified as belonging to one of the above three groups, and that identification should remain with the body.
2. The procedures followed before, during, and after the postmortem examination are similar to those for hepatitis B. All personnel involved in performing an autopsy should wear double gloves, masks, protective eyewear, gowns, waterproof aprons, and waterproof shoe coverings. Instruments and surfaces contaminated during the postmortem examination should be handled as potentially infective items (*5-7*).
3. Morticians should evaluate specific procedures used in providing mortuary care and take appropriate precautions to prevent the parenteral or mucous-membrane exposure of personnel to body fluids.

These and earlier recommendations outline good infection control and laboratory practices and are similar to the recommendations for prevention of hepatitis B. As new information becomes available on the cause and transmission of AIDS, these precautions will be revised as necessary.

*Reported by AIDS Activity, Div of Host Factors, Div of Viral Diseases, Hospital Infections Program, Center for Infectious Diseases, Office of Biosafety, CDC*

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## Recommendations for Preventing Possible Transmission of Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus from Tears

Human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the etiologic agent of acquired immunodeficiency syndrome (AIDS), has been found in various body fluids, including blood, semen, and saliva. Recently, scientists at the National Institutes of Health isolated the virus from the tears of an AIDS patient (*1*). The patient, a 33-year-old woman with a history of *Pneumocystis carinii* pneumonia and disseminated *Mycobacterium avium-intracellulare* infection, had no ocular complaints, and her eye examination was normal. Of the tear samples obtained from six other patients with AIDS or related conditions, three showed equivocal culture results, and three were culture-negative.

The following precautions are judged suitable to prevent spread of HTLV-III/LAV and other microbial pathogens that might be present in tears. They do not apply to the procedures used by individuals in caring for their own lenses, since the concern is the possible virus transmission between individuals.

1. Health-care professionals performing eye examinations or other procedures involving contact with tears should wash their hands immediately after a procedure and between patients. Handwashing alone should be sufficient, but when practical and convenient, disposable gloves may be worn. The use of gloves is advisable when there are cuts, scratches, or dermatologic lesions on the hands. Use of other protective measures, such as masks, goggles, or gowns, is *not* indicated.
2. Instruments that come into direct contact with external surfaces of the eye should be wiped clean and then disinfected by: (a) a 5- to 10-minute exposure to a fresh solution of 3% hydrogen peroxide; or (b) a fresh solution containing 5,000 parts per million (mg/L) free available chlorine—a 1/10 dilution of common household bleach (sodium hypochlorite); or (c) 70% ethanol; or (d) 70% isopropanol. The device should be thoroughly rinsed in tap water and dried before reuse.
3. Contact lenses used in trial fittings should be disinfected between each fitting by one of the following regimens:
   a. Disinfection of trial hard lenses with a commercially available hydrogen peroxide contact lens disinfecting system currently approved for soft contact lenses. (Other hydrogen peroxide preparations may contain preservatives that could discolor the lenses.) Alternatively, most trial hard lenses can be treated with the standard heat disinfection regimen used for soft lenses (78-80 C [172-176 F] for 10 minutes). Practitioners should check with hard lens suppliers to ascertain which lenses can be safely heat-treated.
   b. Rigid gas permeable (RGP) trial fitting lenses can be disinfected using the above hydrogen peroxide disinfection system. RGP lenses may warp if they are heat-disinfected.
   c. Soft trial fitting lenses can be disinfected using the same hydrogen peroxide system. Some soft lenses have also been approved for heat disinfection.

   Other than hydrogen peroxide, the chemical disinfectants used in standard contact lens solutions have not yet been tested for their activity against HTLV-III/LAV. Until other disinfectants are shown to be suitable for disinfecting HTLV-III/LAV, contact lenses used in the eyes of patients suspected or known to be infected with HTLV-III/LAV are most safely handled by hydrogen peroxide disinfection.

The above recommendations are based on data from studies conducted at the National Institutes of Health and CDC on disinfection/inactivation of HTLV-III/LAV virus (*2-4*). Additional information regarding general hospital and laboratory precautions have been previously published (*5-9*).

*Reported by the U.S. Food and Drug Administration; National Institutes of Health; Centers for Disease Control.*

**Editorial Note:** All secretions and excretions of an infected person may contain lymphocytes, host cells for HTLV-III/LAV; therefore, thorough study of these fluids might be expected to sometimes yield this virus. Despite positive cultures from a variety of body fluids of infected persons, however, spread from infected persons to household contacts who have no other identifiable risks for infection has not been documented. Furthermore, there is no evidence to date that HTLV-III/LAV has been transmitted through contact with the tears of infected individuals or through medical instruments used to examine AIDS patients.

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# Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus during Invasive Procedures

## BACKGROUND

On November 15, 1985, "Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus in the Workplace," was published (*1*). That document gave particular emphasis to health-care settings and indicated that formulation of further specific recommendations for preventing human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV) transmission applicable to health-care workers (HCWs) who perform invasive procedures was in progress.

Toward that end, a 2-day meeting was held at CDC to discuss draft recommendations applicable to individuals who perform or assist in invasive procedures.* Following the meeting, revised draft recommendations for HCWs who have contact with tissues or mucous membranes while performing or assisting in operative, obstetric, or dental invasive procedures were sent to participants for comment. In addition, 10 physicians with expertise in infectious diseases and the epidemiology of HTLV-III/LAV infection were consulted to determine whether they felt additional measures or precautions beyond those recommended below were indicated. These 10 experts did not feel that additional recommendations or precautions were indicated.

## DEFINITIONS

In this document, an operative procedure is defined as surgical entry into tissues, cavities, or organs or repair of major traumatic injuries in an operating or delivery room, emergency department, or outpatient setting, including both physicians' and dentists' offices. An obstetric procedure is defined as a vaginal or cesarean delivery or other invasive obstetric procedure where bleeding may occur. A dental procedure is defined as the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, where bleeding occurs or the potential for bleeding exists.

## RECOMMENDATIONS

There have been no reports of HTLV-III/LAV transmission from an HCW to a patient or from a patient to an HCW during operative, obstetric, or dental invasive procedures. Nevertheless, special emphasis should be placed on the following precautions to prevent transmission of bloodborne agents between all patients and all HCWs who perform or assist in invasive procedures.

1. All HCWs who perform or assist in operative, obstetric, or dental invasive procedures must be educated regarding the epidemiology, modes of transmission, and prevention of HTLV-III/LAV infection and the need for routine use of appropriate barrier precautions during procedures and when handling instruments contaminated with blood after procedures.
2. All HCWs who perform or assist in invasive procedures must wear gloves when touching mucous membranes or nonintact skin of all patients and use other appropriate barrier precautions when indicated (e.g., masks, eye coverings, and gowns, if aerosolization or splashes are likely to occur). In the dental setting, as in the operative and obstetric setting, gloves must be worn for touching all mucous membranes and changed between all patient contacts. If a glove is torn or a needlestick or other injury occurs, the glove must be changed as promptly as safety permits and the needle or instrument removed from the sterile field.

*The following organizations were represented at the meeting: American Academy of Family Physicians; American Academy of Periodontology; American Association of Dental Schools; American Association of Medical Colleges; American Association of Oral and Maxillofacial Surgeons; American Association of Physicians for Human Rights; American College of Emergency Physicians; American College of Nurse Midwives; American College of Obstetricians and Gynecologists; American College of Surgeons; American Dental Association; American Dental Hygienists Association; American Hospital Association; American Medical Association; American Nurses' Association; American Public Health Association; Association for Practitioners in Infection Control; Association of Operating Room Nurses; Association of State and Territorial Health Officials; Conference of State and Territorial Epidemiologists; U.S. Food and Drug Administration; Infectious Diseases Society of America; National Association of County Health Officials; National Dental Association; National Institutes of Health; National Medical Association; Nurses Association of the American College of Obstetricians and Gynecologists; Society of Hospital Epidemiologists of America; Surgical Infection Society; and United States Conference of Local Health Officers. In addition, a hospital administrator, a hospital medical director, and representatives from CDC participated in the meeting. These recommendations may not reflect the views of all individual consultants or the organizations they represented.

3. All HCWs who perform or assist in vaginal or cesarean deliveries must use appropriate barrier precautions (e.g., gloves and gowns) when handling the placenta or the infant until blood and amniotic fluid have been removed from the infant's skin. Recommendations for assisting in the prevention of perinatal transmission of HTLV-III/LAV have been published (*2*).
4. All HCWs who perform or assist in invasive procedures must use extraordinary care to prevent injuries to hands caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments following procedures. After use, disposable syringes and needles, scalpel blades, and other sharp items must be placed in puncture-resistant containers for disposal. To prevent needlestick injuries, needles should not be recapped; purposefully bent or broken; removed from disposable syringes; or otherwise manipulated by hand. No data are currently available from controlled studies examining the effect, if any, of the use of needle-cutting devices on the incidence of needlestick injuries.
5. If an incident occurs during an invasive procedure that results in exposure of a patient to the blood of an HCW, the patient should be informed of the incident, and previous recommendations for management of such exposures (*1*) should be followed.
6. No HCW who has exudative lesions or weeping dermatitis should perform or assist in invasive procedures or other direct patient-care activities or handle equipment used for patient care.
7. All HCWs with evidence of any illness that may compromise their ability to adequately and safely perform invasive procedures should be evaluated medically to determine whether they are physically and mentally competent to perform invasive procedures.
8. Routine serologic testing for evidence of HTLV-III/LAV infection is not necessary for HCWs who perform or assist in invasive procedures or for patients undergoing invasive procedures, since the risk of transmission in this setting is so low. Results of such routine testing would not practically supplement the precautions recommended above in further reducing the negligible risk of transmission during operative, obstetric, or dental invasive procedures.

Previous recommendations (*1,3,4*) should be consulted for: (1) preventing transmission of HTLV-III/LAV infection from HCWs to patients and patients to HCWs in health-care settings other than those described in this document; (2) preventing transmission from patient to patient; (3) sterilizing, disinfecting, housekeeping, and disposing of waste; and (4) managing parenteral and mucous-membrane exposures of HCWs and patients. Previously recommended precautions (*1*) are also applicable to HCWs performing or assisting in invasive procedures.

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## Recommended Infection-Control Practices for Dentistry

Dental personnel may be exposed to a wide variety of microorganisms in the blood and saliva of patients they treat in the dental operatory. These include *Mycobacterium tuberculosis*, hepatitis B virus, staphylococci, streptococci, cytomegalovirus, herpes simplex virus types I and II, human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), and a number of viruses that infect the upper respiratory tract. Infections may be transmitted in dental practice by blood or saliva through direct contact, droplets, or aerosols. Although not documented, indirect contact transmission of infection by contaminated instruments is possible. Patients and dental health-care workers (DHCWs) have the potential of transmitting infections to each other (*1*).

A common set of infection-control strategies should be effective for preventing hepatitis B, acquired immunodeficiency syndrome, and other infectious diseases caused by bloodborne viruses (*2-4*). The ability of hepatitis B virus to survive in the environment (*5*) and the high titers of virus in blood (*6*) make this virus a good model for infection-control practices to prevent transmission of a large number of other infectious agents by blood or saliva. Because all infected patients cannot be identified by history, physical examination, or readily available laboratory tests (*3*), the following recommendations should be used routinely in the care of all patients in dental practices.

### MEDICAL HISTORY

Always obtain a thorough medical history. Include specific questions about medications, current illnesses, hepatitis, recurrent illnesses, unintentional weight loss, lymphadenopathy, oral soft tissue lesions, or other infections. Medical consultation may be indicated when a history of active infection or systemic disease is elicited.

### USE OF PROTECTIVE ATTIRE AND BARRIER TECHNIQUES

1. For protection of personnel and patients, gloves must always be worn when touching blood, saliva, or mucous membranes (*7-10*). Gloves must be worn by DHCWs when touching blood-soiled items, body fluids, or secretions, as well as surfaces contaminated with them. Gloves must be worn when examining all oral lesions. All work must be completed on one patient, where possible, and the hands must be washed and regloved before performing procedures on another patient. Repeated use of a single pair of gloves is not recommended, since such use is likely to produce defects in the glove material, which will diminish its value as an effective barrier.

2. Surgical masks and protective eyewear or chin-length plastic face shields must be worn when splashing or spattering of blood or other body fluids is likely, as is common in dentistry (*11,12*).

3. Reusable or disposable gowns, laboratory coats, or uniforms must be worn when clothing is likely to be soiled with blood or other body fluids. If reusable gowns are worn, they may be washed, using a normal laundry cycle. Gowns should be changed at least daily or when visibly soiled with blood (*13*).

4. Impervious-backed paper, aluminum foil, or clear plastic wrap may be used to cover surfaces (e.g., light handles or x-ray unit heads) that may be contaminated by blood or saliva and that are difficult or impossible to disinfect. The coverings should be removed (while DHCWs are gloved), discarded, and then replaced (after ungloving) with clean material between patients.

5. All procedures and manipulations of potentially infective materials should be performed carefully to minimize the formation of droplets, spatters, and aerosols, where possible. Use of rubber dams, where appropriate, high-speed evacuation, and proper patient positioning should facilitate this process.

### HANDWASHING AND CARE OF HANDS

Hands must always be washed between patient treatment contacts (following removal of gloves), after touching inanimate objects likely to be contaminated by blood or saliva from other patients, and before leaving the operatory. The rationale for handwashing after gloves have been worn is that gloves become perforated, knowingly or unknowingly, during use and allow bacteria to enter beneath the glove material and multiply rapidly. For many routine dental procedures, such as examinations and nonsurgical techniques, handwashing with plain soap appears to be adequate, since soap and water will remove transient microorganisms acquired directly or indirectly from patient contact (*13*). For surgical procedures, an antimicro-

bial surgical handscrub should be used (*14*). Extraordinary care must be used to avoid hand injuries during procedures. However, when gloves are torn, cut, or punctured, they must be removed immediately, hands thoroughly washed, and regloving accomplished before completion of the dental procedure. DHCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling dental patient-care equipment until the condition resolves (*15*).

**USE AND CARE OF SHARP INSTRUMENTS AND NEEDLES**

1. Sharp items (needles, scalpel blades, and other sharp instruments) should be considered as potentially infective and must be handled with extraordinary care to prevent unintentional injuries.

2. Disposable syringes and needles, scalpel blades, and other sharp items must be placed into puncture-resistant containers located as close as practical to the area in which they were used. To prevent needlestick injuries, disposable needles should not be recapped; purposefully bent or broken; removed from disposable syringes; or otherwise manipulated by hand after use.

3. Recapping of a needle increases the risk of unintentional needlestick injury. There is no evidence to suggest that reusable aspirating-type syringes used in dentistry should be handled differently from other syringes. Needles of these devices should not be recapped, bent, or broken before disposal.

4. Because certain dental procedures on an individual patient may require multiple injections of anesthetic or other medications from a single syringe, it would be more prudent to place the unsheathed needle into a "sterile field" between injections rather than to recap the needle between injections. A new (sterile) syringe and a fresh solution should be used for each patient.

**INDICATIONS FOR HIGH-LEVEL DISINFECTION OR STERILIZATION OF INSTRUMENTS**

Surgical and other instruments that normally penetrate soft tissue and/or bone (e.g., forceps, scalpels, bone chisels, scalers, and surgical burs) should be sterilized after each use. Instruments that are not intended to penetrate oral soft tissues or bone (e.g., amalgam condensers, plastic instruments, and burs) but that may come into contact with oral tissues should also be sterilized after each use, if possible; however, if sterilization is not feasible, the latter instruments should receive high-level disinfection (*3,13,16*).

**METHODS FOR HIGH-LEVEL DISINFECTION OR STERILIZATION**

Before high-level disinfection or sterilization, instruments should be cleaned to remove debris. Cleaning may be accomplished by a thorough scrubbing with soap and water or a detergent, or by using a mechanical device (e.g., an ultrasonic cleaner). Persons involved in cleaning and decontaminating instruments should wear heavy-duty rubber gloves to prevent hand injuries. Metal and heat-stable dental instruments should be routinely sterilized between use by steam under pressure (autoclaving), dry heat, or chemical vapor. The adequacy of sterilization cycles should be verified by the periodic use of spore-testing devices (e.g., weekly for most dental practices) (*13*). Heat- and steam-sensitive chemical indicators may be used on the outside of each pack to assure it has been exposed to a sterilizing cycle. Heat-sensitive instruments may require up to 10 hours' exposure in a liquid chemical agent registered by the U.S. Environmental Protection Agency (EPA) as a disinfectant/sterilant; this should be followed by rinsing with sterile water. High-level disinfection may be accomplished by immersion in either boiling water for at least 10 minutes or an EPA-registered disinfectant/sterilant chemical for the exposure time recommended by the chemical's manufacturer.

**DECONTAMINATION OF ENVIRONMENTAL SURFACES**

At the completion of work activities, countertops and surfaces that may have become contaminated with blood or saliva should be wiped with absorbent toweling to remove extraneous organic material, then disinfected with a suitable chemical germicide. A solution of sodium hypochlorite (household bleach) prepared fresh daily is an inexpensive and very effective germicide. Concentrations ranging from 5,000 ppm (a 1:10 dilution of household bleach) to 500 ppm (a 1:100 dilution) sodium hypochlorite are effective, depending on the amount of organic material (e.g., blood, mucus, etc.) present on the surface to be cleaned and disinfected. Caution should be exercised, since sodium hypochlorite is corrosive to metals, especially aluminum.

**DECONTAMINATION OF LABORATORY SUPPLIES AND MATERIALS**

Blood and saliva should be thoroughly and carefully cleaned from laboratory supplies and materials that have been used in the mouth (e.g., impression materials, bite registration), especially before polishing and grinding intra-oral devices. Materials, impressions, and intra-oral appliances should be cleaned and disinfected before being handled, adjusted, or sent to a

dental laboratory (*17*). These items should also be cleaned and disinfected when returned from the dental laboratory and before placement in the patient's mouth. *Because of the ever-increasing variety of dental materials used intra-orally, DHCWs are advised to consult with manufacturers as to the stability of specific materials relative to disinfection procedures.* A chemical germicide that is registered with the EPA as a "hospital disinfectant" and that has a label claim for mycobactericidal (e.g., tuberculocidal) activity is preferred, because mycobacteria represent one of the most resistant groups of microorganisms; therefore, germicides that are effective against mycobacteria are also effective against other bacterial and viral pathogens (*15*). Communication between a dental office and a dental laboratory with regard to handling and decontamination of supplies and materials is of the utmost importance.

**USE AND CARE OF ULTRASONIC SCALERS, HANDPIECES, AND DENTAL UNITS**

1. Routine sterilization of handpieces between patients is desirable; however, not all handpieces can be sterilized. The present physical configurations of most handpieces do not readily lend them to high-level disinfection of both external and internal surfaces (see 2 below); therefore, when using handpieces that cannot be sterilized, the following cleaning and disinfection procedures should be completed between each patient: After use, the handpiece should be flushed (see 2 below), then thoroughly scrubbed with a detergent and water to remove adherent material. It should then be thoroughly wiped with absorbent material saturated with a chemical germicide that is registered with the EPA as a "hospital disinfectant" and is mycobactericidal at use-dilution (*15*). The disinfecting solution should remain in contact with the handpiece for a time specified by the disinfectant's manufacturer. Ultrasonic scalers and air/water syringes should be treated in a similar manner between patients. Following disinfection, any chemical residue should be removed by rinsing with sterile water.

2. Because water retraction valves within the dental units may aspirate infective materials back into the handpiece and water line, check valves should be installed to reduce the risk of transfer of infective material (*18*). While the magnitude of this risk is not known, it is prudent for water-cooled handpieces to be run and to discharge water into a sink or container for 20-30 seconds after completing care on each patient. This is intended to physically flush out patient material that may have been aspirated into the handpiece or water line. Additionally, there is some evidence that overnight bacterial accumulation can be significantly reduced by allowing water-cooled handpieces to run and to discharge water into a sink or container for several minutes at the beginning of the clinic day (*19*). Sterile saline or sterile water should be used as a coolant/irrigator when performing surgical procedures involving the cutting of soft tissue or bone.

**HANDLING OF BIOPSY SPECIMENS**

In general, each specimen should be put in a sturdy container with a secure lid to prevent leaking during transport. Care should be taken when collecting specimens to avoid contamination of the outside of the container. If the outside of the container is visibly contaminated, it should be cleaned and disinfected, or placed in an impervious bag (*20*).

**DISPOSAL OF WASTE MATERIALS**

All sharp items (especially needles), tissues, or blood should be considered potentially infective and should be handled and disposed of with special precautions. Disposable needles, scalpels, or other sharp items should be placed intact into puncture-resistant containers before disposal. Blood, suctioned fluids, or other liquid waste may be carefully poured into a drain connected to a sanitary sewer system. Other solid waste contaminated with blood or other body fluids should be placed in sealed, sturdy impervious bags to prevent leakage of the contained items. Such contained solid wastes can then be disposed of according to requirements established by local or state environmental regulatory agencies and published recommendations (*13,20*).

*Developed by Dental Disease Prevention Activity, Center for Prevention Svcs, Hospital Infections Program, Center for Infectious Diseases, CDC.*

**Editorial Note:** All DHCWs must be made aware of sources and methods of transmission of infectious diseases. The above recommendations for infection control in dental practices incorporate procedures that should be effective in preventing the transmission of infectious agents from dental patients to DHCWs and vice versa. Assessment of quantifiable risks to dental personnel and patients for specific diseases requires further research. There is no current documentation of patient-to-patient blood- or saliva-borne disease transmission from procedures performed in dental practice. While few in number, reported outbreaks of dentist-to-patient transmission of hepatitis B have resulted in serious and even fatal consequences (*9*). Herpes simplex virus has been transmitted to over 20 patients from the fingers of a DHCW (*10*).

Serologic markers for hepatitis B in dentists have increased dramatically in the United States over the past several years, which suggests current infection-control practices have been insufficient to prevent the transmission of this infectious agent in the dental operatory. While vaccination for hepatitis B is strongly recommended for dental personnel (*21*), vaccination alone is not cause for relaxation of strict adherence to accepted methods of asepsis, disinfection, and sterilization.

Various infection-control guidelines exist for hospitals and other clinical settings. Dental facilities located in hospitals and other institutional settings have generally utilized existing guidelines for institutional practice. These recommendations are offered as guidance to DHCWs in noninstitutional settings for enhancing infection-control practices in dentistry; they may be useful in institutional settings also.

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# Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus:

## Agent Summary Statement

### INTRODUCTION

In March 1984, CDC and the National Institutes of Health (NIH), in consultation with scientists, physicians, and public health workers in academia, industry, and government, published a manual entitled *Biosafety in Microbiological and Biomedical Laboratories* ("biosafety manual")* (*1*). The manual describes combinations of standard and special microbiologic practices, safety equipment, and facilities recommended for working with infectious agents in various laboratory settings. The recommendations are advisory and provide a voluntary code of safety practices.

A section of this manual is devoted to a number of specific "agent summary statements" consisting of brief descriptions of documented or anecdotal laboratory-associated infections, the nature of the laboratory hazards, and recommended precautions to be taken in handling and working with certain infectious agents. Contributors to the manual recognized that new agents would be discovered from time to time and recommended that a summary statement for each new agent be developed and published in the *MMWR*. The summary statement for human T-lymphotropic virus type III/lymphodenopathy-associated virus (HTLV-III/LAV)† follows. All laboratory directors are requested to put a copy of this summary in each of their copies of the biosafety manual and bring it to the attention of laboratory personnel. The recommendations in the summary statement were compiled from published scientific reports and are consistent with the published guidelines for health-care workers (*2-4*).

### AGENT SUMMARY STATEMENT: HTLV-III/LAV

As of August 15, 1986, no cases of acquired immunodeficiency syndrome (AIDS) that meet the CDC case definition and can be attributed to an inadvertent laboratory exposure have been reported in laboratory workers (*5*). One laboratory worker (*7*) was included among the health-care workers who have had HTLV-III/LAV antibody detected in their serum after sustaining a needlestick injury (*2,3,6-10*), but the source of the infection could not be established. Persons who are infected with HTLV-III/LAV may be asymptomatic, may have AIDS-related complex, or may manifest symptoms of overt AIDS (*11*).

In 1985, two different reagent production laboratories reported that several laboratory workers may have been inadvertently exposed to an aerosol of concentrated HTLV-III/LAV; one worker was cut by a piece of glass from a broken carboy that contained HTLV-III/LAV-infected cells and culture fluid. None of the potentially exposed persons had shown evidence of seroconversion after 6 months in one incident and 12 months in the other as a result of these occupational exposures.

Other reports dealing with HTLV-III/LAV infection in health-care personnel, including laboratory workers (*3,4,6,8-10*), indicate that the risk of bloodborne transmission from inadvertent exposure is considerably less for HTLV-III/LAV than for hepatitis B virus infection. These reports illustrate the need for complete evaluation by a physician and serologic testing of each laboratory worker definitely or possibly exposed to HTLV-III/LAV in a laboratory setting. It is recommended that the Public Health Service guidelines for health-care workers be followed in these instances (*2,3*).

#### Laboratory Hazards

HTLV-III/LAV has been isolated from blood, semen, saliva, tears, urine, cerebrospinal fluid, brain tissue, and cervical secretions and is likely to be present in other body fluids, secretions, and tissues of infected humans or experimentally infected nonhuman primates. Percutaneous or parenteral inoculation and direct contact of cuts, scratches, abrasions, or mucosal surfaces with suspensions of virus or specimens containing live virus are considered potential routes of infection. Possible transmission of infection via the parenteral route can occur through self-inoculation with needles, broken glass, or other sharp objects that contain HTLV-III/LAV. Spillage is a possible means of exposure and infection, especially spills accompanied by spraying or splashing of infected cell cultures, viral concentrates, and other infectious materials that

*Available from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, Stock #01702300167-1, Price: $4.00, and from National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161, Stock #PB84-206879, Price: $6.00

†The Human Retrovirus Subcommittee of the International Committee on the Taxonomy of Viruses has proposed the name human immunodeficiency virus (HIV) for these viruses (Science 1986;232:697).

may come into direct contact with abraded skin or mucous membranes of the eyes, nose, or mouth; however, there are no data documenting or suggesting that transmission of HTLV-III/LAV has occurred in this manner. Ingestion and inhalation have not been documented as modes of transmission of the virus.

**Recommended Precautions**

1. Biosafety Level (BSL) 2 standards and special practices, containment equipment, and facilities as described in the CDC-NIH biosafety manual are recommended for activities involving clinical specimens, body fluids, or tissues from humans or laboratory animals that may contain HTLV-III/LAV. *These are the same practices recommended for all clinical specimens.* Emphasis is placed on the following practices, which are included in the manual (*1*):
   a. Use of syringes, needles and other sharp instruments should be avoided if possible. Used needles and cutting instruments should be discarded into a puncture-resistant container with a lid. Needles should *not* be resheathed, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand.
   b. Gloves should be worn by all personnel engaged in activities that may involve skin contact with potentially infectious fluids, tissues, or cultures and by laboratory workers with dermatitis or other lesions on the hands who may have direct or indirect contact with potentially infectious materials. Handwashing with soap and water should be a routine practice immediately after direct contact with potentially infectious materials and on completion of work, even when gloves are worn.
   c. Generation of aerosols, splashes, and spills of potentially infectious materials should be avoided in procedures involving body fluids or tissues, during necropsy of cadavers, and in similar procedures on animals experimentally infected with HTLV-III/LAV. Laboratory workers should use a biological safety cabinet when propagating the virus to further reduce the risk of exposure. Although the major precautions are listed here, the CDC-NIH biosafety manual contains additional related precautions (see pages 11-13 for BSL 2 and pages 14-17 [*1*] for BSL 3 when large volumes or concentrates of HTLV-III/LAV are involved). In all instances, the laboratory director is responsible for assessing the biosafety level to be used.
   d. Human serum from any source that is used as a control or reagent in a test procedure should be handled at BSL 2 (see pages 11-13 [*1*]). Appended to this Agent Summary Statement is a statement (Addendum 1) issued by CDC on the use of all human control or reagent sera shipped to other laboratories. The Food and Drug Administration requires that manufacturers of human serum reagents use a similarly worded statement.
   e. Animal BSL 2 practices, containment equipment, and facilities are recommended for activities involving nonhuman primates experimentally infected with HTLV-III/LAV. Laboratory coats, gowns, or uniforms should be worn by laboratory workers, as is customary for other BSL 2 or 3 practices, depending on the nature of the work, concentration of the virus, and volume of material being handled. Because many animals bite, and some throw feces, urine, or expectorate at humans, animal-care personnel must wear coats, protective gloves, coveralls or uniforms, and face shields as appropriate to protect the skin and mucous membranes of the eyes, nose, and mouth from potential exposure to these substances when working with animals likely to manifest such behavior.
2. Activities such as growing research-laboratory-scale amounts of HTLV-III/LAV or related viruses or virus-producing cell lines, working with concentrated virus preparations, or conducting procedures that may produce droplets or aerosols should be performed in a BSL 2 facility with the additional practices and containment equipment recommended for BSL 3 (*12*).
3. Activities involving industrial-scale, large-volume, or high-concentration production and manipulation of HTLV-III/LAV are to be conducted with BSL 3 requirements (*12*).
4. All laboratory glassware, equipment, disposable materials, and wastes suspected or known to contain HTLV-III/LAV must be decontaminated, preferably in an autoclave, before washing, discarding, etc. Incineration of solid wastes may be used as an alternate method of disposal.
5. There is no evidence that laboratory clothing soiled with materials known or suspected to contain HTLV-III LAV poses a transmission hazard, and the handling of such clothing is covered under BSL 2 practices. However, to be consistent with BSL 3 recommendations (*1*), when laboratory clothing becomes contaminated with HTLV-III/LAV preparations, it should be decontaminated before being laundered or discarded.

6. Work surfaces should be decontaminated at the end of each day on completion of procedures or when overtly contaminated. Many commonly used chemical disinfectants with such active ingredients as sodium hypochlorite, formaldehyde, glutaraldehyde, or phenols (*4,13-15*) can be used to decontaminate laboratory work surfaces; they can also be used to decontaminate some laboratory instruments, specific areas of contaminated laboratory clothing, and spills of infectious materials. Prompt decontamination of spills and other overt contamination should be standard practice.
7. The prudent and recommended approach to handling human serum known or suspected to contain HTLV-III/LAV is to use the same precautions that should be used routinely to prevent transmission of bloodborne infections, including hepatitis B (*16*). Available data on the effectiveness of heat to destroy HTLV-III/LAV suspected or known to be present in human serum are at variance because of variations in volume of serum, concentration of the virus, temperature, and duration of exposure to heat (*14,15,17*). Similarly, results of chemical analyses or antibody assays may vary when sera are heated before testing according to the analysis or assay being performed (*18-20*). However, there is agreement that testing heated serum for HTLV-III/LAV antibody by enzyme immunoassays often yields false-positive results (*21-23*).
8. No HTLV-III/LAV vaccine has been developed, and no drugs have been shown to be safe and effective for therapy. As part of an ongoing medical surveillance program for employees, all laboratory workers before being assigned to activities with a high potential for exposure should have a serum sample obtained and stored at -40 C (-40 F) for possible future testing. Subsequent serum samples should be obtained and stored in accordance with laboratory policy or following an inadvertent laboratory exposure involving materials described above. When indicated, these serum specimens should be tested by a qualified laboratory using currently recommended procedures for HTLV-III/LAV antibody. Furthermore, the physician requesting serologic testing of these serum specimens must first obtain informed consent from the laboratory worker and describe the confidentiality safeguards available to protect test results. The laboratory workers whose serum specimens are to be tested should understand how the test results are to be used, the implications of a positive or negative test result, and the limits, if any, of the confidentiality safeguards. An employee whose serum HTLV-III/LAV antibody test is reactive and whose subsequent tests and evaluation confirm the presence of HTLV-III/LAV infection should be counseled to follow the Public Health Service recommendations for preventing transmission (*24,25*).
9. In addition to HTLV-III/LAV, other primary, as well as opportunistic, pathogenic agents may be present in the body fluids and tissues of persons who are antibody positive or have AIDS-related complex or AIDS. Laboratory workers should follow accepted biosafety practices to ensure maximum protection against inadvertent laboratory infection with agents other than HTLV-III/LAV that may also be present in clinical specimens.

*Reported by Div of Safety, National Institute of Allergy and Infectious Diseases, National Cancer Institute, National Institutes of Health; AIDS Program, Hospital Infections Program, Center for Infectious Diseases, Laboratory Program Office, Office of Biosafety, Office of the Director, CDC.*

### *ADDENDUM*

CDC cautionary notice for all human serum samples used as controls or reagents:

**WARNING**: Because no test method can offer complete assurance that laboratory specimens do not contain HTLV-III/LAV, hepatitis B virus, or other infectious agents, this specimen(s) should be handled at the BSL 2 as recommended for any potentially infectious human serum or blood specimen in the CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, 1984, pages 11-3.

One or more of the following statements should be included with the above warning statement:

- This specimen is negative for hepatitis B surface antigen (HBsAg).
- This specimen is negative for antibody to HTLV-III/LAV.
- This specimen is positive for hepatitis B surface antigen (HBsAg).
- This specimen is positive for antibody to HTLV-III/LAV.
- This specimen has NOT been tested for hepatitis B surface antigen (HBsAg).
- This specimen has NOT been tested for antibody to HTLV-III/LAV.
- This specimen has been heated at 56 C (133 F) for 30 minutes (which will not inactivate HBsAg but will inactivate HTLV-III/LAV).

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# Update: Human Immunodeficiency Virus Infections in Health-Care Workers Exposed to Blood of Infected Patients

Six persons who provided health care to patients with human immunodeficiency virus (HIV) infection and who denied other risk factors have previously been reported to have HIV infection. Four of these cases followed needle-stick exposures to blood from patients infected with HIV (*1-4*). The two additional cases involved persons who provided nursing care to persons with HIV infection. Although neither of these two persons sustained needle-stick injuries, both had extensive contact with blood or body fluids of the infected patient, and neither observed routinely recommended barrier precautions (*5,6*).

CDC has received reports of HIV infection in three additional health-care workers following non-needle-stick exposures to blood from infected patients. The exposures occurred during 1986 in three different geographic areas. Although these three cases represent rare events, they reemphasize the need for health-care workers to adhere rigorously to existing infection control recommendations for minimizing the risk of exposure to blood and body fluids of all patients (*7-9*).

**Health-Care Worker 1:** A female health-care worker assisting with an unsuccessful attempt to insert an arterial catheter in a patient suffering a cardiac arrest in an emergency room applied pressure to the insertion site to stop the bleeding. During the procedure, she may have had a small amount of blood on her index finger for about 20 minutes before washing her hands. Afterwards, she may also have assisted in cleaning the room but did not recall any other exposures to the patient's blood or body fluids. She had no open wounds, but her hands were chapped. Although she often wore gloves when anticipating exposure to blood, she was not wearing gloves during this incident.

The patient with the cardiac arrest died. A postmortem examination identified *Pneumocystis carinii* pneumonia, and a blood sample was positive for HIV antibody by enzyme immunoassay (EIA) and Western blot methods. Twenty days after the incident, the health-care worker became ill with fever, myalgia, extreme fatigue, sore throat, nausea, vomiting, diarrhea, a 14-pound weight loss, and generalized lymphadenopathy which her physician diagnosed as a viral syndrome. That illness lasted 3 weeks. She felt much better 9 weeks after the incident, and, when she was examined 6 months after the incident, all signs and symptoms had resolved. She had donated blood 8 months before the incident and was negative for HIV antibody by EIA. She donated again 16 weeks after the incident and was positive for HIV by EIA and Western blot (bands p24 and gp41). Serum samples obtained 20 and 23 weeks after the incident were also positive for HIV antibody. She stated that for over 8 years her only sexual partner had been her husband, who denied risk factors for HIV and was seronegative for HIV antibody. She denied ever receiving a blood transfusion, ever using intravenous drugs, or having any needle sticks or other significant exposures to blood or body fluids in the past 8 years. Her serologic test for syphilis was negative. Fifteen other employees who assisted in the care of the patient were seronegative at least 4 months after the exposure.

**Health-Care Worker 2:** A female phlebotomist was filling a 10 ml vacuum blood collection tube with blood from an outpatient with a suspected HIV infection when the top of the tube flew off and blood splattered around the room, on her face, and in her mouth. She was wearing gloves to protect her hands and was wearing eyeglasses so she did not think she got any blood in her eyes. She had facial acne but no open wounds. She washed the blood off immediately after the exposure. The outpatient's blood sample was positive for HIV antibody by EIA and Western blot, and a hepatitis B surface antigen test was negative. The phlebotomist's EIA was negative the day after the incident and again 8 weeks later. When she donated blood 9 months after the exposure, she was positive for HIV antibody by EIA and Western blot (bands p24 and gp41). She has had no symptoms. She denied having any sexual contact during the previous 2 years, ever using drugs intravenously, or ever receiving a transfusion. Two months after the incident, she scratched the back of her hand with a needle used to draw blood from an intravenous drug abuser of unknown HIV-antibody status. She did not bleed as a result of the scratch and has not had any needle-stick injuries in over 2 years. Her serologic tests for syphilis and hepatitis B were negative. A coworker who was splattered with blood on the face and in the mouth during the same incident remains seronegative 1 year after the incident.

**Health-Care Worker 3:** A female medical technologist was manipulating an apheresis machine (a device to separate blood components) to correct a problem that developed during an

outpatient procedure when blood spilled, covering most of her hands and forearms. She was not wearing gloves. She does not recall having any open wounds on her hands or any mucous-membrane exposure. However, she had dermatitis on one ear and may have touched it. She washed the blood off herself and the machine several minutes after the spill. The patient undergoing the apheresis had denied risk factors for HIV infection. However, a blood sample from the patient was positive for HIV antibody by EIA and Western blot methods and negative for hepatitis B surface antigen the next day. The technologist's HIV-antibody tests were negative 5 days after the exposure and again 6 weeks later. Eight weeks after the exposure, she had an influenza-like illness with fever, myalgia, diarrhea, hives, and a pruritic red macular rash on her arms and legs. The illness resolved after a few weeks, and her physician thought the illness was probably a viral syndrome. Three months after the incident, she was positive for HIV antibody by EIA and Western blot methods (band p24 alone). Four months after the incident, a Western blot was positive (bands p24 and gp41). She indicated that for more than 8 years her only sexual partner had been her husband, who denied risk factors for HIV infection and was seronegative for HIV antibody. She denied ever receiving a transfusion, ever using intravenous drugs, or having any needle-stick injuries in over 2 years. Her serologic tests for syphilis and hepatitis B were negative. She has an immunologic disorder which had been treated with corticosteroids in the past, but she had not taken any immunosuppressive medication for the past year. A coworker with a similar exposure during the same procedure remains seronegative after 3 months.

*Reported by: Hospital Infections Program and AIDS Program, Center for Infectious Diseases, CDC.*

**Editorial Note:** Three instances of health-care workers with HIV infections associated with skin or mucous-membrane exposure to blood from HIV-infected patients are reported above. Careful investigation of these three cases did not identify other risk factors for HIV infection, although unrecognized or forgotten needle-stick exposures to other infected patients cannot be totally excluded. The exact route of transmission in these three cases is not known. Health-Care Worker 1 had chapped hands, and the duration of contact with the blood of the patient experiencing a cardiac arrest may have been as long as 20 minutes. Health-Care Worker 2 sustained contamination of oral mucous membranes. This individual also had acne but did not recall having open lesions. In addition, she had sustained a scratch from a needle used to draw blood from an intravenous drug abuser of unknown HIV-infection status. Health-Care Worker 3 had a history of dermatitis involving an ear. Health-Care Workers 1 and 3 were not wearing gloves when direct contact with blood occurred. Health-Care Worker 2 was wearing gloves, but blood contaminated her face and mouth.

Three ongoing prospective studies provide data on the magnitude of the risk of HIV infection incurred when health-care workers are exposed to blood of infected patients through needle-stick wounds or contamination of an open wound or mucous membrane. In a CDC cooperative surveillance project (*10*), a total of 1,097 health-care workers with parenteral or mucous-membrane exposure to the blood of patients with AIDS or other manifestations of HIV infection had been enrolled as of March 31, 1987. Needle-stick injuries and cuts with sharp objects accounted for 969 (89%) of the exposures to blood; 298 of these had paired serum samples tested for HIV antibody. One (0.3%) seroconverted (*2*), indicating that the risk of transmission during these exposures is very low. In addition, 70 health-care workers had open wounds exposed to blood, and 58 had mucous membrane exposed to blood. Postexposure serum samples from 82 of these 128 workers have been tested for antibody to HIV; none was seropositive.

In a study at the National Institutes of Health (*11*) through April 30, 1987, none of the 103 workers with percutaneous exposures and none of the 229 workers with mucous-membrane exposures to blood or body fluids of patients with AIDS was seropositive. At the University of California (*12*), none of 63 workers with open wounds or mucous membranes exposed to blood or body fluids of patients with AIDS was seropositive. Although the precise risk of transmission during exposures of open wounds or mucous membranes to contaminated blood cannot be defined, these studies indicate that it must be very low.

The three cases reported here suggest that exposure of skin or mucous membranes to contaminated blood may rarely result in transmission of HIV. The magnitude of the risk is not known since data on the frequency with which such exposures occur are not available. Skin and mucous-membrane exposures are thought to occur much more commonly than needle sticks, and the risk associated with skin or mucous-membrane exposures is likely to be far lower than that associated with needle-stick injuries. Nonetheless, the increasing prevalence of HIV infection increases the potential for such exposures, especially when routinely recommended precautions are not followed.

It is unlikely that routine serologic testing for HIV infection of all patients admitted to hospitals would have prevented these exposures since two of the three exposures occurred in the outpatient clinic setting, and one occurred during a resuscitation effort in an emergency room shortly after the arrival of the patient. At the time of exposure, Health-Care Worker 2 suspected that the source patient was infected with HIV, but Health-Care Workers 1 and 3 did not. The hospital where Health-Care Worker 3 was exposed has a protocol for apheresis which normally involves HIV-antibody testing of donors; however, such testing was not done in advance of the procedure. Previous CDC recommendations have emphasized the value of HIV serologic testing for patient diagnosis and management and for prevention and control of HIV transmission (*13*) and have stated that some hospitals in certain geographic areas may deem it appropriate to initiate serologic testing of patients (*7*). Such testing may also provide an opportunity to reduce the risk of HIV infection to health-care workers, but it has not been established that knowledge of a patient's serologic status increases the compliance of health-care workers with recommended precautions.

These cases emphasize again the need to implement and strictly enforce previously published recommendations for minimizing the risk of exposure to blood and body fluids of all patients in order to prevent transmission of HIV infection in the workplace and during invasive procedures (*7-9*).

1. As previously recommended, routine precautions must be followed when there is a possibility of exposure to blood or other body fluids. The anticipated exposure may require gloves alone (e.g., when placing an intravascular catheter or handling items soiled with blood or equipment contaminated with blood or other body fluids). Procedures involving more extensive contact with blood or potentially infective body fluids (e.g., some dental or endoscopic procedures or postmortem examinations) may require gloves, gowns, masks, and eye-coverings. Hands and other contaminated skin surfaces should be washed thoroughly and immediately if accidentally contaminated with blood (*7*). These precautions deserve particular emphasis in emergency care settings in which the risk of blood exposure is increased and the infectious status of the patient is usually unknown (*14*).
2. Previous recommendations have emphasized management of parenteral and mucous-membrane exposures of health-care workers*. In addition, health-care workers who are involved in incidents that result in cutaneous exposures involving large amounts of blood or prolonged contact with blood—especially when the exposed skin is chapped, abraded, or afflicted with dermatitis—should follow these same recommendations. Moreover, serologic testing should be available to all health-care workers who are concerned that they may have been infected with HIV.

*If a HCW [health-care worker] has a parenteral (e.g., needlestick or cut) or mucous membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids, the source patient should be assessed clinically and epidemiologically to determine the likelihood of HTLV-III/LAV [sic] infection. If the assessment suggests that infection may exist, the patient should be informed of the incident and requested to consent to serologic testing for evidence of HTLV-III LAV [sic] infection. If the source patient has AIDS or other evidence of HTLV-III/LAV [sic] infection, declines testing, or has a positive test, the HCW should be evaluated clinically and serologically for evidence of HTLV-III/LAV [sic] infection as soon as possible after the exposure, and, if seronegative, retested after 6 weeks and on a periodic basis thereafter (e.g., 3, 6, and 12 months following exposure) to determine if transmission has occurred. During this follow-up period, especially the first 6-12 weeks, when most infected persons are expected to seroconvert, exposed HCWs should receive counseling about the risk of infection and follow U.S. Public Health Service (PHS) recommendations for preventing transmission of AIDS (*15,16*). If the source patient is seronegative and has no other evidence of HTLV-III LAV [sic] infection, no further follow-up of the HCW is necessary. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposure and the likelihood that the source patient was infected (*7*).

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# Recommendations for Prevention of HIV Transmission in Health-Care Settings

## Introduction

Human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS), is transmitted through sexual contact and exposure to infected blood or blood components and perinatally from mother to neonate. HIV has been isolated from blood, semen, vaginal secretions, saliva, tears, breast milk, cerebrospinal fluid, amniotic fluid, and urine and is likely to be isolated from other body fluids, secretions, and excretions. However, epidemiologic evidence has implicated only blood, semen, vaginal secretions, and possibly breast milk in transmission.

The increasing prevalence of HIV increases the risk that health-care workers will be exposed to blood from patients infected with HIV, especially when blood and body-fluid precautions are not followed for all patients. Thus, this document emphasizes the need for health-care workers to consider all patients as potentially infected with HIV and/or other blood-borne pathogens and to adhere rigorously to infection-control precautions for minimizing the risk of exposure to blood and body fluids of all patients.

The recommendations contained in this document consolidate and update CDC recommendations published earlier for preventing HIV transmission in health-care settings: precautions for clinical and laboratory staffs (*1*) and precautions for health-care workers and allied professionals (*2*); recommendations for preventing HIV transmission in the workplace (*3*) and during invasive procedures (*4*); recommendations for preventing possible transmission of HIV from tears (*5*); and recommendations for providing dialysis treatment for HIV-infected patients (*6*). These recommendations also update portions of the "Guideline for Isolation Precautions in Hospitals" (*7*) and reemphasize some of the recommendations contained in "Infection Control Practices for Dentistry" (*8*). The recommendations contained in this document have been developed for use in health-care settings and emphasize the need to treat blood and other body fluids from all patients as potentially infective. These same prudent precautions also should be taken in other settings in which persons may be exposed to blood or other body fluids.

## Definition of Health-Care Workers

Health-care workers are defined as persons, including students and trainees, whose activities involve contact with patients or with blood or other body fluids from patients in a health-care setting.

## Health-Care Workers with AIDS

As of July 10, 1987, a total of 1,875 (5.8%) of 32,395 adults with AIDS, who had been reported to the CDC national surveillance system and for whom occupational information was available, reported being employed in a health-care or clinical laboratory setting. In comparison, 6.8 million persons—representing 5.6% of the U.S. labor force—were employed in health services. Of the health-care workers with AIDS, 95% have been reported to exhibit high-risk behavior; for the remaining 5%, the means of HIV acquisition was undetermined. Health-care workers with AIDS were significantly more likely than other workers to have an undetermined risk (5% versus 3%, respectively). For both health-care workers and non-health-care workers with AIDS, the proportion with an undetermined risk has not increased since 1982.

AIDS patients initially reported as not belonging to recognized risk groups are investigated by state and local health departments to determine whether possible risk factors exist. Of all health-care workers with AIDS reported to CDC who were initially characterized as not having an identified risk and for whom follow-up information was available, 66% have been reclassified because risk factors were identified or because the patient was found not to meet the surveillance case definition for AIDS. Of the 87 health-care workers currently categorized as having no identifiable risk, information is incomplete on 16 (18%) because of death or refusal to be interviewed; 38 (44%) are still being investigated. The remaining 33 (38%) health-care workers were interviewed or had other follow-up information available. The occupations of these 33 were as follows: five physicians (15%), three of whom were surgeons; one dentist (3%); three nurses (9%); nine nursing assistants (27%); seven housekeeping or maintenance workers (21%); three clinical laboratory technicians (9%); one therapist (3%); and four others who did not have contact with patients (12%). Although 15 of these 33 health-care workers reported parenteral and/or other non-needlestick exposure to blood or body fluids from patients in the 10 years preceding their diagnosis of AIDS, none of these exposures involved a patient with AIDS or known HIV infection.

## Risk to Health-Care Workers of Acquiring HIV in Health-Care Settings

Health-care workers with documented percutaneous or mucous-membrane exposures to blood or body fluids of HIV-infected patients have been prospectively evaluated to determine the risk of infection after such exposures. As of June 30, 1987, 883 health-care workers have been tested for antibody to HIV in an ongoing surveillance project conducted by CDC (*9*). Of these, 708 (80%) had percutaneous exposures to blood, and 175 (20%) had a mucous membrane or an open wound contaminated by blood or body fluid. Of 396 health-care workers, each of whom had only a convalescent-phase serum sample obtained and tested ≥90 days post-exposure, one—for whom heterosexual transmission could not be ruled out—was seropositive for HIV antibody. For 425 additional health-care workers, both acute- and convalescent-phase serum samples were obtained and tested; none of 74 health-care workers with nonpercutaneous exposures seroconverted, and three (0.9%) of 351

with percutaneous exposures seroconverted. None of these three health-care workers had other documented risk factors for infection.

Two other prospective studies to assess the risk of nosocomial acquisition of HIV infection for health-care workers are ongoing in the United States. As of April 30, 1987, 332 health-care workers with a total of 453 needlestick or mucous-membrane exposures to the blood or other body fluids of HIV-infected patients were tested for HIV antibody at the National Institutes of Health (*10*). These exposed workers included 103 with needlestick injuries and 229 with mucous-membrane exposures; none had seroconverted. A similar study at the University of California of 129 health-care workers with documented needlestick injuries or mucous-membrane exposures to blood or other body fluids from patients with HIV infection has not identified any seroconversions (*11*). Results of a prospective study in the United Kingdom identified no evidence of transmission among 150 health-care workers with parenteral or mucous-membrane exposures to blood or other body fluids, secretions, or excretions from patients with HIV infection (*12*).

In addition to health-care workers enrolled in prospective studies, eight persons who provided care to infected patients and denied other risk factors have been reported to have acquired HIV infection. Three of these health-care workers had needlestick exposures to blood from infected patients (*13-15*). Two were persons who provided nursing care to infected persons; although neither sustained a needlestick, both had extensive contact with blood or other body fluids, and neither observed recommended barrier precautions (*16,17*). The other three were health-care workers with non-needlestick exposures to blood from infected patients (*18*). Although the exact route of transmission for these last three infections is not known, all three persons had direct contact of their skin with blood from infected patients, all had skin lesions that may have been contaminated by blood, and one also had a mucous-membrane exposure.

A total of 1,231 dentists and hygienists, many of whom practiced in areas with many AIDS cases, participated in a study to determine the prevalence of antibody to HIV; one dentist (0.1%) had HIV antibody. Although no exposure to a known HIV-infected person could be documented, epidemiologic investigation did not identify any other risk factor for infection. The infected dentist, who also had a history of sustaining needlestick injuries and trauma to his hands, did not routinely wear gloves when providing dental care (*19*).

## Precautions To Prevent Transmission of HIV

### Universal Precautions

Since medical history and examination cannot reliably identify all patients infected with HIV or other blood-borne pathogens, blood and body-fluid precautions should be consistently used for all patients. This approach, previously recommended by CDC (*3,4*), and referred to as "universal blood and body-fluid precautions" or "universal precautions," should be used in the care of all patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown (*20*).

1. All health-care workers shculd routinely use appropriate barrier precautions to prevent skin and mucous-membrane exposure when contact with blood or other body fluids of any patient is anticipated. Gloves should be worn for touching blood and body fluids, mucous membranes, or non-intact skin of all patients, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Masks and protective eyewear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of the mouth, nose, and eyes. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids.
2. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids. Hands should be washed immediately after gloves are removed.
3. All health-care workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures. To prevent needlestick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal; the puncture-resistant containers should be located as close as practical to the use area. Large-bore reusable needles should be placed in a puncture-resistant container for transport to the reprocessing area.
4. Although saliva has not been implicated in HIV transmission, to minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices should be available for use in areas in which the need for resuscitation is predictable.
5. Health-care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.
6. Pregnant health-care workers are not known to be at greater risk of contracting HIV infection than health-care workers who are not pregnant; however, if a health-care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health-care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission.

Implementation of universal blood and body-fluid precautions for <u>all</u> patients eliminates the need for use of the isolation category of "Blood and Body Fluid Precautions" previously recommended by CDC (*7*) for patients known or suspected to be infected with blood-borne pathogens. Isolation precautions (e.g., enteric, "AFB" [*7*]) should be used as necessary if associated conditions, such as infectious diarrhea or tuberculosis, are diagnosed or suspected.

## Precautions for Invasive Procedures

In this document, an invasive procedure is defined as surgical entry into tissues, cavities, or organs or repair of major traumatic injuries 1) in an operating or delivery

room, emergency department, or outpatient setting, including both physicians' and dentists' offices; 2) cardiac catheterization and angiographic procedures; 3) a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or 4) the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists. The universal blood and body-fluid precautions listed above, combined with the precautions listed below, should be the minimum precautions for all such invasive procedures.

1. All health-care workers who participate in invasive procedures must routinely use appropriate barrier precautions to prevent skin and mucous-membrane contact with blood and other body fluids of all patients. Gloves and surgical masks must be worn for all invasive procedures. Protective eyewear or face shields should be worn for procedures that commonly result in the generation of droplets, splashing of blood or other body fluids, or the generation of bone chips. Gowns or aprons made of materials that provide an effective barrier should be worn during invasive procedures that are likely to result in the splashing of blood or other body fluids. All health-care workers who perform or assist in vaginal or cesarean deliveries should wear gloves and gowns when handling the placenta or the infant until blood and amniotic fluid have been removed from the infant's skin and should wear gloves during post-delivery care of the umbilical cord.
2. If a glove is torn or a needlestick or other injury occurs, the glove should be removed and a new glove used as promptly as patient safety permits; the needle or instrument involved in the incident should also be removed from the sterile field.

## Precautions for Dentistry*

Blood, saliva, and gingival fluid from all dental patients should be considered infective. Special emphasis should be placed on the following precautions for preventing transmission of blood-borne pathogens in dental practice in both institutional and non-institutional settings.

1. In addition to wearing gloves for contact with oral mucous membranes of all patients, all dental workers should wear surgical masks and protective eyewear or chin-length plastic face shields during dental procedures in which splashing or spattering of blood, saliva, or gingival fluids is likely. Rubber dams, high-speed evacuation, and proper patient positioning, when appropriate, should be utilized to minimize generation of droplets and spatter.
2. Handpieces should be sterilized after use with each patient, since blood, saliva, or gingival fluid of patients may be aspirated into the handpiece or waterline. Handpieces that cannot be sterilized should at least be flushed, the outside surface cleaned and wiped with a suitable chemical germicide, and then rinsed. Handpieces should be flushed at the beginning of the day and after use with each patient. Manufacturers' recommendations should be followed for use and maintenance of waterlines and check valves and for flushing of handpieces. The same precautions should be used for ultrasonic scalers and air/water syringes.

*General infection-control precautions are more specifically addressed in previous recommendations for infection-control practices for dentistry (*8*).

3. Blood and saliva should be thoroughly and carefully cleaned from material that has been used in the mouth (e.g., impression materials, bite registration), especially before polishing and grinding intra-oral devices. Contaminated materials, impressions, and intra-oral devices should also be cleaned and disinfected before being handled in the dental laboratory and before they are placed in the patient's mouth. Because of the increasing variety of dental materials used intra-orally, dental workers should consult with manufacturers as to the stability of specific materials when using disinfection procedures.
4. Dental equipment and surfaces that are difficult to disinfect (e.g., light handles or X-ray-unit heads) and that may become contaminated should be wrapped with impervious-backed paper, aluminum foil, or clear plastic wrap. The coverings should be removed and discarded, and clean coverings should be put in place after use with each patient.

## Precautions for Autopsies or Morticians' Services

In addition to the universal blood and body-fluid precautions listed above, the following precautions should be used by persons performing postmortem procedures:

1. All persons performing or assisting in postmortem procedures should wear gloves, masks, protective eyewear, gowns, and waterproof aprons.
2. Instruments and surfaces contaminated during postmortem procedures should be decontaminated with an appropriate chemical germicide.

## Precautions for Dialysis

Patients with end-stage renal disease who are undergoing maintenance dialysis and who have HIV infection can be dialyzed in hospital-based or free-standing dialysis units using conventional infection-control precautions (*21*). Universal blood and body-fluid precautions should be used when dialyzing all patients.

Strategies for disinfecting the dialysis fluid pathways of the hemodialysis machine are targeted to control bacterial contamination and generally consist of using 500-750 parts per million (ppm) of sodium hypochlorite (household bleach) for 30-40 minutes or 1.5%-2.0% formaldehyde overnight. In addition, several chemical germicides formulated to disinfect dialysis machines are commercially available. None of these protocols or procedures need to be changed for dialyzing patients infected with HIV.

Patients infected with HIV can be dialyzed by either hemodialysis or peritoneal dialysis and do not need to be isolated from other patients. The type of dialysis treatment (i.e., hemodialysis or peritoneal dialysis) should be based on the needs of the patient. The dialyzer may be discarded after each use. Alternatively, centers that reuse dialyzers—i.e., a specific single-use dialyzer is issued to a specific patient, removed, cleaned, disinfected, and reused several times on the same patient only—may include HIV-infected patients in the dialyzer-reuse program. An individual dialyzer must never be used on more than one patient.

## Precautions for Laboratories†

Blood and other body fluids from all patients should be considered infective. To supplement the universal blood and body-fluid precautions listed above, the following precautions are recommended for health-care workers in clinical laboratories.

†Additional precautions for research and industrial laboratories are addressed elsewhere (*22,23*).

1. All specimens of blood and body fluids should be put in a well-constructed container with a secure lid to prevent leaking during transport. Care should be taken when collecting each specimen to avoid contaminating the outside of the container and of the laboratory form accompanying the specimen.
2. All persons processing blood and body-fluid specimens (e.g., removing tops from vacuum tubes) should wear gloves. Masks and protective eyewear should be worn if mucous-membrane contact with blood or body fluids is anticipated. Gloves should be changed and hands washed after completion of specimen processing.
3. For routine procedures, such as histologic and pathologic studies or microbiologic culturing, a biological safety cabinet is not necessary. However, biological safety cabinets (Class I or II) should be used whenever procedures are conducted that have a high potential for generating droplets. These include activities such as blending, sonicating, and vigorous mixing.
4. Mechanical pipetting devices should be used for manipulating all liquids in the laboratory. Mouth pipetting must not be done.
5. Use of needles and syringes should be limited to situations in which there is no alternative, and the recommendations for preventing injuries with needles outlined under universal precautions should be followed.
6. Laboratory work surfaces should be decontaminated with an appropriate chemical germicide after a spill of blood or other body fluids and when work activities are completed.
7. Contaminated materials used in laboratory tests should be decontaminated before reprocessing or be placed in bags and disposed of in accordance with institutional policies for disposal of infective waste (*24*).
8. Scientific equipment that has been contaminated with blood or other body fluids should be decontaminated and cleaned before being repaired in the laboratory or transported to the manufacturer.
9. All persons should wash their hands after completing laboratory activities and should remove protective clothing before leaving the laboratory.

Implementation of universal blood and body-fluid precautions for <u>all</u> patients eliminates the need for warning labels on specimens since blood and other body fluids from all patients should be considered infective.

## Environmental Considerations for HIV Transmission

No environmentally mediated mode of HIV transmission has been documented. Nevertheless, the precautions described below should be taken routinely in the care of <u>all</u> patients.

### Sterilization and Disinfection

Standard sterilization and disinfection procedures for patient-care equipment currently recommended for use (*25,26*) in a variety of health-care settings—including hospitals, medical and dental clinics and offices, hemodialysis centers, emergency-care facilities, and long-term nursing-care facilities—are adequate to sterilize or disinfect instruments, devices, or other items contaminated with blood or other body fluids from persons infected with blood-borne pathogens including HIV (*21,23*).

Instruments or devices that enter sterile tissue or the vascular system of any patient or through which blood flows should be sterilized before reuse. Devices or items that contact intact mucous membranes should be sterilized or receive high-level disinfection, a procedure that kills vegetative organisms and viruses but not necessarily large numbers of bacterial spores. Chemical germicides that are registered with the U.S. Environmental Protection Agency (EPA) as "sterilants" may be used either for sterilization or for high-level disinfection depending on contact time.

Contact lenses used in trial fittings should be disinfected after each fitting by using a hydrogen peroxide contact lens disinfecting system or, if compatible, with heat (78 C-80 C [172.4 F-176.0 F]) for 10 minutes.

Medical devices or instruments that require sterilization or disinfection should be thoroughly cleaned before being exposed to the germicide, and the manufacturer's instructions for the use of the germicide should be followed. Further, it is important that the manufacturer's specifications for compatibility of the medical device with chemical germicides be closely followed. Information on specific label claims of commercial germicides can be obtained by writing to the Disinfectants Branch, Office of Pesticides, Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

Studies have shown that HIV is inactivated rapidly after being exposed to commonly used chemical germicides at concentrations that are much lower than used in practice (*27-30*). Embalming fluids are similar to the types of chemical germicides that have been tested and found to completely inactivate HIV. In addition to commercially available chemical germicides, a solution of sodium hypochlorite (household bleach) prepared daily is an inexpensive and effective germicide. Concentrations ranging from approximately 500 ppm (1:100 dilution of household bleach) sodium hypochlorite to 5,000 ppm (1:10 dilution of household bleach) are effective depending on the amount of organic material (e.g., blood, mucus) present on the surface to be cleaned and disinfected. Commercially available chemical germicides may be more compatible with certain medical devices that might be corroded by repeated exposure to sodium hypochlorite, especially to the 1:10 dilution.

## Survival of HIV in the Environment

The most extensive study on the survival of HIV after drying involved greatly concentrated HIV samples, i.e., 10 million tissue-culture infectious doses per milliliter (*31*). This concentration is at least 100,000 times greater than that typically found in the blood or serum of patients with HIV infection. HIV was detectable by tissue-culture techniques 1-3 days after drying, but the rate of inactivation was rapid. Studies performed at CDC have also shown that drying HIV causes a rapid (within several hours) 1-2 log (90%-99%) reduction in HIV concentration. In tissue-culture fluid, cell-free HIV could be detected up to 15 days at room temperature, up to 11 days at 37 C (98.6 F), and up to 1 day if the HIV was cell-associated.

When considered in the context of environmental conditions in health-care facilities, these results do not require any changes in currently recommended sterilization, disinfection, or housekeeping strategies. When medical devices are contaminated with blood or other body fluids, existing recommendations include the cleaning of these instruments, followed by disinfection or sterilization, depending on the type of medical device. These protocols assume "worst-case" conditions of

extreme virologic and microbiologic contamination, and whether viruses have been inactivated after drying plays no role in formulating these strategies. Consequently, no changes in published procedures for cleaning, disinfecting, or sterilizing need to be made.

## Housekeeping

Environmental surfaces such as walls, floors, and other surfaces are not associated with transmission of infections to patients or health-care workers. Therefore, extraordinary attempts to disinfect or sterilize these environmental surfaces are not necessary. However, cleaning and removal of soil should be done routinely.

Cleaning schedules and methods vary according to the area of the hospital or institution, type of surface to be cleaned, and the amount and type of soil present. Horizontal surfaces (e.g., bedside tables and hard-surfaced flooring) in patient-care areas are usually cleaned on a regular basis, when soiling or spills occur, and when a patient is discharged. Cleaning of walls, blinds, and curtains is recommended only if they are visibly soiled. Disinfectant fogging is an unsatisfactory method of decontaminating air and surfaces and is not recommended.

Disinfectant-detergent formulations registered by EPA can be used for cleaning environmental surfaces, but the actual physical removal of microorganisms by scrubbing is probably at least as important as any antimicrobial effect of the cleaning agent used. Therefore, cost, safety, and acceptability by housekeepers can be the main criteria for selecting any such registered agent. The manufacturers' instructions for appropriate use should be followed.

## Cleaning and Decontaminating Spills of Blood or Other Body Fluids

Chemical germicides that are approved for use as "hospital disinfectants" and are tuberculocidal when used at recommended dilutions can be used to decontaminate spills of blood and other body fluids. Strategies for decontaminating spills of blood and other body fluids in a patient-care setting are different than for spills of cultures or other materials in clinical, public health, or research laboratories. In patient-care areas, visible material should first be removed and then the area should be decontaminated. With large spills of cultured or concentrated infectious agents in the laboratory, the contaminated area should be flooded with a liquid germicide before cleaning, then decontaminated with fresh germicidal chemical. In both settings, gloves should be worn during the cleaning and decontaminating procedures.

## Laundry

Although soiled linen has been identified as a source of large numbers of certain pathogenic microorganisms, the risk of actual disease transmission is negligible. Rather than rigid procedures and specifications, hygienic and common-sense storage and processing of clean and soiled linen are recommended (*26*). Soiled linen should be handled as little as possible and with minimum agitation to prevent gross microbial contamination of the air and of persons handling the linen. All soiled linen should be bagged at the location where it was used; it should not be sorted or rinsed in patient-care areas. Linen soiled with blood or body fluids should be placed and transported in bags that prevent leakage. If hot water is used, linen should be washed

with detergent in water at least 71 C (160 F) for 25 minutes. If low-temperature(≤70 C [158 F]) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration should be used.

### Infective Waste

There is no epidemiologic evidence to suggest that most hospital waste is any more infective than residential waste. Moreover, there is no epidemiologic evidence that hospital waste has caused disease in the community as a result of improper disposal. Therefore, identifying wastes for which special precautions are indicated is largely a matter of judgment about the relative risk of disease transmission. The most practical approach to the management of infective waste is to identify those wastes with the potential for causing infection during handling and disposal and for which some special precautions appear prudent. Hospital wastes for which special precautions appear prudent include microbiology laboratory waste, pathology waste, and blood specimens or blood products. While any item that has had contact with blood, exudates, or secretions may be potentially infective, it is not usually considered practical or necessary to treat all such waste as infective (*23,26*). Infective waste, in general, should either be incinerated or should be autoclaved before disposal in a sanitary landfill. Bulk blood, suctioned fluids, excretions, and secretions may be carefully poured down a drain connected to a sanitary sewer. Sanitary sewers may also be used to dispose of other infectious wastes capable of being ground and flushed into the sewer.

## Implementation of Recommended Precautions

Employers of health-care workers should ensure that policies exist for:

1. Initial orientation and continuing education and training of all health-care workers—including students and trainees—on the epidemiology, modes of transmission, and prevention of HIV and other blood-borne infections and the need for routine use of universal blood and body-fluid precautions for all patients.
2. Provision of equipment and supplies necessary to minimize the risk of infection with HIV and other blood-borne pathogens.
3. Monitoring adherence to recommended protective measures. When monitoring reveals a failure to follow recommended precautions, counseling, education, and/or re-training should be provided, and, if necessary, appropriate disciplinary action should be considered.

Professional associations and labor organizations, through continuing education efforts, should emphasize the need for health-care workers to follow recommended precautions.

# Serologic Testing for HIV Infection

## Background

A person is identified as infected with HIV when a sequence of tests, starting with repeated enzyme immunoassays (EIA) and including a Western blot or similar, more specific assay, are repeatedly reactive. Persons infected with HIV usually develop antibody against the virus within 6-12 weeks after infection.

The sensitivity of the currently licensed EIA tests is at least 99% when they are performed under optimal laboratory conditions on serum specimens from persons infected for ≥12 weeks. Optimal laboratory conditions include the use of reliable reagents, provision of continuing education of personnel, quality control of procedures, and participation in performance-evaluation programs. Given this performance, the probability of a false-negative test is remote except during the first several weeks after infection, before detectable antibody is present. The proportion of infected persons with a false-negative test attributed to absence of antibody in the early stages of infection is dependent on both the incidence and prevalence of HIV infection in a population (Table 1).

The specificity of the currently licensed EIA tests is approximately 99% when repeatedly reactive tests are considered. Repeat testing of initially reactive specimens by EIA is required to reduce the likelihood of laboratory error. To increase further the specificity of serologic tests, laboratories must use a supplemental test, most often the Western blot, to validate repeatedly reactive EIA results. Under optimal laboratory conditions, the sensitivity of the Western blot test is comparable to or greater than that of a repeatedly reactive EIA, and the Western blot is highly specific when strict criteria are used to interpret the test results. The testing sequence of a repeatedly reactive EIA and a positive Western blot test is highly predictive of HIV infection, even in a population with a low prevalence of infection (Table 2). If the Western blot test result is indeterminant, the testing sequence is considered equivocal for HIV infection.

**TABLE 1. Estimated annual number of patients infected with HIV not detected by HIV-antibody testing in a hypothetical hospital with 10,000 admissions/year***

| Beginning prevalence of HIV infection | Annual incidence of HIV infection | Approximate number of HIV-infected patients | Approximate number of HIV-infected patients not detected |
|---|---|---|---|
| 5.0% | 1.0% | 550 | 17-18 |
| 5.0% | 0.5% | 525 | 11-12 |
| 1.0% | 0.2% | 110 | 3-4 |
| 1.0% | 0.1% | 105 | 2-3 |
| 0.1% | 0.02% | 11 | 0-1 |
| 0.1% | 0.01% | 11 | 0-1 |

*The estimates are based on the following assumptions: 1) the sensitivity of the screening test is 99% (i.e., 99% of HIV-infected persons with antibody will be detected); 2) persons infected with HIV will not develop detectable antibody (seroconvert) until 6 weeks (1.5 months) after infection; 3) new infections occur at an equal rate throughout the year; 4) calculations of the number of HIV-infected persons in the patient population are based on the mid-year prevalence, which is the beginning prevalence plus half the annual incidence of infections.

When this occurs, the Western blot test should be repeated on the same serum sample, and, if still indeterminant, the testing sequence should be repeated on a sample collected 3-6 months later. Use of other supplemental tests may aid in interpreting of results on samples that are persistently indeterminant by Western blot.

## Testing of Patients

Previous CDC recommendations have emphasized the value of HIV serologic testing of patients for: 1) management of parenteral or mucous-membrane exposures of health-care workers, 2) patient diagnosis and management, and 3) counseling and serologic testing to prevent and control HIV transmission in the community. In addition, more recent recommendations have stated that hospitals, in conjunction with state and local health departments, should periodically determine the prevalence of HIV infection among patients from age groups at highest risk of infection (*32*).

Adherence to universal blood and body-fluid precautions recommended for the care of all patients will minimize the risk of transmission of HIV and other blood-borne pathogens from patients to health-care workers. The utility of routine HIV serologic testing of patients as an adjunct to universal precautions is unknown. Results of such testing may not be available in emergency or outpatient settings. In addition, some recently infected patients will not have detectable antibody to HIV (Table 1).

Personnel in some hospitals have advocated serologic testing of patients in settings in which exposure of health-care workers to large amounts of patients' blood may be anticipated. Specific patients for whom serologic testing has been advocated include those undergoing major operative procedures and those undergoing treatment in critical-care units, especially if they have conditions involving uncontrolled bleeding. Decisions regarding the need to establish testing programs for patients should be made by physicians or individual institutions. In addition, when deemed appropriate, testing of individual patients may be performed on agreement between the patient and the physician providing care.

In addition to the universal precautions recommended for all patients, certain additional precautions for the care of HIV-infected patients undergoing major surgical operations have been proposed by personnel in some hospitals. For example, surgical procedures on an HIV-infected patient might be altered so that hand-to-hand passing of sharp instruments would be eliminated; stapling instruments rather than

**TABLE 2. Predictive value of positive HIV-antibody tests in hypothetical populations with different prevalences of infection**

| | Prevalence of infection | Predictive value of positive test* |
|---|---|---|
| Repeatedly reactive enzyme immunoassay (EIA)† | 0.2% | 28.41% |
| | 2.0% | 80.16% |
| | 20.0% | 98.02% |
| Repeatedly reactive EIA followed by positive Western blot (WB)§ | 0.2% | 99.75% |
| | 2.0% | 99.97% |
| | 20.0% | 99.99% |

*Proportion of persons with positive test results who are actually infected with HIV.
†Assumes EIA sensitivity of 99.0% and specificity of 99.5%.
§Assumes WB sensitivity of 99.0% and specificity of 99.9%.

hand-suturing equipment might be used to perform tissue approximation; electrocautery devices rather than scalpels might be used as cutting instruments; and, even though uncomfortable, gowns that totally prevent seepage of blood onto the skin of members of the operative team might be worn. While such modifications might further minimize the risk of HIV infection for members of the operative team, some of these techniques could result in prolongation of operative time and could potentially have an adverse effect on the patient.

Testing programs, if developed, should include the following principles:

- Obtaining consent for testing.
- Informing patients of test results, and providing counseling for seropositive patients by properly trained persons.
- Assuring that confidentiality safeguards are in place to limit knowledge of test results to those directly involved in the care of infected patients or as required by law.
- Assuring that identification of infected patients will not result in denial of needed care or provision of suboptimal care.
- Evaluating prospectively 1) the efficacy of the program in reducing the incidence of parenteral, mucous-membrane, or significant cutaneous exposures of health-care workers to the blood or other body fluids of HIV-infected patients and 2) the effect of modified procedures on patients.

### Testing of Health-Care Workers

Although transmission of HIV from infected health-care workers to patients has not been reported, transmission during invasive procedures remains a possibility. Transmission of hepatitis B virus (HBV)—a blood-borne agent with a considerably greater potential for nosocomial spread—from health-care workers to patients has been documented. Such transmission has occurred in situations (e.g., oral and gynecologic surgery) in which health-care workers, when tested, had very high concentrations of HBV in their blood (at least 100 million infectious virus particles per milliliter, a concentration much higher than occurs with HIV infection), and the health-care workers sustained a puncture wound while performing invasive procedures or had exudative or weeping lesions or microlacerations that allowed virus to contaminate instruments or open wounds of patients (*33,34*).

The hepatitis B experience indicates that only those health-care workers who perform certain types of invasive procedures have transmitted HBV to patients. Adherence to recommendations in this document will minimize the risk of transmission of HIV and other blood-borne pathogens from health-care workers to patients during invasive procedures. Since transmission of HIV from infected health-care workers performing invasive procedures to their patients has not been reported and would be expected to occur only very rarely, if at all, the utility of routine testing of such health-care workers to prevent transmission of HIV cannot be assessed. If consideration is given to developing a serologic testing program for health-care workers who perform invasive procedures, the frequency of testing, as well as the issues of consent, confidentiality, and consequences of test results—as previously outlined for testing programs for patients—must be addressed.

## Management of Infected Health-Care Workers

Health-care workers with impaired immune systems resulting from HIV infection or other causes are at increased risk of acquiring or experiencing serious complications of infectious disease. Of particular concern is the risk of severe infection following exposure to patients with infectious diseases that are easily transmitted if appropriate precautions are not taken (e.g., measles, varicella). Any health-care worker with an impaired immune system should be counseled about the potential risk associated with taking care of patients with any transmissible infection and should continue to follow existing recommendations for infection control to minimize risk of exposure to other infectious agents (*7,35*). Recommendations of the Immunization Practices Advisory Committee (ACIP) and institutional policies concerning requirements for vaccinating health-care workers with live-virus vaccines (e.g., measles, rubella) should also be considered.

The question of whether workers infected with HIV—especially those who perform invasive procedures—can adequately and safely be allowed to perform patient-care duties or whether their work assignments should be changed must be determined on an individual basis. These decisions should be made by the health-care worker's personal physician(s) in conjunction with the medical directors and personnel health service staff of the employing institution or hospital.

## Management of Exposures

If a health-care worker has a parenteral (e.g., needlestick or cut) or mucous-membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids or has a cutaneous exposure involving large amounts of blood or prolonged contact with blood—especially when the exposed skin is chapped, abraded, or afflicted with dermatitis—the source patient should be informed of the incident and tested for serologic evidence of HIV infection after consent is obtained. Policies should be developed for testing source patients in situations in which consent cannot be obtained (e.g., an unconscious patient).

If the source patient has AIDS, is positive for HIV antibody, or refuses the test, the health-care worker should be counseled regarding the risk of infection and evaluated clinically and serologically for evidence of HIV infection as soon as possible after the exposure. The health-care worker should be advised to report and seek medical evaluation for any acute febrile illness that occurs within 12 weeks after the exposure. Such an illness—particularly one characterized by fever, rash, or lymphadenopathy—may be indicative of recent HIV infection. Seronegative health-care workers should be retested 6 weeks post-exposure and on a periodic basis thereafter (e.g., 12 weeks and 6 months after exposure) to determine whether transmission has occurred. During this follow-up period—especially the first 6-12 weeks after exposure, when most infected persons are expected to seroconvert—exposed health-care workers should follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV (*36,37*).

No further follow-up of a health-care worker exposed to infection as described above is necessary if the source patient is seronegative unless the source patient is at high risk of HIV infection. In the latter case, a subsequent specimen (e.g., 12 weeks following exposure) may be obtained from the health-care worker for antibody

testing. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized. Serologic testing should be available to all health-care workers who are concerned that they may have been infected with HIV.

If a patient has a parenteral or mucous-membrane exposure to blood or other body fluid of a health-care worker, the patient should be informed of the incident, and the same procedure outlined above for management of exposures should be followed for both the source health-care worker and the exposed patient.

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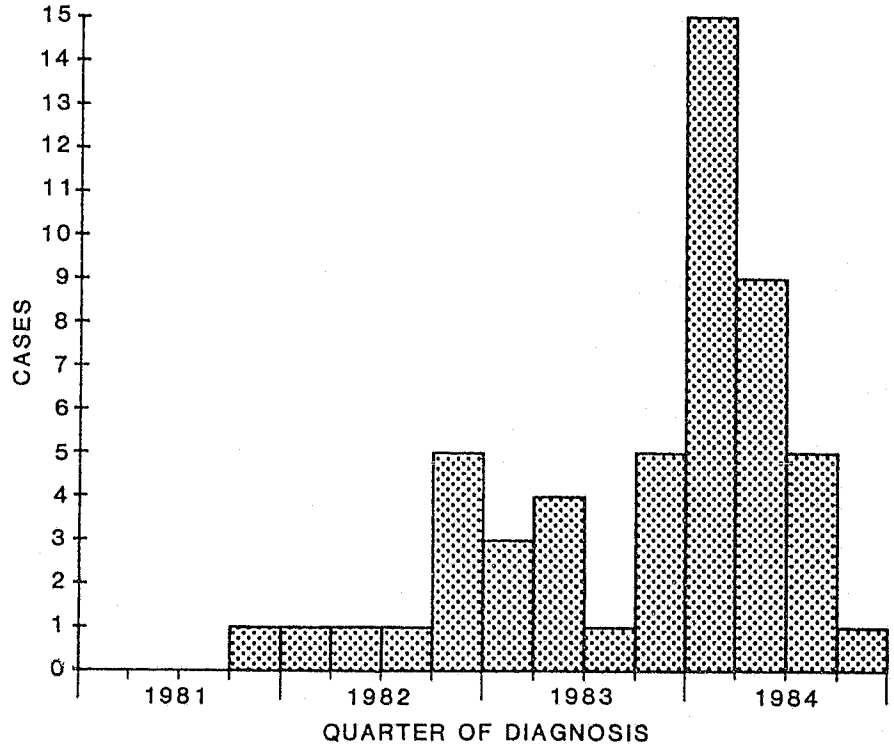
# III. HEMOPHILIA PATIENTS

1984 Oct. 26;33:589–91

## Update: Acquired Immunodeficiency Syndrome (AIDS) in Persons with Hemophilia

Reports of hemophilia-associated acquired immunodeficiency syndrome (AIDS) in the United States were first published in July 1982 (*1*). Since then, the number of U.S. patients with underlying coagulation disorders who develop AIDS has increased each year. In 1981, one U.S. case was reported; in 1982, eight; in 1983, 14; and, as of October 15, 29 cases have been reported in 1984, for a total of 52 cases (Figure 1). Two of these 52 patients had hemophilia B; one, a factor V deficiency; and one, factor VIII deficiency due to her postpartum acquisition of a factor VIII inhibitor. The remaining 48 cases occurred among hemophilia A patients. Three patients are known to have had risk factors for AIDS other than hemophilia. These 52 persons resided in 22 states. Only 10 states have reported more than one case, and no state has reported more than eight cases.

**FIGURE 1. Hemophilia-associated acquired immunodeficiency syndrome (AIDS), by quarter — United States, 1981-October 15, 1984**




With the exception of one 31-year-old factor V-deficient individual with Kaposi's sarcoma (and without risk factors for AIDS other than his hemophilia), each patient had at least one opportunistic infection suggestive of an underlying cellular immune deficiency. *Pneumocystis carinii* pneumonia has been the most common opportunistic infection, occurring in 44 (85%) of the 52 patients. Other opportunistic infections have included toxoplasmic encephalitis (two cases), disseminated *Mycobacterium avium intracellulare* (one), disseminated cytomegalovirus infection (two), disseminated candidiasis (one), and cryptococcal meningitis (one). Thirty hemophilia patients with AIDS have died; only three of the survivors were diagnosed more than 1 year ago.

CDC has investigated the blood product usage of the majority of these cases. In nine cases, factor VIII concentrates have been the only blood product reportedly used in the 5 years before diagnosis of AIDS. These nine persons had no risk factors for AIDS other than hemophilia. The factor V-deficient patient with Kaposi's sarcoma had not used factor VIII concentrate products but had used large volumes of plasma and factor IX concentrates.

The sera of 22 (42%) of the 52 hemophilia-associated AIDS patients have been tested for antibody to antigens of the AIDS virus using Western blot analysis (*2*). Eighteen (82%) of these specimens contained antibody to one or more antigens (*2,3*). In cooperation with numerous hemophilia treatment centers and physicians, CDC has studied over 200 recipients of factor VIII and 36 recipients of factor IX concentrates containing materials from U.S. donors. Rates of AIDS virus antibody prevalence were 74% for factor VIII recipients and 39% for factor IX recipients (*3,4*). Only prospective evaluation will determine what risk of AIDS exists for seropositive individuals. A recently published study evaluated the thermostability of murine retroviruses inoculated into factor concentrates, using a cell transformation assay (*5*). After 48 hours at 68 C (154.4 F), viral titers dropped from $10^8$ to two infectious particles/ml. In studies done at CDC, in cooperation with Cutter Laboratories, AIDS virus was added to factor VIII concentrate (virus titer $10^5$) and the factor was lyophilized and heated to 68 C (154.4 F). The residual virus titer was determined by an infectivity assay (*6*). Virus was undetectable after 24 hours of heat treatment, the shortest time period examined.

*Reported by P Levine, MD, Medical Director, National Hemophilia Foundation, New York City; Div of Host Factors, Center for Infectious Diseases, CDC.*

**Editorial Note:** The possibility of blood or blood products being vehicles for AIDS transmission to hemophilia patients has been supported by the finding of risk of acquisition of AIDS for intravenous drug abusers (*7*) and, subsequently, by reports of transfusion-associated AIDS cases (*8*). The mainstays of therapy for the hemorrhagic phenomena of hemophilia are cryoprecipitate, fresh frozen plasma, and plasma factor preparations; these have been associated with the transmission of several known viral agents, including cytomegalovirus, hepatitis B virus, and the virus(es) of non-A, non-B hepatitis (*9*). While many U.S. hemophilia-associated AIDS patients have received blood products other than factor concentrates in the 5 years preceding their AIDS diagnosis, the occurrence of nine cases with no known risk factor or exposure other than the use of factor VIII preparations implicates these products as potential vehicles of AIDS transmission.

The Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) has recently issued revised recommendations for the therapy of hemophilia (*10*). To physicians treating patients with hemophilia, they recommend that (1) cryoprecipitate be used in factor VIII-deficient newborn infants and children under 4 years of age and in newly identified patients never treated with factor VIII concentrates; (2) fresh frozen plasma be used in factor IX-deficient patients in the same categories; and (3) desmopressin (DDAVP) be used whenever possible in patients with mild or moderate hemophilia A. The majority of hemophilia patients do not fit in categories (1) through (3). For these patients, MASAC recommends that, "because heat-treated products appear to have no increase in untoward effects attributable to the heat treatment, treaters using coagulation factor concentrates should strongly consider changing to heat-treated products with the understanding that protection against AIDS is yet to be proven." They also recommend that all elective surgical procedures for hemophilia patients be evaluated with respect to possible advantages and disadvantages of surgical delays.

Although the total number of hemophilia patients who have thus far developed clinical manifestations of AIDS is small relative to other AIDS risk groups, incidence rates for this group are high (3.6 cases/1,000 hemophilia A patients and 0.6/1,000 hemophilia B patients). Continued surveillance is important. Physicians diagnosing opportunistic infections or unusual neoplasms in hemophilia patients who have not received antecedent immunosuppressive therapy are requested to report these findings to local or state health departments and to CDC.

In March 1983, the U.S. Public Health Service recommended that members of groups at increased risk of acquiring AIDS should refrain from donating plasma and/or blood (*11*). A specific serologic test will soon become available for screening purposes, and thus a safer factor concentrate product should result. The preliminary evidence concerning the effects of heat-treatment on the viability of the AIDS virus is strongly supportive of the usefulness of heat-treatment in reducing the potential for transmission of the AIDS virus in factor concentrate products and suggest that the use of nonheat-treated factor concentrates should be limited. CDC and NHF will continue to study the effects of heat-treated factor on the immune status of patients with hemophilia.

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# IV. PATIENTS WITH SPECIAL DISEASE CONDITIONS

1986 June 13;35:376–78, 383

## Recommendations for Providing Dialysis Treatment to Patients Infected with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus

Patients with end-stage renal disease who are undergoing maintenance dialysis and who have manifestations of human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV)* infection, including acquired immunodeficiency syndrome (AIDS), or who are positive for antibody to HTLV-III/LAV can be dialyzed in hospital-based or free-standing dialysis units using conventional infection-control precautions. Standard blood and body fluid precautions and disinfection and sterilization strategies routinely practiced in dialysis centers are adequate to prevent transmission of HTLV-III/LAV.

Soon after AIDS was recognized in the United States, it became apparent that risk factors for persons with AIDS were similar to risk factors for persons with hepatitis B virus (HBV) infection (*1*). Prevention measures applied to control HBV infection in health-care institutions were used as a model to develop infection-control guidelines for patients with AIDS before the identification of the etiologic agent and the development of serologic tests for antibody to HTLV-III/LAV (anti-HTLV-III). Isolation of infected patients and nonreuse of a dialyzer by the same patient were initially recommended for patients receiving dialysis in dialysis centers (*2*). These strategies are not currently believed necessary for preventing HTLV-III/LAV transmission.

No transmission of HTLV-III/LAV infection in the dialysis-center environment has been reported (*3*), and the possibility of such transmission appears extremely unlikely when routine infection-control precautions are followed (*4*). The routine infection-control precautions used in all dialysis centers when dialyzing all patients are considered adequate to prevent HTLV-III/LAV transmission. These would include: blood precautions; routine cleaning and disinfection of dialysis equipment and surfaces that are frequently touched; and restriction of nondisposable supplies to individual patients unless such supplies are sterilized between uses (*2*).

The following recommendations take into consideration recent knowledge about HTLV-III/LAV and update infection-control strategies for dialyzing patients infected with HTLV-III/LAV:

1. Procedures for environmental control and for disinfection and sterilization of hemodialysis machines have been described (*5*). The hemodialysis machine pumps dialysis fluid into the dialyzer (artificial kidney) where circulating blood from the patient is separated from the dialysis fluid by a membrane. The dialyzer, along with the associated blood lines, is disposable. Strategies for disinfecting the dialysis fluid pathways of the hemodialysis machine are targeted to control bacterial contamination and generally consist of using about 500-750 ppm of sodium hypochlorite for 30-40 minutes or 1.5%-2.0% formaldehyde overnight. In addition, several chemical germicides formulated to disinfect dialysis machines are commercially available. None of these protocols or procedures need to be altered after dialyzing patients infected with HTLV-III/LAV. Chemical germicides used for disinfection and sterilization of devices in the dialysis center are effective against HTLV-III/LAV (*4*).
2. Patients infected with HTLV-III/LAV can be dialyzed by either hemodialysis or peritoneal dialysis and do not need to be isolated from other patients. The type of dialysis treatment (i.e., hemodialysis or peritoneal dialysis) should be based on the needs of the patient. The dialyzer may be discarded after each use. Alternatively, centers that have dialyzer-reuse programs, in which a specific dialyzer is issued to a specific patient, removed, cleaned, disinfected, and reused several times on the same patient only, may include HTLV-III/LAV-infected patients in the dialyzer-reuse program. An individual dialyzer must never be used on more than one patient.

*An international committee on taxonomy has proposed the name human immunodeficiency virus (HIV).

3. Standard infection-control strategies that are used routinely in dialysis units for all dialysis patients and personnel should be used to prevent HTLV-III/LAV transmission. Specifically, these strategies include blood precautions and barrier techniques, such as the use of gloves, gowns, and handwashing techniques, that have been described elsewhere (*4-8*).
4. Precautions against needlestick injuries, as well as the appropriate use of barrier precautions, such as wearing gloves when handling items contaminated with blood or serum, should be practiced by all personnel caring for all dialysis patients. Such injuries constitute the major potential risk for HTLV-III/LAV transmission to personnel. Extraordinary care should be taken to prevent injuries to hands caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments following procedures. After use, disposable syringes and needles, scalpel blades, and other sharp items must be placed in puncture-resistant containers for disposal. To prevent needlestick injuries, needles should not be recapped; purposefully bent or broken; removed from disposable syringes; or otherwise manipulated by hand. No data are currently available from controlled studies examining the effect, if any, of the use of needle-cutting devices on the incidence of needlestick injuries.

*Reported by Hospital Infections Program, AIDS Program, Center for Infectious Diseases, CDC.*

**Editorial Note:** In a study of 520 dialysis patients, 25 were reactive for anti-HTLV-III/LAV by enzyme immunoassay (EIA), but only four were confirmed by the Western blot technique (*3*). The rate of falsely reactive EIA tests among these dialysis patients was 4%, much higher than the falsely reactive rate for blood donors (0.17%). The rate of truly reactive tests was 0.8%, much lower than in high-risk groups but higher than in blood donors. The higher rate of falsely reactive tests is probably due to the exposure of dialysis patients to H9-cell-associated antigens during blood transfusions that are common among these patients. These antigens are also present in cell lines used to grow HTLV-III/LAV for use as reagents in serologic tests for anti-HTLV-III/LAV (*9*). Identification of antibody to H9 lymphoid cell lines in the absence of isolation of HTLV-III/LAV in dialysis patients with reactive EIA and nonreactive Western blot tests supports the conclusion that these test results are falsely reactive. The higher rate of truly reactive tests most likely reflects the frequency of blood transfusion in this patient population before initiation of blood donor screening for anti-HTLV-III/LAV. None of the four infected persons identified in that study were dialyzed in the same dialysis center.

CDC is initiating a cooperative study to further assess the prevalence of anti-HTLV-III/LAV among patients undergoing chronic hemodialysis. Representatives of dialysis centers who are interested in participating in such a study and who regularly have more than 60 patients on dialysis should contact the Hospital Infections Program, Center for Infectious Diseases, CDC, Building 1, Room 5065, Atlanta, Georgia 30333 (telephone [404] 329-3406).

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# Diagnosis and Management of Mycobacterial Infection and Disease in Persons with Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus Infection

In 1985, the number of new tuberculosis cases reported to CDC was essentially the same as that reported in 1984 (*1*). In contrast, the average annual decline in morbidity during the past 32 years has been 5%. The failure of tuberculosis morbidity to decline as expected in 1985 is probably related to the occurrence of tuberculosis among persons with acquired immunodeficiency syndrome (AIDS) or human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV/LAV)* infection. Several reports have indicated that mycobacterial disease is common among AIDS patients and among persons at risk for AIDS (*2-9*). The most common mycobacterial species isolated from patients with diagnosed AIDS is *Mycobacterium avium* complex (MAC), although in some groups in which tuberculous infection is highly prevalent, disease caused by *M. tuberculosis* is more common (*10-12*). Even among groups in which MAC is the most common mycobacterial pathogen, *M. tuberculosis* accounts for a substantial proportion of the mycobacterial isolates. The association between mycobacterial disease and AIDS raises several important clinical and public health issues that are addressed below.

## DIAGNOSIS OF TUBERCULOSIS IN PATIENTS LIKELY TO HAVE HTLV-III/LAV INFECTION

Clinicians should consider the diagnosis of tuberculosis in patients with, or at risk of, HTLV-III/LAV infection, even if the clinical presentation is unusual (*4,13,14*). Available data indicate that extrapulmonary forms of tuberculosis, particularly lymphatic and disseminated (miliary), are seen much more frequently among patients with HTLV-III/LAV infection than among those without such infection. Pulmonary tuberculosis in patients with HTLV-III/LAV infection cannot readily be distinguished from other pulmonary infections, such as *Pneumocystis carinii* pneumonia, on the basis of clinical and radiographic findings. Patients with tuberculosis may have infiltrates in any lung zone, often associated with mediastinal and/or hilar lymphadenopathy. Cavitation is uncommon. Appropriate specimens to establish a culture-confirmed diagnosis of tuberculosis include respiratory secretions, urine, blood, lymph node, bone marrow, liver, or other tissue or body fluid that is indicated clinically. All tissue specimens should be stained for acid-fast bacilli and cultured for mycobacteria. In the presence of undiagnosed pulmonary infiltrates, bronchoscopy with lavage and transbronchial biopsy (if not contraindicated) may be needed to obtain material for both culture and histologic examination. A tuberculin skin test should be administered, but the absence of a reaction does not rule out the diagnosis of tuberculosis because immunosuppression associated with HTLV-III/LAV infection may cause false-negative results.

## TREATMENT OF MYCOBACTERIAL DISEASE IN A PATIENT WITH HTLV-III/LAV INFECTION

**Chemotherapy should be started whenever acid-fast bacilli are found in a specimen from a patient with HTLV-III/LAV infection and clinical evidence of mycobacterial disease.** Because it is difficult to distinguish tuberculosis from MAC disease by any criterion other than culture, and because of the individual and public health implications of tuberculosis, it is important to treat patients with a regimen effective against tuberculosis. With some exceptions, patients with tuberculosis and HTLV-III/LAV infection respond relatively well to standard antituberculosis drugs (*15*); however, their treatment should include at least three drugs initially, and treatment may need to be longer than the standard duration of 9 months (*16*). The recommended regimen is isoniazid (INH), 10-15 mg/kg/day up to 300 mg/day; rifampin (RIF), 10-15 mg/kg/day up to 600 mg/day; and either ethambutol (EMB), 25 mg/kg/day, or pyrazinamide (PZA), 20-30 mg/kg/day. The last two drugs are usually given only during the first 2 months of therapy. The addition of a fourth drug may be indicated in certain situations, such as central nervous system or disseminated disease or when INH resistance is suspected. An initial drug-susceptibility test should always be performed, and the treatment regimen, revised if resistance is found to any of the drugs being used. The appropriate duration of treatment for patients with tuberculosis and HTLV-III/LAV infection is unknown; how-

*The Human Retrovirus Subcommittee of the International Committee on the Taxonomy of Viruses has proposed the name human immunodeficiency virus (HIV) for this virus (Science 1986;232:697).

ever, it is recommended that treatment continue for a minimum of 9 months and for at least 6 months after documented culture conversion. If INH or RIF is not included in the treatment regimen, therapy should continue for a minimum of 18 months and for at least 12 months following culture conversion. After therapy is completed, patients should be followed closely, and mycobacteriologic examinations should be repeated if clinically indicated.

Some clinicians would take a different approach to treatment than that outlined above, to cover the possibility of MAC disease. Although the clinical significance and optimal therapy of MAC disease in these patients is not well defined, and there are no definitive data on the efficacy of treatment, one regimen commonly used to treat MAC disease substitutes rifabutin (ansamycin LM 427) for rifampin, combined with INH, EMB, and clofazimine. Rifabutin and clofazimine are experimental drugs available to qualified investigators only under investigational new drug protocols. Rifabutin is distributed by the CDC Drug Service (telephone: [404] 329-3670), and clofazimine, by Ciba-Geigy: (telephone: [201] 277-5787). If *M. tuberculosis* is isolated from a patient receiving this four-drug regimen, treatment should be switched to one of the three-drug regimens outlined above (INH, RIF, and EMB or PZA). If MAC is isolated from a patient who has been started on a three-drug regimen, the clinician may continue the three-drug regimen or switch to the four-drug regimen of INH, EMB, rifabutin, and clofazimine.

Although experience is very limited, patients with disease due to *M. kansasii* should respond to INH, RIF, and EMB. Some clinicians advocate the addition of streptomycin (SM), 1 gram twice weekly, for the first 3 months. Therapy should continue for a minimum of 15 months following culture conversion.

Monitoring for toxicity of antimycobacterial drugs may be difficult for patients who may be receiving a variety of other drugs and may have other concomitant conditions. Because hepatic and hematologic abnormalities may be caused by the mycobacterial disease, AIDS, or other drugs and conditions, the presence of such abnormalities is not an absolute contraindication to the use of the treatment regimens outlined above.

**INFECTION CONTROL**

Recommendations for preventing transmission of HTLV-III/LAV infection to health-care workers have been published (*17*). In addition, infection-control procedures applied to patients with HTLV-III/LAV infection who have undiagnosed pulmonary disease should always take the possibility of tuberculosis into account. This is especially true when diagnostic procedures, such as sputum induction or bronchoscopy, are being performed. Previously published guidelines for preventing tuberculosis transmission in hospitals should be followed (*18*).

**CONTACT INVESTIGATION FOR TUBERCULOSIS**

Patients with pulmonary tuberculosis and HTLV-III/LAV infection should be considered potentially infectious for tuberculosis, and standard procedures for tuberculosis contact investigation should be followed (*19*). Specific data on the infectiousness of tuberculosis in patients with HTLV-III/LAV infection are not yet available.

**EXAMINING HTLV-III/LAV-INFECTED PERSONS FOR TUBERCULOSIS AND TUBERCULOUS INFECTION**

Individuals who are known to be HTLV-III/LAV seropositive should be given a Mantoux skin test with 5 tuberculin units of purified protein derivative as part of their clinical evaluation. Although some false-negative skin test results may be encountered in this setting as a result of immunosuppression induced by HTLV-III/LAV infection, significant reactions are still meaningful (*20*). If the skin test reaction is significant, a chest radiograph should be obtained, and if abnormalities are detected, additional diagnostic procedures for tuberculosis should be undertaken. Patients with clinical AIDS or other Class IV HTLV-III/LAV infections (*21*) should receive *both* a tuberculin skin test and a chest radiograph because of the higher probability of false-negative tuberculin reactions in immunosuppressed patients.

**EXAMINING PATIENTS WITH CLINICALLY ACTIVE TUBERCULOSIS OR LATENT TUBERCULOUS INFECTION FOR HTLV-III/LAV INFECTION**

As part of the evaluation of patients with tuberculosis and tuberculous infection, risk factors for HTLV-III/LAV should be identified. Voluntary testing of all persons with these risk factors is recommended (*22*). In addition, testing for HTLV-III/LAV antibody should be considered for patients of all ages who have severe or unusual manifestations of tuberculosis. The presence of HTLV-III/LAV infection has implications regarding treatment (see above), alerts the physician to the possibility of other opportunistic infections, and allows for counselling about transmission of HTLV-III/LAV infection (*23*). Testing for HTLV-III/LAV antibody is especially important for persons over age 35 with *asymptomatic* tuberculous infection, because INH would not usually be indicated for persons in this age group unless they are also HTLV-III/LAV seropositive.

## PREVENTIVE THERAPY

HTLV-III/LAV seropositivity in a person of any age with a significant tuberculin reaction is an indication for INH preventive therapy (*16*). Although it is not known whether INH therapy is as efficacious in preventing tuberculosis in HTLV-III/LAV-infected persons as in other groups, the usually good response of HTLV-III/LAV-infected persons with tuberculosis to standard therapy suggests that INH preventive therapy would also be effective. Before instituting preventive therapy, clinically active tuberculosis should be excluded.

*Developed by Center for Prevention Svcs, Center for Infectious Diseases, CDC, with consultation from: RS Holzman, MD, New York University Medical Center, New York City; PC Hopewell, MD, San Francisco General Hospital Medical Center, California; AE Pitchenik, MD, University of Miami Medical Center, Florida; LB Reichman, MD, University of Medicine and Dentistry of New Jersey, New Jersey Medical School, University Hospital, Newark, New Jersey; RL Stoneburner, MD, New York City Dept of Health.*

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# V. DONORS OF BODY FLUIDS AND TISSUES

1985 January 11;34:1–5

## 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 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, 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 or 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 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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## Testing Donors of Organs, Tissues, and Semen for Antibody to Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus

The U.S. Public Health Service has recommended that all donated blood and plasma be tested for antibody to human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the virus that causes acquired immunodeficiency syndrome (AIDS) (*1*). It is additionally recommended that blood or serum from donors of organs, tissues, or semen intended for human use be similarly tested and that the test result be used to evaluate the appropriate use of such materials from these donors. Although AIDS has not been reported to have been associated with such use, semen and other body fluids, including blood, may harbor the virus. Thus, organs, tissues, and semen obtained from HTLV-III/LAV antibody-positive persons must be considered as potentially infectious. Persons in groups having an increased risk for AIDS should not donate organs, tissues, or semen, regardless of the result of the antibody test; this is the same policy currently followed for blood donations. It is recognized that the circumstances of organ procurement and the logistics of transplantation may in some instances not permit the use of an HTLV-III/LAV test. However, when feasible such testing is prudent.

*Reported by U.S. Food and Drug Administration; Alcohol, Drug Abuse, and Mental Health Administration; National Institutes of Health; Health Resources and Svcs Administration; CDC.*

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# Update: Revised Public Health Service Definition of Persons Who Should Refrain from Donating Blood and Plasma — United States

Since March 1985, blood- and plasma-collection centers in the United States have used a two-phase screening procedure to decrease transmission of human T-lymphotropic virus type III (HTLV-III) through transfusion of blood or blood products. First, potential donors are informed that if they have a risk factor for AIDS they should not donate (*1*); second, the blood or plasma of persons accepted as donors is screened for antibody to HTLV-III (*2,3*). The low frequency of enzyme immunoassay (EIA)-positive tests among blood donors (*3,4*) shows that the deferral criteria have been effective. Interviews with the small number of blood donors found infected with HTLV-III, however, have shown that most have a risk factor for HTLV-III infection; homosexual contact was the most common risk factor identified (*5*). To further reduce the risk of HTLV-III infection from blood and plasma, the U.S. Food and Drug Administration (FDA) has reworded the donor-deferral recommendations to state that any man who has had sex with another man since 1977 should not donate blood or plasma. This applies even to men who may have had only a single contact and who do not consider themselves homosexual or bisexual.

*Reported by Center for Drugs and Biologics, US Food and Drug Administration; AIDS Br, Div of Viral Diseases, Center for Infectious Diseases, CDC.*

**Editorial Note:** Recommendations to decrease transmission of HTLV-III through transfusion of blood or blood products were disseminated in March 1983 (*1*) and were rapidly adopted by blood and plasma centers throughout the United States. These recommendations centered on informing all blood or plasma donors that people with a risk factor for AIDS should not donate and asked for voluntary compliance. In March 1985, the second phase of screening blood and plasma was instituted with licensure of test kits to detect antibody to HTLV-III (*2,3*). The test kits are both highly sensitive and specific (*4*), but donors with a risk factor for HTLV-III infection continue to be asked not to donate blood, since the two-phase screening procedure provides additional safety. This revised wording of the deferral recommendations is intended to inform persons who may have been infected with HTLV-III through occasional or intermittent homosexual activity that they should not donate blood or plasma, even if they do not believe they are at risk of having been infected through their contacts.

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## Human Immunodeficiency Virus Infection Transmitted From an Organ Donor Screened for HIV Antibody — North Carolina

In August 1986, a cadaveric organ donor was found positive for antibody to the human immunodeficiency virus (HIV) by both enzyme immunoassay (EIA) and Western blot methods after some of the donated organs had been transplanted. A blood sample, which was taken after the donor had received a large number of blood transfusions, had been negative for HIV antibody. Two days later, when the organs were removed, more blood samples were collected. These were forwarded with the donated organs to the various transplantation centers. At one of these centers, one of these later samples was found to be seropositive.

Three persons received organs from this donor. Two of them were subsequently found to be seropositive for HIV antibody. The third, who had received the donor's heart, did not survive the transplant procedure. This is the first report of HIV transmission by organ transplantation from a donor screened for HIV antibody. A summary of the investigation of the donor and the two surviving recipients follows.

**Donor.** A 30-year-old man who was involved in a motor vehicle accident was admitted, while in a coma, to a North Carolina hospital. He was hypotensive because of bleeding from multiple head and neck lacerations. On admission, a blood sample was collected for type- and cross-matching, and blood transfusions were started within 1 hour. The donor's bleeding persisted despite surgery to improve hemostasis. Approximately 11 hours after admission, he had received a total of 56 units of blood and blood components (1 unit of whole blood, 28 units of packed red blood cells, 7 units of fresh frozen plasma, and 20 units of platelets). At this time, another blood sample was collected and tested for HIV antibody. The specimen was negative by EIA (Abbott Laboratories, North Chicago, Illinois; optical density ratio, sample/control = .103/.131). The donor's condition did not improve, and he was declared brain-dead 2 days after testing for HIV antibody. Family members consented to organ donation and denied any knowledge of the donor's having a risk factor for HIV infection.

The donor's kidneys, heart, and liver were removed and transported to other medical centers for transplantation. Samples of the donor's blood, which were collected when the organs were removed, were sent with each organ. As part of one center's routine procedure, one of these blood samples was tested for HIV antibody and was found positive by EIA (Genetic Systems, Seattle, Washington; optical density ratio = .95/<.30) and was subsequently found positive by Western blot assay. The transplantation teams were notified of the test result, but the heart, liver, and one kidney had already been transplanted.

Personnel from the hospital where the organs had been removed were contacted. They located both the serum sample collected on admission and the serum sample previously found negative for HIV antibody. The serum collected at the time of admission, before any transfusions were administered, was highly reactive on the Abbott EIAs performed at the hospital (optical density ratios = .766/.126, .556/.126) and at the North Carolina State Laboratory of Public Health (optical density ratios = .842/.108, .698/.137) and was also positive by Western blot assay at the state laboratory. When testing was repeated, the serum collected after the blood transfusions was again seronegative by EIA at the hospital and by both EIA and Western blot methods at the state laboratory.

**Recipient 1.** A man with end-stage renal disease received the donated kidney that was transplanted. The recipient is married and denied risk factors for HIV infection. He was negative for HIV antibody 3 days after transplantation. A blood specimen collected 10 weeks after transplantation was positive for HIV antibody by EIA, and a specimen collected 1 week later was positive by both EIA and Western blot assay. The recipient had a fever 8 days after receiving the renal allograft, and a biopsy of it showed acute rejection. He improved with additional immunosuppressive therapy. To date, he has not developed any opportunistic illness and continues to feel well.

**Recipient 2.** A man with sclerosis of the bilary ducts and progressive liver failure received the donated liver. He is married and denied risk factors for HIV infection. He was tested 4 days after transplantation and was negative for HIV antibody. Twelve weeks after the procedure, he was positive for HIV antibody by EIA, and a specimen collected 4 weeks later was positive by both the conventional EIA and an EIA using recombinant viral proteins (ENVACORE, Abbott Laboratories). Four months after transplantation, the recipient developed fever and malaise. A liver biopsy showed moderate allograft rejection. The recipient's condition improved with an adjustment in immunosuppressive therapy, and he returned home the following month.

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**Editorial Note:** Previous reports have linked kidney-transplant recipients who have subsequently become HIV-seropositive with donors who were later found to have risks for HIV infection (*1-4*). However, this is the first report of transplantation-associated HIV transmission from a cadaveric organ donor screened for HIV antibody. This donor appears to have been false-negative for HIV antibody by EIA as a result of the large number of transfusions he received before serum was collected for testing.

The Public Health Service recommended in May 1985 that potential organ donors be screened for HIV antibody (*5*). In January 1986, CDC conducted an anonymous survey of representatives from 44 transplantation programs attending a meeting of the Southeastern Organ Procurement Foundation. All of the 26 representatives who responded reported that their centers screened donors for HIV antibody. Three of these representatives (12%) also reported identifying at least one potential organ donor who was positive for HIV antibody by EIA and Western blot methods.

Organs from donors who are HIV-seropositive should not be used for transplantation except in very unusual circumstances. If an urgent need requires considering transplantation of an organ from a seropositive donor, the potential recipient or the appropriate family members should be informed of the risks of acquiring HIV infection. Such transplantation should not take place without the consent of either the potential recipient or the appropriate family members. When donors have been transfused before their organs are removed, testing for HIV antibody should be conducted on serum collected at the time of admission rather than on serum obtained after multiple transfusions. If donor serum collected at the time of admission is not available from other sources, a pretransfusion sample may be available from the blood bank since many blood banks hold specimens collected for compatibility testing for at least 7 days (*6*).

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# VI. VACCINES

1984 December 14;33:685–87

## Hepatitis B Vaccine: Evidence Confirming Lack of AIDS Transmission

Recent studies have provided important additional assurances concerning the safety of hepatitis B (HB) vaccine. The vaccine currently licensed in the United States is produced from pooled plasma of hepatitis B surface antigen-positive individuals, some of whom are also in high-risk groups for acquired immunodeficiency syndrome (AIDS). Concern has been expressed that the etiologic agent of AIDS might be present in the vaccine and survive the inactivation steps used in the manufacturing procedure. The concerns persisted, despite the fact that these steps were reportedly able to inactivate representative members of all known virus groups. The recent identification of a retrovirus as the etiologic agent of AIDS has allowed workers to (1) directly test the inactivation of the AIDS virus by the inactivation steps used in the vaccine manufacturing procedure; (2) look for the AIDS virus' nucleic acid sequences in the vaccine; and (3) look for serologic markers of infection from the AIDS virus in vaccine recipients. Concurrently, monitoring of AIDS patients and high-risk groups has continued in order to look for any epidemiologic evidence of an association between HB vaccine and AIDS.

The effect of the HB vaccine inactivation process on the AIDS virus and two other human retroviruses (HTLV-I and HTLV-II) was studied. Three separate inactivation steps are used in the manufacture of the U.S.-licensed HB vaccine: (1) 1 $\mu$g/ml pepsin, pH 2, 37 C (98.6 F), 18 hours; (2) 8 molar urea, 37 C (98.6 F), 4 hours; and (3) 0.01% formaldehyde, 37 C (98.6 F), 72 hours. In separate studies conducted between CDC and the vaccine manufacturer Merck, Sharp & Dohme (MSD), and between State University of New York (SUNY) Upstate Medical Center and MSD, cell culture supernatant fluid containing the AIDS virus and cultured cells containing HTLV-I, HTLV-II, and the AIDS virus were transported to MSD and individually exposed to the three inactivation steps. The materials were then returned to CDC and SUNY for detection of residual viral infectivity. Virus infectivity was assayed by adding the treated material to cultured lymphocytes and periodically monitoring these for signs of viral replication (reverse transcriptase activity and virus antigen expression) (*1*) and in the case of HTLV-I and HTLV-II, transformation (*2,3*). No residual virus was detected in material treated with formalin or urea, while material treated with pepsin at pH 2 did have residual virus present. Heat, an inactivation step used in vaccines manufactured outside the United States, has also been shown to inactivate the AIDS virus (*4*).

The second approach, which attempted to detect AIDS virus-related nucleic acid sequences using dot blot hybridization analysis of the vaccine with an AIDS virus deoxyribonucleic acid (DNA) probe, was done at MSD using as a positive control infected cellular (ribonucleic acid) RNA preparations provided by CDC. The vaccine contained no detectable AIDS virus-related sequences at a sensitivity of less than one picogram of DNA per 20-$\mu$g dose of vaccine.

The third approach attempted to detect seroconversion to AIDS virus antibodies in paired sera of HB vaccine recipients. Paired sera were examined at CDC using a highly sensitive and specific ELISA assay for the AIDS virus. No seroconversions were detected in 19 individuals who had received vaccine manufactured from plasma pools that contained plasma of homosexual men. Previous workers have reported that sera of HB vaccine recipients did not show helper-T/supressor-T ratio inversion, a finding common in AIDS patients (*5*).

Epidemiologic approaches to detect an association between HB vaccine and AIDS have included analysis of data on AIDS cases reported to CDC concerning their receipt of HB vaccine and monitoring rates of AIDS in groups of homosexually active men who did or did not receive HB vaccine in the vaccine trials conducted by CDC in Denver, Colorado, and San Francisco, California. To date, 68 AIDS cases have been reported among approximately 700,000 U.S. HB vaccine recipients; 65 have occurred among persons with known AIDS risk factors, while risk factors for the remaining three are under investigation. In addition, the rate of AIDS

for HB vaccine recipients in CDC vaccine trials among homosexually active men in Denver and San Francisco does not differ from that for men screened for possible participation in the trials but who received no HB vaccine because they were found immune to HB.

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**Editorial Note:** The Immunization Practices Advisory Committee (ACIP) (*6*) has recommended preexposure HB vaccination for susceptible members of the following groups in the United States: health-care workers (medical, dental, laboratory, and support groups) judged to have significant exposure to blood or blood products; clients and selected staff of institutions for the mentally retarded; hemodialysis patients; homosexually active males; users of illicit, injectable drugs; recipients of certain blood products (patients with clotting factor disorders); and household and sexual contacts of HB virus (HBV) carriers. In addition, vaccine may be warranted for classroom contacts of deinstitutionalized mentally retarded HBV carriers; special high-risk populations (Alaskan Eskimos and immigrants and refugees from areas with highly endemic disease); inmates of long-term correctional facilities; and some U.S. citizens living or traveling abroad (*7*). The ACIP has also recommended screening all pregnant women belonging to high-risk groups for HB and treating their newborn infants with hepatitis B immune globulin and HB vaccine (*8*).

HB vaccine acceptance in the United States has been seriously hindered by the fear of possible AIDS transmission from the vaccine. The recent identification of AIDS' etiologic agent has made possible direct laboratory measurement of virus inactivation, nucleic acid presence, and serologic evidence of infection. These studies were unable to detect the AIDS virus' viral protein or nucleic acid in the purified vaccine product and clearly indicate that if virus were present, it would be killed by the manufacturing procedures. In addition, epidemiologic monitoring of AIDS cases and high-risk groups confirms the lack of AIDS transmission by HB vaccine. This information should remove a major impediment to vaccine use.

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# Safety of Therapeutic Immune Globulin Preparations with Respect to Transmission of Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus Infection

Immune globulins produced by plasma fractionation methods approved for use in the United States have not been implicated in the transmission of infectious agents. Nevertheless, because immune globulins manufactured before 1985 were derived from plasma of human donors who were not screened for antibody to human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), CDC and the U.S. Food and Drug Administration (FDA) have received inquiries concerning the safety of immune globulin (IG), hepatitis B immune globulin (HBIG), and intravenous immune globulin (IVIG). Current epidemiologic and laboratory evidence shows that these preparations carry no discernable risk of transmitting HTLV-III/LAV infection and that current indications for their clinical use should not be changed based on such concerns.

## BACKGROUND

The IG, HBIG, IVIG, and other special immune globulins used in the United States are produced by several manufacturers using the Cohn-Oncley fractionation process (*1,2*). This process involves a series of precipitation steps performed in the cold with addition of varying concentrations of ethanol. Production lots of IG and IVIG are made from plasma pools from at least 1,000 donors; HBIG and other specific immune globulins (e.g., varicella-zoster IG) may be prepared from plasma pools from fewer donors.

Before 1985, donors were screened only for hepatitis B surface antigen but not by other tests for specific diagnosis of viral infections. Since April 1985, all donor units also have been screened for antibodies to HTLV-III/LAV, and all repeatedly reactive units have been discarded. Tests conducted at FDA and CDC have shown that as many as two-thirds of HBIG lots, as well as some lots of IG and IVIG, produced between 1982 and 1985 may have been positive for HTLV-III/LAV antibody. The question of safety arises out of concern that some immune globulins currently available were prepared from plasma pools that included units from donors who may have had HTLV-III/LAV viremia.

## EPIDEMIOLOGIC STUDIES

Several studies have shown that recipients of HBIG and IG, including recipients of lots known to be positive for antibody to HTLV-III/LAV, did not seroconvert to antibody to HTLV-III/LAV-positivity and have not developed signs and symptoms of acquired immunodeficiency syndrome (AIDS) or other illnesses suggesting HTLV-III/LAV infection.

Since August 1983, CDC has enrolled 938 individuals who have had parenteral or mucous-membrane exposures to blood or body fluids of AIDS patients in a prospective surveillance study. To date, 451 entrants have been followed and tested for HTLV-III/LAV antibody. Of these, 183 persons received IG and/or HBIG as prophylaxis against hepatitis B infection; 100 (55%) received only IG; 65 (36%) received only HBIG; and 18 (10%) received both. One of the 183 HBIG recipients is now positive for HTLV-III/LAV antibody, but no preexposure serum was available for this individual, and seropositivity may have predated the needlestick exposure and IG prophylaxis. Further, heterosexual transmission of HTLV-III/LAV infection in this individual cannot be ruled out. No documented seroconversions have occurred in any of the 183 health-care workers who received IG or HBIG.

Studies have been reported of 16 subjects who received HBIG that was strongly positive for HTLV-III/LAV antibody (*3*). Each patient had been given one to five ampules. A total of 31 doses were administered to 16 individuals. Low levels of passively acquired HTLV-III/LAV antibody were detected shortly after injection, but reactivity did not persist. Six months after the last HBIG injection, none of the 16 individuals had antibody to HTLV-III/LAV.

In a study of prophylaxis against cytomegalovirus (CMV) infections among kidney-transplant patients, 16 patients received CMV-specific IVIG preparations subsequently found to contain HTLV-III/LAV antibody. After 10 months or longer of follow-up, none of the 16 recipients developed antibody or other evidence of HTLV-III/LAV infection.

In studies of a group of IVIG recipients, most of whom had idiopathic thrombocytopenia, none of 134 patients developed antibodies or other evidence of HTLV-III/LAV infection.

Information regarding past therapy with immune globulins is available from 10,227 of 17,115 AIDS patients reported to CDC. Three hundred fifty-eight (4%) reported receipt of an IG preparation. All but seven of these patients also were members of groups known to be at

high risk for developing AIDS. The percentage of patients with no recognized risk factors for AIDS was not significantly different among those who received immune globulins (7/358 [2%]) than among those who did not (358/9,869 [4%]).

## LABORATORY STUDIES

Scientists at FDA recently evaluated the basic fractionation processes (*1,2*) used for production of immune globulins to determine effectiveness of those procedures in eliminating HTLV-III/LAV infectivity (*4*). Six sequential steps in a typical process were evaluated. The study was designed so that efficiency of eliminating HTLV-III/LAV at each step was measured. The degree to which HTLV-III/LAV was reduced by partitioning or inactivation at individual steps ranged from $10^{-1}$ to more than $10^{-4}$ of in vitro infectious units (IVIU)/ml. The effectiveness of virus removal in the entire process by partitioning and inactivation was calculated to be greater than $1 \times 10^{15}$ IVIU/ml.

Concentrations of infectious HTLV-III/LAV in plasma of infected persons have been estimated to be less than 100 IVIU/ml. Further, FDA scientists have shown that the geometric mean infectivity titer of plasma from 43 HTLV-III/LAV infected persons was 0.02 IVIU/ml (*4*). Thus, the margin of safety based on the removal of infectivity by the fractionation process is extremely high.

Scientists at CDC and FDA also cultured 38 lots of HBIG, IVIG, and IG, most of which contained HTLV-III/LAV antibody. HTLV-III/LAV was not recovered from any lot tested.

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**Editorial Note:** The laboratory and epidemiologic studies referred to have shown that concern about HTLV-III/LAV infection associated with the use of immune globulins available in the United States is not warranted. Strategies for using immune globulins recommended by the Immunization Practices Advisory Committee should be followed (*5*).

Recently, concern has been expressed that patients who received IG prepared from plasma of donors not screened for HTLV-III/LAV antibody may have a passively acquired false-positive reaction for antibody (*6*). Passively acquired HTLV-III/LAV antibody from HBIG known to contain high levels of antibody has been reported (*3*). Based on the estimated half-life of globulins in plasma, it can be calculated that passively acquired antibodies might be detected in sera of recipients for as long as 6 months after administration of immune globulins. It is important to recognize this possibility when attempting to determine the significance of HTLV-III/LAV antibody in a person who has recently received immune globulins, especially HBIG.

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# Immunization of Children Infected with Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus

## INTRODUCTION

This document is intended to summarize available information and to assist health-care providers in developing policies for the immunization of children infected with human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV),* the virus that causes acquired immunodeficiency syndrome (AIDS). These policies may vary depending upon the prevalence of HTLV-III/LAV infection and the incidence of vaccine-preventable diseases in the community, individual assessment of a child's health status, and the risks and benefits of immunization in a particular situation. This discussion considers the risks and benefits of immunization for children residing in the United States based on the risks of vaccine-preventable diseases and the prevalence of HTLV-III/LAV infection and is intended for use by health-care providers in the United States. The recommendations may not pertain to other countries with different risks of vaccine-preventable diseases and prevalence of HTLV-III/LAV infection among children. Since these recommendations are based upon information and knowledge available at this time, periodic reassessment and revision will be required as more data concerning risk and benefits associated with immunization of HTLV-III/LAV-infected children become known and as the prevalences of specific vaccine-preventable diseases and HTLV-III infection change.

## HTLV-III/LAV INFECTION AMONG CHILDREN

In the period June 1, 1981-September 2, 1986, physicians and health departments in the United States reported 24,430 cases of AIDS to CDC (*1*). Three hundred forty-five (1%) of the case-patients were children under 13 years of age who met the AIDS case definition; 75% of these pediatric cases were reported from New York, Florida, New Jersey, and California. Children with less severe manifestations of HTLV-III/LAV infection (AIDS-related complex, or ARC) or with asymptomatic infections are not now reported to CDC, and no seroprevalence studies have been conducted among children. Thus, the number of less severely affected children and the number of infected but presently asymptomatic children are uncertain. In one recently published case series, 14 (48%) of 29 symptomatic HTLV-III/LAV-infected children met the CDC criteria for AIDS (*2*).

Fifty percent of children reported to CDC were diagnosed as having AIDS during the first year of life; 82%, by 3 years of age (*1*). Sixty-five percent of pediatric AIDS cases reported to CDC were fatal (*3*). Short-term fatality rates are lower for children with less severe disease (ARC) who have not developed opportunistic infections; however, the ultimate prognosis of these children and of asymptomatic infected children is unknown.

## MECHANISMS OF TRANSMISSION OF HTLV-III/LAV AMONG CHILDREN

Two risk factors are predominately associated with HTLV-III/LAV infection in children: a) being born to a mother who has HTLV-III/LAV infection, and b) receiving blood or clotting factors containing HTLV-III/LAV. Most case-patients (79%) are children whose mothers probably are infected with the virus. The major risk factors for infection of these women are intravenous (IV) drug abuse and sexual contact with men at risk of HTLV-III/LAV infection (primarily through drug abuse or bisexual contacts); women of Haitian or central African origin are also at a higher risk of acquiring HTLV-III/LAV infection, and a small percentage of infected women have a history of being transfused with blood (*4*). Approximately 15% of pediatric AIDS case-patients have received transfusions of blood or blood products, and 4% have hemophilia and have been treated with clotting-factor concentrates. Information about risk factors is incomplete for 3% of children with AIDS.

*The AIDS virus has been variously termed human T-lymphotropic virus type III (HTLV-III/LAV), lymphadenopathy-associated virus (LAV), AIDS-associated retrovirus (ARV), or human immunodeficiency virus (HIV). The designation "human immunodeficiency virus" (HIV) has been accepted by a subcommittee of the International Committee for the Taxonomy of Viruses as the appropriate name for the retrovirus that has been implicated as the causative agent of AIDS (Science 1986;232:697).

Currently available data indicate that most pediatric HTLV-III/LAV infections are acquired from infected women during pregnancy, during labor and delivery, or perhaps shortly after birth. The risk of perinatal transmission from an infected mother to her infant is not known, although prospective studies indicate the rate of transmission has ranged from 0% (0/3) to 65% (13/20) (*5-7*). Seropositive women who had previously delivered an infected child had the highest of these transmission rates (65%) in subsequent pregnancies (*5*). In a retrospective study evaluating nine children whose mothers were later diagnosed as having AIDS, two (22%) children had antibody to HTLV-III/LAV (*8*). Additional prospective studies are needed to define more precisely the rate of perinatal transmission of HTLV-III/LAV.

**PREVALENCE OF HTLV-III/LAV INFECTION AMONG WOMEN OF CHILD-BEARING AGE**

The prevalence of HTLV-III/LAV infection among women of child-bearing age varies depending on the patient group and geographic area (*4*). Reported confirmed seroprevalences are less than 0.01% among female blood donors in Atlanta and 0.06% among female U.S. military recruit applicants (*4,9*). In contrast, the reported prevalence of HTLV-III/LAV antibody among IV drug abusers has ranged from 2% to 59%, with the highest prevalence in New York City and northern New Jersey. Female sex partners of IV drug-abusing men with AIDS or with ARC had a reported seroprevalence of 40%-71%, whereas 10% of female partners of asymptomatic infected hemophiliacs were reported to be seropositive (*4*). Seroprevalence among prostitutes has varied greatly (5%-40%) depending on the geographic area and has been largely attributed to a coincidental history of IV drug abuse (*4*). Seroprevalence has been reported to be as high as 5% among persons born in countries in which heterosexual transmission of HTLV-III/LAV is thought to play a major role (e.g., Haiti, central African countries) (*1,10,11*).

**IMMUNOLOGIC ABNORMALITIES ASSOCIATED WITH HTLV-III/LAV INFECTION**

Children with symptomatic HTLV-III/LAV infection (AIDS or ARC) have immunologic abnormalities similar to those of adult AIDS patients, including hypergammaglobulinemia, decreased T4 lymphocytes, reversed helper/suppressor T-cell ratios, poor T-lymphocyte responses to mitogen stimulation, and altered humoral immunity. Lymphopenia (cell counts less than 1,500 cells/$mm^3$) is uncommon. Antibody responses of children with AIDS or ARC to diphtheria and tetanus toxoid boosters and to pneumococcal vaccine were absent or lower than those of age-matched controls, which is consistent with defective humoral immunity (*12,13*). Some HTLV-III/LAV-infected children responded adequately to immunization; 60% of AIDS and ARC patients given measles-mumps-rubella vaccine (MMR) prior to diagnosis had protective levels of measles antibodies 5-66 months after immunization (*14*).

Asymptomatic HTLV-III/LAV-infected adults as a group generally have less severe abnormalities of immunologic function than adults with AIDS or ARC, and some may have normal immunologic function, although individual asymptomatic adults may have severe abnormalities (*15*). Immunologic function of asymptomatic HTLV-III/LAV-infected children has not yet been adequately studied but presumably would be more intact than that of symptomatic HTLV-III/LAV-infected children. In a small prospective study, all 29 children with symptomatic HTLV-III/LAV infection had immunologic abnormalities within 5-13 months of being found infected, compared with only two of seven (29%) children reported to have asymptomatic HTLV-III/LAV infection (*2*).

**CONCERNS ABOUT IMMUNIZATION OF HTLV-III/LAV-INFECTED CHILDREN**

The immunologic abnormalities associated with symptomatic HTLV-III/LAV infection have raised concerns about the immunization of infected children. Replication of live, attenuated vaccine viruses may be enhanced in persons with immunodeficiency diseases and theoretically may produce serious adverse events following immunization of symptomatic HTLV-III/LAV-infected (AIDS and ARC) patients (*16*). Concerns have been expressed on theoretical grounds that antigenic stimulation by immunization with inactivated vaccines might lead to a deterioration of clinical status of HTLV-III/LAV-infected children, but this effect has not been documented (*17*). Since symptomatic HTLV-III/LAV-infected patients have abnormal primary and secondary antibody responses, the efficacy of immunization may be decreased (*18*). The efficacy of immunization for asymptomatic HTLV-III/LAV-infected children is unknown, but presumably would be higher than for symptomatic HTLV-III/LAV-infected children.

Because most HTLV-III/LAV-infected children become infected perinatally, it is to be expected that their mothers are infected with HTLV-III/LAV. Other family members may also be infected with HTLV-III/LAV and may have abnormal immunologic function.† Prospective evaluation of 16 asymptomatic HTLV-III/LAV-infected mothers of children diagnosed as having AIDS or ARC showed that 12 (75%) mothers developed AIDS or ARC during a 30-month follow-up period (*6*). Regardless of the immune status of the recipient, poliovaccine virus is often excreted by children vaccinated with oral poliovaccine (OPV) and may be transmitted to close contacts (*19*). Immune-deficient individuals (either recipients or contacts) have a higher risk of developing vaccine-associated poliomyelitis than normal individuals. There is no risk of transmitting the viruses contained in measles, mumps, rubella (MMR) vaccine to family members (*20-22*).

While the risks of vaccination are not known with certainty, potential risks may exist if HTLV-III/LAV-infected children are not vaccinated. If local outbreaks of measles occur in geographic areas in which there is both a cluster of unvaccinated children and a high prevalence of HTLV-III/LAV infection, the risk of measles for unvaccinated, HTLV-III/LAV-infected children may be high. Measles infection among patients with immune deficiency may be severe, protracted, and fatal (*23*).

## EXPERIENCES WITH IMMUNIZATION OF HTLV-III/LAV-INFECTED PERSONS

Some children infected perinatally with HTLV-III/LAV have received routine immunization with OPV and MMR before their illnesses were recognized. Out-patient medical records from New York City and Miami for 213 children with symptomatic HTLV-III/LAV infection (AIDS and ARC), presumably acquired during the perinatal period, were reviewed to determine immunization history and possible vaccine-associated adverse events (*24,25*). One hundred seventy-one children (80%) had received at least one dose of OPV and diphtheria and tetanus toxoids and pertussis vaccine (DTP), 95 (45%) had completed primary immunization with OPV and DTP (three doses and four doses, respectively), and 63 (30%) had received MMR or measles vaccine. Thirty-eight (39%) of 98 children who had available records of dates of immunization and onset of symptoms consistent with HTLV-III/LAV infection had received at least one live-virus vaccine after symptom onset. No serious or unusual adverse events were noted in the medical records of these children following immunization.

Only one adverse event following immunization of an HTLV-III/LAV-infected person has been documented. A 19-year-old asymptomatic army recruit received multiple immunizations during basic training, including primary immunization with smallpox vaccine (*26*). Two and one-half weeks later, he developed cryptococcal meningitis and was diagnosed as having AIDS. One and one-half weeks later, while being treated for meningitis, he developed lesions of disseminated vaccinia. He was treated with vaccinia immune globulin and recovered from vaccinia, but has since died of AIDS.

CDC has not received any reports of vaccine-associated poliomyelitis among HTLV-III/LAV-infected vaccine recipients or their contacts or among other persons known to be infected with HTLV-III/LAV. There have been no reports of serious adverse events following MMR administration from areas in which pediatric AIDS cases are occurring.

## IMMUNIZING CHILDREN WHO MAY BE INFECTED WITH HTLV-III/LAV: SPECIAL CONSIDERATIONS

Children born to women who are at risk of HTLV-III/LAV infection or who are known to be infected with HTLV-III/LAV should be evaluated for infection with the virus—including being tested for antibody (*4,27*). For asymptomatic children presenting for immunization, this evaluation and testing is not necessary to make decisions about immunizations. Children infected with HTLV-III/LAV are best cared for by pediatricians knowledgeable in the management of patients with this infection. Since little information is currently available on the safety and efficacy of immunizing children who may be infected with HTLV-III/LAV, special studies of these children need to be conducted.

†Such family members may have been infected by sexual contact with an HTLV-III/LAV-infected person, by parenteral exposure to infected blood (e.g., by sharing needles), or as hemophiliacs who received clotting factors, or by perinatal transmission.

## RECOMMENDATIONS

### Children with symptomatic HTLV-III/LAV infection

A. Live-virus and live-bacterial vaccines (e.g., MMR, OPV, BCG) should not be given to children and young adults who are immunosuppressed in association with AIDS or other clinical manifestations of HTLV-III/LAV infection. For routine immunizations, these persons should receive inactivated poliovaccine (IPV) and should be excused for medical reasons from regulations requiring measles, rubella, and/or mumps immunization.

B. Concerns have been raised that stimulation of the immune system by immunization with inactivated vaccines in these individuals might cause deterioration in immunologic function. However, such effects have not been noted thus far among children with AIDS or among other immunosuppressed individuals after immunization with inactivated vaccines. The potential benefits of immunization of these children outweigh the concerns of theoretical adverse events. Immunization with DTP, IPV, and *Haemophilus influenzae* type b vaccines is recommended in accordance with the ACIP recommendations, although immunization may be less effective than it would be for immunocompetent children (*28-30*).

C. As with other conditions that produce chronic immunosuppression, the Committee recommends annual immunization with inactivated influenza vaccine for children over 6 months of age and one-time administration of pneumococcal vaccine for children over 2 years of age (*31-33*).

D. Children and young adults with AIDS or other clinical manifestations of HTLV-III/LAV infection—as other immunosuppressed patients—may be at increased risk of having serious complications of infectious diseases, such as measles and varicella. Following significant exposure to measles or varicella, these persons should receive passive immunization with immune globulin (IG) or varicella-zoster immune globulin (VZIG), respectively (*20,34*).¶

### Children with previously diagnosed asymptomatic HTLV-III/LAV infection

A. A small number of children and young adults known to be infected with HTLV-III/LAV but without overt clinical manifestations of immunosuppression have received live-virus vaccines without adverse consequences. Further experience needs to be monitored, but on the basis of data now available, the Committee believes that such persons should be vaccinated with MMR in accordance with ACIP recommendations (*20-22*). Vaccinees should be followed for possible adverse reactions and for the occurrence of vaccine-preventable diseases since immunization may be less effective than for uninfected persons.

B. Available data suggest that OPV can be administered without adverse consequences to HTLV-III/LAV-infected children who do not have overt clinical manifestations of immunosuppression. However, because family members of such children may be immunocompromised due to AIDS or HTLV-III/LAV infection and therefore at increased risk of paralysis from contact with spread vaccine virus, it may be prudent to use IPV routinely to immunize asymptomatic children with previously diagnosed HTLV-III/LAV infection (*28*).

C. Immunization with DTP and *Haemophilus influenzae* type b vaccines is recommended in accordance with ACIP recommendations (*29,30*).

### Children not known to be infected with HTLV-III/LAV

Children and young adults not known to be infected with HTLV-III/LAV should be immunized in accordance with ACIP recommendations.

### Children residing in the household of a patient with AIDS

Children whose household members are known to be immunocompromised due to AIDS or other HTLV-III/LAV infections should not receive OPV because vaccine viruses are excreted by the recipient of the vaccine and may be communicable to their immunosuppressed contacts. These children should receive IPV for routine immunization (*28*). Because extensive experience has shown that live, attenuated MMR vaccine viruses are not transmitted from vaccinated individuals to others, MMR may be given to a child residing in the household of a patient with AIDS (*20-22*).

¶ Some physicians administer full replacement doses of intravenous IG on a 2-4 week schedule to children with AIDS and other clinical manifestations of HTLV-III/LAV infection. This therapy may provide some protection against such diseases as measles and varicella.

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# VII. MATERNAL AND CHILD HEALTH

1985 August 30;34:517–21

## Education and Foster Care of Children Infected with Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus

The information and recommendations contained in this document were developed and compiled by CDC in consultation with individuals appointed by their organizations to represent the Conference of State and Territorial Epidemiologists, the Association of State and Territorial Health Officers, the National Association of County Health Officers, the Division of Maternal and Child Health (Health Resources and Services Administration), the National Association for Elementary School Principals, the National Association of State School Nurse Consultants, the National Congress of Parents and Teachers, and the Children's Aid Society. The consultants also included the mother of a child with acquired immunodeficiency syndrome (AIDS), a legal advisor to a state education department, and several pediatricians who are experts in the field of pediatric AIDS. This document is made available to assist state and local health and education departments in developing guidelines for their particular situations and locations.

These recommendations apply to all children known to be infected with human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV). This includes children with AIDS as defined for reporting purposes (Table 1); children who are diagnosed by their physicians as having an illness due to infection with HTLV-III/LAV but who do not meet the case definition; and children who are asymptomatic but have virologic or serologic evidence of infection with HTLV-III/LAV. These recommendations do not apply to siblings of infected children unless they are also infected.

### BACKGROUND

**The Scope of the Problem.** As of August 20, 1985, 183 of the 12,599 reported cases of AIDS in the United States were among children under 18 years of age. This number is expected to double in the next year. Children with AIDS have been reported from 23 states, the District of Columbia, and Puerto Rico, with 75% residing in New York, California, Florida, and New Jersey.

The 183 AIDS patients reported to CDC represent only the most severe form of HTLV-III/LAV infection, i.e., those children who develop opportunistic infections or malignancies (Table 1). As in adults with HTLV-III/LAV infection, many infected children may have milder illness or may be asymptomatic.

**Legal Issues.** Among the legal issues to be considered in forming guidelines for the education and foster care of HTLV-III/LAV-infected children are the civil rights aspects of public school attendance, the protections for handicapped children under 20 U.S.C. 1401 et seq. and 29 U.S.C. 794, the confidentiality of a student's school record under state laws and under 20 U.S.C. 1232g, and employee right-to-know statutes for public employees in some states.

**Confidentiality Issues.** The diagnosis of AIDS or associated illnesses evokes much fear from others in contact with the patient and may evoke suspicion of life styles that may not be acceptable to some persons. Parents of HTLV-III/LAV-infected children should be aware of the potential for social isolation should the child's condition become known to others in the care or educational setting. School, day-care, and social service personnel and others involved in educating and caring for these children should be sensitive to the need for confidentiality and the right to privacy in these cases.

**TABLE 1. Provisional case definition for acquired immunodeficiency syndrome (AIDS) surveillance of children**

For the limited purposes of epidemiologic surveillance, CDC defines a case of pediatric acquired immunodeficiency syndrome (AIDS) as a child who has had:

1. A reliably diagnosed disease at least moderately indicative of underlying cellular immunodeficiency, and
2. No known cause of underlying cellular immunodeficiency or any other reduced resistance reported to be associated with that disease.

The diseases accepted as sufficiently indicative of underlying cellular immunodeficiency are the same as those used in defining AIDS in adults. In the absence of these opportunistic diseases, a histologically confirmed diagnosis of chronic lymphoid interstitial pneumonitis will be considered indicative of AIDS unless test(s) for HTLV-III/LAV are negative. Congenital infections, e.g., toxoplasmosis or herpes simplex virus infection in the first month after birth or cytomegalovirus infection in the first 6 months after birth must be exluded.

Specific conditions that must be excluded in a child are:

1. Primary immunodeficiency diseases—severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome, ataxia-telangiectasia, graft versus host disease, neutropenia, neutrophil function abnormality, agammaglobulinemia, or hypogammaglobulinemia with raised IgM.
2. Secondary immunodeficiency associated with immunosuppressive therapy, lymphoreticular malignancy, or starvation.

## ASSESSMENT OF RISKS

**Risk Factors for Acquiring HTLV-III/LAV Infection and Transmission.** In adults and adolescents, HLTV-III/LAV is transmitted primarily through sexual contact (homosexual or heterosexual) and through parenteral exposure to infected blood or blood products. HTLV-III/LAV has been isolated from blood, semen, saliva, and tears but transmission has not been documented from saliva and tears. Adults at increased risk for acquiring HTLV-III/LAV include homosexual/bisexual men, intravenous drug abusers, persons transfused with contaminated blood or blood products, and sexual contacts of persons with HTLV-III/LAV infection or in groups at increased risk for infection.

The majority of infected children acquire the virus from their infected mothers in the perinatal period (*1-4*). In utero or intrapartum transmission are likely, and one child reported from Australia apparently acquired the virus postnatally, possibly from ingestion of breast milk (*5*). Children may also become infected through transfusion of blood or blood products that contain the virus. Seventy percent of the pediatric cases reported to CDC occurred among children whose parent had AIDS or was a member of a group at increased risk of acquiring HTLV-III/LAV infection; 20% of the cases occurred among children who had received blood or blood products; and for 10%, investigations are incomplete.

**Risk of Transmission in the School, Day-Care or Foster-Care Setting.** None of the identified cases of HTLV-III/LAV infection in the United States are known to have been transmitted in the school, day-care, or foster-care setting or through other casual person-to-person contact. Other than the sexual partners of HTLV-III/LAV-infected patients and infants born to infected mothers, none of the family members of the over 12,000 AIDS patients reported to CDC have been reported to have AIDS. Six studies of family members of patients with HTLV-III/LAV infection have failed to demonstrate HTLV-III/LAV transmission to adults who were not sexual contacts of the infected patients or to older children who were not likely at risk from perinatal transmission (*6-11*).

Based on current evidence, casual person-to-person contact as would occur among schoolchildren appears to pose no risk. However, studies of the risk of transmission through contact between younger children and neurologically handicapped children who lack control of their body secretions are very limited. Based on experience with other communicable diseases, a theoretical potential for transmission would be greatest among these children. It should be emphasized that any theoretical transmission would most likely involve exposure of open skin lesions or mucous membranes to blood and possibly other body fluids of an infected person.

**Risks to the Child with HTLV-III/LAV Infection.** HTLV-III/LAV infection may result in immunodeficiency. Such children may have a greater risk of encountering infectious agents in a school or day-care setting than at home. Foster homes with multiple children may also increase the risk. In addition, younger children and neurologically handicapped children who may display behaviors such as mouthing of toys would be expected to be at greater risk for acquiring infections. Immunodepressed children are also at greater risk of suffering severe

complications from such infections as chickenpox, cytomegalovirus, tuberculosis, herpes simplex, and measles. Assessment of the risk to the immunodepressed child is best made by the child's physician who is aware of the child's immune status. The risk of acquiring some infections, such as chickenpox, may be reduced by prompt use of specific immune globulin following a known exposure.

RECOMMENDATIONS

1. Decisions regarding the type of educational and care setting for HTLV-III/LAV-infected children should be based on the behavior, neurologic development, and physical condition of the child and the expected type of interaction with others in that setting. These decisions are best made using the team approach including the child's physician, public health personnel, the child's parent or guardian, and personnel associated with the proposed care or educational setting. In each case, risks and benefits to both the infected child and to others in the setting should be weighed.
2. For most infected school-aged children, the benefits of an unrestricted setting would outweigh the risks of their acquiring potentially harmful infections in the setting and the apparent nonexistent risk of transmission of HTLV-III/LAV. These children should be allowed to attend school and after-school day-care and to be placed in a foster home in an unrestricted setting.
3. For the infected preschool-aged child and for some neurologically handicapped children who lack control of their body secretions or who display behavior, such as biting, and those children who have uncoverable, oozing lesions, a more restricted environment is advisable until more is known about transmission in these settings. Children infected with HTLV-III/LAV should be cared for and educated in settings that minimize exposure of other children to blood or body fluids.
4. Care involving exposure to the infected child's body fluids and excrement, such as feeding and diaper changing, should be performed by persons who are aware of the child's HTLV-III/LAV infection and the modes of possible transmission. In any setting involving an HTLV-III/LAV-infected person, good handwashing after exposure to blood and body fluids and before caring for another child should be observed, and gloves should be worn if open lesions are present on the caretaker's hands. Any open lesions on the infected person should also be covered.
5. Because other infections in addition to HTLV-III/LAV can be present in blood or body fluids, all schools and day-care facilities, regardless of whether children with HTLV-III/LAV infection are attending, should adopt routine procedures for handling blood or body fluids. Soiled surfaces should be promptly cleaned with disinfectants, such as household bleach (diluted 1 part bleach to 10 parts water). Disposable towels or tissues should be used whenever possible, and mops should be rinsed in the disinfectant. Those who are cleaning should avoid exposure of open skin lesions or mucous membranes to the blood or body fluids.
6. The hygienic practices of children with HTLV-III/LAV infection may improve as the child matures. Alternatively, the hygienic practices may deteriorate if the child's condition worsens. Evaluation to assess the need for a restricted environment should be performed regularly.
7. Physicians caring for children born to mothers with AIDS or at increased risk of acquiring HTLV-III/LAV infection should consider testing the children for evidence of HTLV-III/LAV infection for medical reasons. For example, vaccination of infected children with live virus vaccines, such as the measles-mumps-rubella vaccine (MMR), may be hazardous. These children also need to be followed closely for problems with growth and development and given prompt and aggressive therapy for infections and exposure to potentially lethal infections, such as varicella. In the event that an antiviral agent or other therapy for HTLV-III/LAV infection becomes available, these children should be considered for such therapy. Knowledge that a child is infected will allow parents and other caretakers to take precautions when exposed to the blood and body fluids of the child.
8. Adoption and foster-care agencies should consider adding HTLV-III/LAV screening to their routine medical evaluations of children at increased risk of infection before placement in the foster or adoptive home, since these parents must make decisions regarding the medical care of the child and must consider the possible social and psychological effects on their families.

9. Mandatory screening as a condition for school entry is not warranted based on available data.
10. Persons involved in the care and education of HTLV-III/LAV-infected children should respect the child's right to privacy, including maintaining confidential records. The number of personnel who are aware of the child's condition should be kept at a minimum needed to assure proper care of the child and to detect situations where the potential for transmission may increase (e.g., bleeding injury).
11. All educational and public health departments, regardless of whether HTLV-III/LAV-infected children are involved, are strongly encouraged to inform parents, children, and educators regarding HTLV-III/LAV and its transmission. Such education would greatly assist efforts to provide the best care and education for infected children while minimizing the risk of transmission to others.

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# Recommendations for Assisting in the Prevention of Perinatal Transmission of Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus and Acquired Immunodeficiency Syndrome

The information and recommendations in this document are intended to assist health-care providers and state and local health departments in developing procedures to prevent perinatal transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the virus that causes acquired immunodeficiency syndrome (AIDS).

This document contains recommendations for providing counselling and, when indicated, testing for antibody to HTLV-III/LAV for women who are at increased risk of acquiring the virus and who are either pregnant or may become pregnant. It is important that these women know they are at risk, as well as know and understand their HTLV-III/LAV-antibody status, so they can make informed decisions to help prevent perinatally acquired HTLV-III/LAV.

Through counselling, uninfected women can learn how to avoid becoming infected, and infected women can choose to delay pregnancy until more is known about perinatal transmission of the virus. If already pregnant, infected women can be provided information for managing the pregnancy and caring for the child.

Currently available data indicate that most pediatric HTLV-III/LAV infections and AIDS are acquired perinatally from infected women, but additional studies are needed to better quantify the risk of transmission from an infected pregnant woman to the fetus or newborn.

The recommendations below pertain to women. However, men who are HTLV-III/LAV-antibody positive should also be counselled regarding the risks of sexual and perinatal transmission, so they can refer for counselling and testing their sex partners who may be pregnant or considering pregnancy.

## BACKGROUND

**Pediatric AIDS Cases due to Perinatal Transmission.** As of December 1, 1985, 217 (1%) of the 15,172 AIDS cases reported to CDC occurred among children under 13 years of age. Sixty percent of these children are known to have died. These 217 cases represent only the more severe manifestations of HTLV-III/LAV infection. Less severe manifestations, often described as AIDS-related complex (ARC), are not reported to CDC, so the number of children with clinically significant illness attributable to HTLV-III/LAV infection is greater than the reported cases of pediatric AIDS. In addition, a number of infected children are probably asymptomatic.

Of the 217 reported pediatric AIDS patients, 165 (76%) have as their only known risk factor a mother belonging to a group with increased prevalence of HTLV-III/LAV infection. An additional 18% of the pediatric cases are attributable to transfusions of blood or blood products, while risk factor information is missing or incomplete on the remaining 6%. Of the 217 children with AIDS, 48% had mothers who were intravenous (IV) drug abusers; 17% had mothers who were born in Haiti; and 10% had mothers who were sex partners of either IV drug abusers or bisexual men.

Of the patients with perinatally acquired AIDS, 45% resided in New York City, while Florida and New Jersey accounted for an additional 32%.

**Mechanisms of Perinatal Transmission.** It is believed that HTLV-III/LAV is transmitted from infected women to their fetuses or offspring during pregnancy, during labor and delivery, or perhaps shortly after birth. Transmission of the virus during pregnancy or labor and delivery is demonstrated by two reported AIDS cases occurring in children who had no contact with their infected mothers after birth. One was delivered by Cesarean section (*1,2*).

Transmission of the virus after birth has been implicated in one case of HTLV-III/LAV infection in a child born to a mother reported to have acquired the infection from a postpartum blood transfusion. Since she breastfed the child for 6 weeks, the authors suggested breastfeeding as the possible mode of transmission (*3*). Recently, HTLV-III/LAV has been isolated from the breast milk of infected women (*4*).

**Risk of Perinatal Transmission from Infected Mothers.** The rate of perinatal transmission of HTLV-III/LAV from infected pregnant women is unknown; however, available data suggest a high rate. In one study of 20 infants born to infected mothers who had already delivered one infant with AIDS, 13 (65%) had serologic and/or clinical evidence of infection with HTLV-III/LAV several months after birth (*5,6*). Since these women were selected on the basis of having previously transmitted HTLV-III/LAV perinatally, this study may overestimate the average risk of transmission for all infected pregnant women.

Perinatal transmission from an infected mother to her newborn is not inevitable. Of three children born to women who became infected with HTLV-III/LAV by artificial insemination from an infected donor, all were in good health and negative for antibody to the virus more than 1 year after birth (*7*). Another child, born to a woman who was already pregnant at the time of AIDS diagnosis and was demonstrated to be viremic, was seronegative, culture negative, and healthy at birth and at 4 months of age (*8*). In a retrospective study evaluating nine children under 5 years of age whose mothers were later diagnosed with AIDS, two (22%) had antibody to HTLV-III/LAV (*9*). The infection status of these women during pregnancy was unknown.

In these studies, the rate of transmission ranged from 0% (0/3) to 65% (13/20). Additional studies are needed to better define the rate of transmission and variables associated with it.

**Risk of Illness among Infected Pregnant Women.** Pregnancy is associated with suppression of cell-mediated immunity and increased susceptibility to some infections (*10*). The T-helper to T-suppressor ratio is decreased during normal pregnancy, being lowest in the third trimester, and returns to normal approximately 3 months postpartum (*10*). It is not known whether pregnancy increases an infected woman's risk of developing AIDS or ARC, but one study suggests it does (*6*). Fifteen infected women who were well at time of delivery were followed an average of 30 months after the births of their children. Five (33%) subsequently developed AIDS; seven (47%) developed AIDS-related conditions; and only three (20%) remained asymptomatic. These results may not apply to all infected pregnant women, but they do suggest an increased likelihood of developing disease when an HTLV-III/LAV infection occurs in association with pregnancy.

**Prevalence of HTLV-III/LAV Infection.** Counselling and testing for antibody to HTLV-III/LAV, when indicated, to reduce perinatal transmission of AIDS will be most beneficial in populations of women with increased prevalence of the virus (Table 1). These include: women who have used drugs intravenously for nonmedical purposes; women who were born in countries where heterosexual transmission is thought to play a major role (*11,12*); women who have engaged in prostitution; and women who are or have been sex partners of men who abuse IV drugs, are bisexual, have hemophilia, were born in countries where heterosexual transmission is thought to play a major role (*11,12*), or have evidence of HTLV-III/LAV infection.

**TABLE 1. Prevalence of HTLV-III/LAV antibody in heterosexual populations — United States**

| Populations | Location | No. tested | Prevalence (%) |
|---|---|---|---|
| Intravenous drug abusers (*16,17*) | New York City | 274 | 59 |
| | NJ* < 5 miles from NYC† | 204 | 56 |
| | NJ 5-10 miles from NYC | 124 | 43 |
| | NJ > 100 miles from NYC | 55 | 2 |
| | San Francisco | 53 | 9 |
| Persons with hemophilia (*13,14*) | | | |
| Factor VIII concentrate recipients | | 234 | 74 |
| Factor IX concentrate recipients | | 36 | 39 |
| Cryoprecipitate only recipients | | 15 | 40 |
| Female prostitutes (*21*) | Seattle, Washington | 92 | 5 |
| | Miami, Florida | 25 | 40 |
| Female sex partners of men with AIDS or ARC | | 42 | 47 |
| (two separate studies) (*19,20*) | | 7 | 71 |
| Female sex partners of men with asymptomatic HTLV-III/LAV infection (*18*) | | 21 | 10 |
| Haitians (*12*) | New York City | 97 | 4 |
| | Miami, Florida | 129 | 8 |
| Female blood donors (*15*) | Atlanta, Georgia | 28,354 | 0.01 |

*New Jersey.
†New York City.

The prevalence of antibody to HTLV-III/LAV in U.S. populations of men and women ranges from less than 0.01% in female blood donors to as high as 74% in men with hemophilia (*13-15*). Among heterosexual IV drug abusers, the prevalence of HTLV-III/LAV infection ranges from 2% to 59% in various geographic areas (*16,17*). Seroprevalence among the heterosexual partners of persons at increased risk for AIDS varies from 10% in female partners of asymptomatic, seropositive hemophilia patients to 71% in the female partners of men with AIDS or ARC (*18-20*). Among prostitutes, the HTLV-III/LAV antibody prevalence varies from 5% to 40%, depending on geographic area, with most of the women with positive tests relating histories of IV drug abuse (*21*). Among female blood donors in Atlanta, Georgia, who denied belonging to high-risk groups, 0.01% had repeatedly reactive enzyme-linked immunosorbent assays (ELISAs) followed by reactive Western blot tests (*15*).

Commercially available tests to detect antibody to HTLV-III/LAV are ELISAs using antigens derived from whole disrupted HTLV-III/LAV. When the ELISA is reactive on initial testing, it is standard procedure to repeat the test on the same specimen. Repeatedly reactive tests are highly sensitive and specific for antibody to HTLV-III/LAV. However, when the ELISA is used to screen populations in which the prevalence of infection is very low (such as blood donors or women not in high-risk groups), the proportion of repeatedly reactive results that are falsely positive will be higher. For that reason, an additional test, such as a Western blot, is recommended following repeatedly reactive ELISA results, especially in low-prevalence populations. In populations with high prevalence of infection (e.g. homosexual men or IV drug abusers), most repeatedly reactive ELISAs are reactive by Western blot or another test. For example, among 109 IV drug abusers whose sera were repeatedly reactive by ELISA, over 85% were reactive by Western blot (*22*). In contrast, in a low-prevalence population of 69 female blood donors whose sera were repeatedly reactive by ELISA, only 5% were reactive by Western blot (*15*).

Due to the seriousness of the implications of HTLV-III/LAV-antibody reactivity, it is recommended that repeatedly reactive ELISAs be followed by an additional test, such as the Western blot. Women with sera repeatedly reactive by ELISA and reactive by Western blot should have a thorough medical evaluation. HTLV-III/LAV has been isolated from a single specimen in 67%-95% of persons with specific antibody (*23,24*). Because infection has been demonstrated in asymptomatic persons, the presence of specific antibody should be considered presumptive evidence of current infection and infectiousness.

## RECOMMENDATIONS

**Women Who Should be Offered Counselling and Testing.** *Counselling services and testing for antibody to HTLV-III/LAV should be offered to pregnant women and women who may become pregnant in the following groups*: (1) those who have evidence of HTLV-III/LAV infection; (2) those who have used drugs intravenously for nonmedical purposes; (3) those who were born in countries where heterosexual transmission is thought to play a major role (*11,12*); (4) those who have engaged in prostitution; (5) those who are or have been sex partners of: IV drug abusers, bisexual men, men with hemophilia, men who were born in countries where heterosexual transmission is thought to play a major role (*11,12*), or men who otherwise have evidence of HTLV-III/LAV infection. If data become available to show that HTLV-III/LAV-antibody prevalence is increased in other groups or settings, counselling and testing programs should be extended to include them. Routine counselling and testing of women who are not included in the above-mentioned groups is not recommended due to low prevalence of infection and concern about interpretation of test results in a low-prevalence population. However if a woman requests it, the service should be provided in accordance with these recommendations.

**Settings for Offering Counselling and Testing.** Counselling and testing for antibody to HTLV-III/LAV to prevent perinatal transmission is recommended in the setting of any medical service in which women at increased risk are commonly encountered. These include services for treating IV drug abuse (i.e., detoxification and methadone maintenance), comprehensive hemophilia treatment centers, sexually transmitted disease clinics, and clinics that serve female prostitutes. In addition, services related to reproduction, such as family planning and infertility services, gynecologic, premarital, or preconceptual examinations, and prenatal and obstetric services should also consider offering counselling and testing if high-risk women are seen at these facilities. Testing for antibody to HTLV-III/LAV should be performed with the woman's consent after counselling is provided regarding risk factors for infection, the inter-

pretation of test results, the risks of transmission, and the possible increased likelihood of disease among women infected with HTLV-III/LAV in association with pregnancy. The counselling and testing must be conducted in an environment in which confidentiality can be assured. In settings where confidential counselling and testing cannot be assured, information should be provided and referrals made to appropriate facilities.

**Frequency of Testing.** Detectable antibodies to HTLV-III/LAV may not develop until 2-4 months after exposure. This, and whether the woman is continuously exposed, should be taken into account when considering the need for, and frequency of, repeat testing. High-risk women should be offered counselling and testing before they become pregnant. During pregnancy, counselling and testing should be offered as soon as the woman is known to be pregnant. If the initial test is negative, repeat testing may be indicated near delivery to aid in the clinical management of the pregnant woman and newborn. If this final test is negative and the mother's risk of exposure no longer exists, she may safely consider breastfeeding the child, and management of the child need not include the same concerns that would be appropriate if the woman had had a positive test or if she were at high risk and had not been tested at all.

**Counselling Women with Positive Results.** Women with virologic or serologic evidence of HTLV-III/LAV infection should be counselled regarding their own risk of AIDS and the risk of perinatal and sexual transmission of HTLV-III/LAV. Infected women should be counselled to refer their sex partners for counselling and testing. If the partners of these women are not infected, both members of the couple should be counselled on how they may modify their sexual practices to reduce the risk of HTLV-III/LAV transmission to the uninfected partner. In addition, the couple should be told not to donate blood, organs, or sperm and should be discouraged from using IV drugs and advised against sharing needles and syringes. When seeking medical or dental care for intercurrent illness, they should inform those responsible for their care of their positive antibody status so appropriate evaluation can be undertaken. Recommendations for providing information and advice to individuals infected with HTLV-III/LAV have been published (*25*).

Infected women should be advised to consider delaying pregnancy until more is known about perinatal transmission of the virus. Pregnant infected women may require additional medical and social support services due to an enhanced risk of opportunistic infections and psychosocial difficulties during and after pregnancy. Obstetric-care providers should be alert to signs and symptoms of HTLV-III/LAV and related opportunistic infections in these pregnant women and to the need for specialized medical care.

HTLV-III/LAV-infected women should be advised against breastfeeding to avoid postnatal transmission to a child who may not yet be infected. The child should receive follow-up pediatric evaluations to determine whether he/she has HTLV-III/LAV infection, and to diagnose and treat promptly any diseases that may be secondary to HTLV-III/LAV infection. Recommendations for educating and providing foster care for infected children have been published (*26*).

**Counselling Women with Negative Test Results.** A negative ELISA for HTLV-III/LAV antibody in women who have no clinical or laboratory evidence of HTLV-III/LAV infection is evidence that they have probably not been infected. However, uninfected women who have sex partners with evidence of HTLV-III/LAV infection or with an increased risk of becoming infected should be informed that sexual intercourse increases their risk of infection. These women should be informed of the risks associated with pregnancy if they become infected and advised to consider delaying pregnancy until more is known about perinatal transmission of the virus or until they are no longer considered to be at risk for acquiring the virus. In addition to preventing pregnancy, the consistent and proper use of condoms can offer some protection against HTLV-III/LAV infection.

High-risk women, even if seronegative, should be told not to donate blood or organs. To decrease their risk of becoming infected, IV drug abusers should be encouraged to seek treatment for their drug abuse. Persons counselling IV drug abusers should know that IV drug abuse is often strongly ingrained and compulsive. Despite educational efforts and encouragement for treatment, some addicts will continue to abuse drugs or relapse after treatment. If drug abuse continues, they should be advised not to share needles or syringes and to use only sterile equipment.

**Additional Considerations.** These recommendations will be revised as additional information becomes available. It is recognized that provision of the recommended professional counselling, HTLV-III/LAV-antibody testing and associated specialized medical services will take

time to implement and may stress available resources, particularly in public facilities, which are most greatly affected. Health-care providers, social-service personnel, and others involved in educating and caring for HTLV-III/LAV-infected persons should be aware of the potential for social isolation and should be sensitive to the need for confidentiality. They should be familiar with federal and state laws, regulations, and policies that protect the confidentiality of clinical data and test results. Each institution should assure that specific mechanisms are in place to protect the confidentiality of all records and to prevent the misuse of information. Anonymous testing would not be appropriate if it prevents adequate counselling and medical follow-up evaluation.

Hospital precautions for managing infected women and infants should be patterned after those for caring for patients with HTLV-III/LAV infection (*27,28*). Additional recommendations will follow.

## DEVELOPMENT OF THESE RECOMMENDATIONS

The information and recommendations contained in this document were developed and compiled by CDC and the U.S. Public Health Service in consultation with individuals representing: the Conference of State and Territorial Epidemiologists, the Association of State and Territorial Health Officials, the American Public Health Association, the United States Conference of Local Health Officers, the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Planned Parenthood Federation of America, the American Venereal Disease Association, the Division of Maternal and Child Health of the Health Resources and Services Administration, the National Institute on Drug Abuse of the Alcohol, Drug Abuse, and Mental Health Administration, the National Hemophilia Foundation, the Haitian Medical Association, the American Bar Foundation, and the Kennedy Institute of Ethics at Georgetown University. The consultants also included representatives of the departments of health of the areas with the largest number of perinatally transmitted pediatric AIDS cases: New York City, Florida, and New Jersey. These recommendations may not reflect the views of all individual consultants or the organizations they represented.

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# Classification System for Human Immunodeficiency Virus (HIV) Infection in Children Under 13 Years of Age

## INTRODUCTION

With the identification of the causative agent of the acquired immunodeficiency syndrome (AIDS), a broad spectrum of clinical manifestations has been attributed to infection with the human immunodeficiency virus (HIV). With the exception of the CDC surveillance definition for AIDS (*1,2*), no standard definitions for other manifestations of HIV infection have been developed for children. Classification systems published to date have been developed primarily to categorize clinical presentations in adult patients and may not be entirely applicable to infants and children (*3-5*).

Physicians from institutions caring for relatively large numbers of HIV-infected children report that only about half of their patients with symptomatic illness related to the infection fulfill the criteria of the CDC surveillance definition for AIDS (*6,7*).

To develop a classification system for HIV infection in children, CDC convened a panel of consultants* consisting of clinicians experienced in the diagnosis and management of children with HIV infection; public health physicians; representatives from the American Academy of Pediatrics, the Council of State and Territorial Epidemiologists, the Association for Maternal Child Health and Crippled Children's Programs, the National Institute on Drug Abuse, Alcohol, Drug Abuse and Mental Health Administration, the National Institute of Allergy and Infectious Diseases/National Institutes of Health, and the Division of Maternal and Child Health/Health Resources and Services Administration; and CDC.

## GOALS AND OBJECTIVES OF THE CLASSIFICATION SYSTEM

The system was designed primarily for public health purposes, including epidemiologic studies, disease surveillance, prevention programs, and health-care planning and policy. The panel attempted to devise a simple scheme that could be subdivided as needed for different purposes.

## DEFINITION OF HIV INFECTION IN CHILDREN (Table 1)

Ideally, HIV infection in children is identified by the presence of the virus in blood or tissues, confirmed by culture or other laboratory detection methods. However, current tests—including culture—for detecting the virus or its antigens are not standardized and are not readily available. Detection of specific antibody to the virus is a sensitive and specific indicator of HIV infection in adults, since the majority of adults with antibody have had culture evidence of infection (*8-10*). Similar studies involving children have not been reported. Also, the presence of passively transferred maternal antibody in infants limits the interpretation of a positive antibody test result in this age group. Most of the consultants believed that passively transferred maternal HIV antibody could sometimes persist for up to 15 months. For this reason, two definitions for infection in children are needed: one for infants and children up to 15 months of age who have been exposed to their infected mothers perinatally, and another for older children with perinatal infection and for infants and children of all ages acquiring the virus through other means.

**Infants and children under 15 months of age with perinatal infection**—Infection in infants and children up to 15 months of age who were exposed to infected mothers in the perinatal period may be defined by one or more of the following: 1) the identification of the virus in blood or tissues, 2) the presence of HIV antibody as indicated by a repeatedly reactive screening test (e.g., enzyme immunoassay) plus a positive confirmatory test (e.g., Western blot, immunofluorescence assay) in an infant or child who has abnormal immunologic test results indicating both humoral and cellular immunodeficiency (increased immunoglobulin

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TABLE 1. Summary of the definition of HIV infection in children

**Infants and children under 15 months of age with perinatal infection**

1) Virus in blood or tissues
or
2) HIV antibody
and
evidence of both cellular and humoral immune deficiency
and
one or more categories in Class P-2
or
3) Symptoms meeting CDC case definition for AIDS

**Older children with perinatal infection and children with HIV infection acquired through other modes of transmission**

1) Virus in blood or tissues
or
2) HIV antibody
or
3) Symptoms meeting CDC case definition for AIDS

levels, depressed T4 [T-helper] absolute cell count, absolute lymphopenia, decreased T4/T8 ratio) and who meets the requirements of one or more of the subclasses listed under class P-2 (described below), or 3) the confirmation that a child's symptoms meet the previously published CDC case definition for pediatric AIDS (*1,2*).

The infection status of other perinatally exposed seropositive infants and children up to 15 months of age who lack one of the above immunologic or clinical criteria is indeterminate. These infants should be followed up for HIV-related illness, and they should be tested at regular intervals for persistence of antibody to HIV. Infants and children who become seronegative, are virus-culture negative (if blood or tissue samples are cultured), and continue to have no clinical or laboratory-confirmed abnormalities associated with HIV infection are unlikely to be infected.

**Older children with perinatal infection and children with HIV infection acquired through other modes of transmission**—HIV infection in these children is defined by one or more of the following: 1) the identification of virus in blood or tissues, 2) the presence of HIV antibody (positive screening test plus confirmatory test) regardless of whether immunologic abnormalities or signs or symptoms are present, or 3) the confirmation that the child's symptoms meet the previously published CDC case definition for pediatric AIDS (*1,2*).

These definitions apply to children under 13 years of age. Persons 13 years of age and older should be classified according to the adult classification system (*3*).

**CLASSIFICATION SYSTEM (Table 2)**

Children fulfilling the definition of HIV infection discussed above may be classified into one of two mutually exclusive classes based on the presence or absence of clinical signs and symptoms (Table 2). Class Pediatric-1 (P-1) is further subcategorized on the basis of the presence or absence of immunologic abnormalities, whereas Class P-2 is subdivided by specific disease patterns. Once a child has signs and symptoms and is therefore classified in P-2, he or she should not be reassigned to class P-1 if signs and symptoms resolve.

Perinatally exposed infants and children whose infection status is indeterminate are classified into class P-0.

**Class P-0. Indeterminate infection.** Includes perinatally exposed infants and children up to 15 months of age who cannot be classified as definitely infected according to the above definition but who have antibody to HIV, indicating exposure to a mother who is infected.

**Class P-1. Asymptomatic infection.** Includes patients who meet one of the above definitions for HIV infection but who have had no previous signs or symptoms that would have led to classification in Class P-2.

These children may be subclassified on the basis of immunologic testing. This testing should include quantitative immunoglobulins, complete blood count with differential, and T-lymphocyte subset quantitation. Results of functional testing of lymphocytes (mitogens, such as pokeweed) may also be abnormal in HIV-infected children, but it is less specific in comparison with immunoglobulin levels and lymphocyte subset analysis, and it may be impractical.

**TABLE 2. Summary of the classification of HIV infection in children under 13 years of age**

**Class P-0. Indeterminate infection**

**Class P-1. Asymptomatic infection**

- Subclass A. Normal immune function
- Subclass B. Abnormal immune function
- Subclass C. Immune function not tested

**Class P-2. Symptomatic infection**

- Subclass A. Nonspecific findings
- Subclass B. Progressive neurologic disease
- Subclass C. Lymphoid interstitial pneumonitis
- Subclass D. Secondary infectious diseases
  - Category D-1. Specified secondary infectious diseases listed in the CDC surveillance definition for AIDS
  - Category D-2. Recurrent serious bacterial infections
  - Category D-3. Other specified secondary infectious diseases
- Subclass E. Secondary cancers
  - Category E-1. Specified secondary cancers listed in the CDC surveillance definition for AIDS
  - Category E-2. Other cancers possibly secondary to HIV infection
- Subclass F. Other diseases possibly due to HIV infection

***Subclass A - Normal immune function.*** Includes children with no immune abnormalities associated with HIV infection.

***Subclass B - Abnormal immune function.*** Includes children with one or more of the commonly observed immune abnormalities associated with HIV infection, such as hypergammaglobulinemia, T-helper (T4) lymphopenia, decreased T-helper/T-suppressor (T4/T8) ratio, and absolute lymphopenia. Other causes of these abnormalities must be excluded.

***Subclass C - Not tested.*** Includes children for whom no or incomplete (see above) immunologic testing has been done.

**Class P-2. Symptomatic infection**. Includes patients meeting the above definitions for HIV infection and having signs and symptoms of infection. Other causes of these signs and symptoms should be excluded. Subclasses are defined based on the type of signs and symptoms that are present. Patients may be classified in more than one subclass.

***Subclass A - Nonspecific findings.*** Includes children with two or more unexplained nonspecific findings persisting for more than 2 months, including fever, failure-to-thrive or weight loss of more than 10% of baseline, hepatomegaly, splenomegaly, generalized lymphadenopathy (lymph nodes measuring at least 0.5 cm present in two or more sites, with bilateral lymph nodes counting as one site), parotitis, and diarrhea (three or more loose stools per day) that is either persistent or recurrent (defined as two or more episodes of diarrhea accompanied by dehydration within a 2-month period).

***Subclass B - Progressive neurologic disease.*** Includes children with one or more of the following progressive findings: 1) loss of developmental milestones or intellectual ability, 2) impaired brain growth (acquired microcephaly and/or brain atrophy demonstrated on computerized tomographic scan or magnetic resonance imaging scan), or 3) progressive symmetrical motor deficits manifested by two or more of these findings: paresis, abnormal tone, pathologic reflexes, ataxia, or gait disturbance.

***Subclass C - Lymphoid interstitial pneumonitis.*** Includes children with a histologically confirmed pneumonitis characterized by diffuse interstitial and peribronchiolar infiltration of lymphocytes and plasma cells and without identifiable pathogens, or, in the absence of a histologic diagnosis, a chronic pneumonitis—characterized by bilateral reticulonodular interstitial infiltrates with or without hilar lymphadenopathy—present on chest X-ray for a period of at least 2 months and unresponsive to appropriate antimicrobial therapy. Other causes of interstitial infiltrates should be excluded, such as tuberculosis, *Pneumocystis carinii* pneumonia, cytomegalovirus infection, or other viral or parasitic infections.

***Subclass D - Secondary infectious diseases.*** Includes children with a diagnosis of an infectious disease that occurs as a result of immune deficiency caused by infection with HIV.

*Category D-1* Includes patients with secondary infectious disease due to one of the specified infectious diseases listed in the CDC surveillance definition for AIDS: *Pneumocystis carinii* pneumonia; chronic cryptosporidiosis; disseminated toxoplasmosis with onset after 1 month of age; extra-intestinal strongyloidiasis; chronic isosporiasis, candidiasis (esophageal, bronchial, or pulmonary); extrapulmonary cryptococcosis; disseminated histoplasmosis; noncutaneous, extrapulmonary, or disseminated mycobacterial infection (any species other than leprae); cytomegalovirus infection with onset after 1 month of age; chronic mucocutaneous or disseminated herpes simplex virus infection with onset after 1 month of age; extrapulmonary or disseminated coccidioidomycosis; nocardiosis; and progressive multifocal leukoencephalopathy.

*Category D-2.* Includes patients with unexplained, recurrent, serious bacterial infections (two or more within a 2-year period) including sepsis, meningitis, pneumonia, abscess of an internal organ, and bone/joint infections.

*Category D-3.* Includes patients with other infectious diseases, including oral candidiasis persisting for 2 months or more, two or more episodes of herpes stomatitis within a year, or multidermatomal or disseminated herpes zoster infection.

***Subclass E - Secondary cancers.*** Includes children with any cancer described below in categories E-1 and E-2.

*Category E-1.* Includes patients with the diagnosis of one or more kinds of cancer known to be associated with HIV infection as listed in the surveillance definition of AIDS and indicative of a defect in cell-mediated immunity: Kaposi's sarcoma, B-cell non-Hodgkin's lymphoma, or primary lymphoma of the brain.

*Category E-2.* Includes patients with the diagnosis of other malignancies possibly associated with HIV infection.

***Subclass F - Other diseases.*** Includes children with other conditions possibly due to HIV infection not listed in the above subclasses, such as hepatitis, cardiopathy, nephropathy, hematologic disorders (anemia, thrombocytopenia), and dermatologic diseases.

*Reported by: AIDS Program, Center for Infectious Diseases, CDC.*

**Editorial Note:** This classification system is based on present knowledge and understanding of pediatric HIV infection and may need to be revised as new information becomes available. New diagnostic tests, particularly antigen detection tests and HIV-specific IgM tests, may lead to a better definition of HIV infection in infants and children. Information from several natural history studies currently under way may necessitate changes in the subclasses based on clinical signs and symptoms.

A definitive diagnosis of HIV infection in perinatally exposed infants and children under 15 months of age can be difficult. The infection status of these HIV-seropositive infants and children who are asymptomatic without immune abnormalities cannot be determined unless virus culture or other antigen-detection tests are positive. Negative virus cultures do not necessarily mean the child is not infected, since the sensitivity of the culture may be low. Decreasing antibody titers have been helpful in diagnosing other perinatal infections, such as toxoplasmosis and cytomegalovirus. However, the pattern of HIV-antibody production in infants is not well defined. At present, close follow-up of these children (Class P-0) for signs and symptoms indicative of HIV infection and or persistence of HIV antibody is recommended.

The parents of children with HIV infection should be evaluated for HIV infection, particularly the mother. The child is often the first person in such families to become symptomatic. When HIV infection in a child is suspected, a careful history should be taken to elicit possible risk factors for the parents and the child. Appropriate laboratory tests, including HIV serology, should be offered. If the mother is seropositive, other children should be evaluated regarding their risk of perinatally acquired infection. Intrafamilial transmission, other than perinatal or sexual, is extremely unlikely. Identification of other infected family members allows for appropriate medical care and prevention of transmission to sexual partners and future children (*11,12*).

The nonspecific term AIDS-related complex has been widely used to describe symptomatic HIV-infected children who do not meet the CDC case definition for AIDS. This classification system categorizes these children more specifically under Class P-2.

The development and publication of this classification system does not imply any immediate change in the definition of pediatric AIDS used by CDC for reporting purposes (*1,2*). Changes in this definition require approval by state and local health departments. However, changes in the definition for reporting cases have been proposed by CDC and are awaiting state and local approval.

Written comments are encouraged. They should be mailed to the AIDS Program, Center for Infectious Diseases, Centers for Disease Control, Atlanta, GA 30333.

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# VIII. WORLD HEALTH ORGANIZATION GUIDELINES

1985 May 17;34:275–76

## World Health Organization Workshop: Conclusions and Recommendations on Acquired Immunodeficiency Syndrome

An international conference on acquired immunodeficiency syndrome (AIDS), sponsored by the U.S. Department of Health and Human Services and the World Health Organization (WHO), was held in Atlanta, Georgia, April 15-17, 1985. It was attended by over 3,000 participants from 50 countries and was followed on April 18-19 by a WHO consultation to review the information presented at the conference and to assess its international implications.

The group of WHO consultants concluded that information is now sufficient to permit health authorities to take actions that may decrease the incidence of AIDS among certain risk groups. The group submitted the following conclusions and recommendations:

1. WHO should:
   a. Establish a network of collaborating centers with special expertise in the field. The centers should assist in training staff members and providing reference panels of sera, evaluation of diagnostic tests, and provision of advice on the production of working reagents. They should also assist in preparing educational material and organizing studies to determine the natural history of the disease and the extent of infection in different parts of the world.
   b. Coordinate global surveillance of AIDS using a compatible reporting format and the currently accepted case definition. WHO should disseminate these data and other important developments on the disease as widely and as rapidly as possible.
   c. Assist in developing an effective vaccine, and when appropriate, developing international requirements for the vaccines. WHO should take an active role in facilitating the evaluation of candidate vaccines.
   d Encourage and assist in periodic serologic studies in countries where AIDS has yet to be recognized and should ensure the collection of comparable data and representative selections of sera, since lymphadenopathy-associated virus/human T-lymphotropic virus type III (LAV/HTLV-III) infection precedes AIDS in an individual or a community, early recognition will require serologic studies in groups with potential risk of infections.
2. Member countries should:
   a. Inform the public that LAV/HTLV-III infection is acquired through heterosexual and homosexual intercourse, needle-sharing by intravenous drug abusers, transfusion of contaminated blood and blood products, transmission by infected mothers to their babies, and probably repeated use of needles and other unsterile instruments used for piercing skin/mucous membranes. Information should be provided about the risk of LAV/HTLV-III infection and AIDS, especially to those men and women who may be at increased risk because of multiple sexual partners. There is currently no evidence of spread of LAV/HTLV-III by casual social contact even within households. Provision of timely and accurate information on these points is recommended to allay inappropriate public concern.
   b. Ensure that health-care workers are informed about AIDS and LAV/HTLV-III infection, modes of transmission, clinical spectrum, available programs of management (including psychosocial support), and methods for prevention and control.
   c. Assess the risk that AIDS poses to each country's population and establish methods of diagnosis, surveillance, and laboratory testing, including specific tests for LAV/HTLV-III.

d. Screen, where feasible, potential donors of blood and plasma for antibody to LAV/HTLV-III, and not use positive units for transfusion or for the manufacture of products where there is a risk of transmitting infectious agents. Potential donors should be informed about the testing in advance of the donation.
e. Reduce the risk of transmission of LAV/HTLV-III by factor VIII and IX concentrates by treating them by heat or other proven methods of inactivation. The use of such products is recommended.
f. Inform potential donors of organs, sperm, or other human material about AIDS, and encourage groups at increased risk of infection to exclude themselves from donating. Whenever possible, serologic testing should be performed before these materials are used. This is particularly important when donor material is collected from an unconscious or deceased patient on whom relevant information may be absent.
g. Refer individuals with positive tests for antibody to LAV/HTLV-III for medical evaluation and counseling. Such people should be encouraged to inform their health-care attendants of their status.
h. Develop guidelines for the total care of patients and for handling their specimens in hospital and other settings. These guidelines should be similar to those that have been effective for care of patients with hepatitis B.
i. Develop codes of good laboratory practice to protect staff against risk of infection. Such recommendations may be based on those found in the Laboratory Biosafety Manual published by WHO (*1*). The level of care required for work with specimens from patients infected with LAV/HTLV-III is similar to that required with hepatitis B. The use of class II biologic safety cabinets is recommended. These cabinets are adequate for containment of other agents, such as herpes and hepatitis viruses, mycobacteria, and protozoa, that may be present in the specimens. For work involving production and purification of LAV/HTLV-III, P3 biosafety containment levels must be employed.
j. Collect and store serum samples from representative laboratory workers at the time of employment and at regular intervals thereafter, to be able to assess the risk of laboratory acquired infection and effectiveness of biosafety guidelines. Countries should provide this information to WHO for collation and dissemination. Provision of samples and testing should be carried out with the informed consent of the subjects.
k. Be aware of the importance of keeping confidential information about the results of serologic testing and the identity of AIDS patients. Serologic testing should be undertaken with the informed consent of the subject.

*Abstracted from WHO* Weekly Epidemiological Record *1985;60:129-39.*

*Reference*

1. WHO. Biological safety. Weekly Epidemiological Record 1983;58:289-90.

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