State of Wisconsin
Department of Health and Social Services

Information and Recommendations for

Preventing the Transmission of HTLV-III in Division of Care and Treatment Facilities' Institutions

Acquired Immunodeficiency Syndrome (AIDS)

Wisconsin Department of Health and Social Services

Recommendations for Preventing the Transmission of Human T-Lymphotropic Virus Type III in Division of Care and Treatment Facilities' Institutions

June 1986

Madison, Wisconsin

Acknowledgments

This document was prepared by the staff of the Wisconsin Division of Health (Bureau of Community Health and Prevention) and the Division of Care and Treatment Facilities, with input provided by the Wisconsin Public Health Task Force on AIDS. The following reference materials were utilized in developing this document:

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Wisconsin Department of Health and Social Services

Linda Reivitz, Secretary, Department of Health and Social Services
Kathryn Morrison, Administrator, Division of Health
Michael Moore, Administrator, Division of Care and Treatment Facilities

Bureau of Community Health and Prevention

Ivan Imm, Director, Bureau of Community Health and Prevention
Nancy Kaufman, R.N., Deputy Director
Jeffrey P. Davis, M.D., State Epidemiologist
James M. Vergeront, M.D., Medical Epidemiologist
Holly M. Dowling, Health Educator/Epidemiologist
Holly R. Frisby, D.V.M., Health Educator/Epidemiologist
Edward Belongia, M.D., AIDS Program Physician
Virginia E. Stauffacher, Word Processing Operator

Division of Care and Treatment Facilities

Claudetta Wright-Fuller, Administrative Assistant
Barb Bergum, R.N., Mendota Mental Health Institute
Connie Lee, M.S., Winnebago Mental Health Institute
John Toussaint, M.D., Central Wisconsin Center
Jim Yeadon, J.D., Client Advocacy Program
Donna Spatt, R.N., Wisconsin Resource Center
Greg Hupfer, R.N., Winnebago Mental Health Institute
Nathan Page, M.D., Central Wisconsin Center

Public Health Task Force on AIDS

David Kindig, M.D., Chairperson
Professor of Preventive Medicine, Director of Administrative Medicine and Health Services Administration Programs
University of Wisconsin-Madison

Ray Bachhuber, M.D.
St. Vincent Hospital, Bellin Memorial Hospital, Green Bay

Starkey Davis, M.D.
Professor and Chairman, Department of Pediatrics, Medical College of Wisconsin; Pediatrician in Chief, Milwaukee Children's Hospital, Milwaukee

Susan Dietz, R.N.
Director, Milwaukee AIDS Project

Norman Fost, M.D., Professor of Pediatrics and History of Medicine Director, Program in Medical Ethics, University of Wisconsin Clinical Sciences Center, Madison

Tim Franson, M.D.
Assistant Professor of Medicine, Medical College of Wisconsin
Hospital Epidemiologist, Veterans Administration Hospital, Milwaukee

Will Handy, MSSW
Moon Tree Collective, Madison

Jane DeGroot-Kosolcharoen, R.N.
Infection Control Nurse, Wm. S. Middleton Memorial Veterans Administration Hospital, Madison

Dennis Maki, M.D.
Professor of Medicine, Head, Section of Infectious Diseases
University of Wisconsin Clinical Sciences Center, Madison

Jay Menitove, M.D.
Medical Director, Blood Center of Southeastern Wisconsin, Milwaukee

Paul Meyer
Program Director, Dane County Unified Services Board, Madison

Doug Mormann
Director, La Crosse County Health Department, La Crosse

Margaret Schmelzer, R.N.
Director of Public Health Nursing, City of Madison Health Department, Madison

Richard Theado
Executive Director, The Planning Council for Mental Health and Social Services, Milwaukee

Tim Tillotson
Sexually Transmitted Disease Program Coordinator, University Health Service, Madison

Paul Turner, M.D.
Assistant Professor, Division of Infectious Diseases, Medical College of Wisconsin, Milwaukee

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Wisconsin Department Of Health And Social Services Recommendations For Preventing The Transmission Of Human T-Lymphotropic Virus Type III In Division Of Care And Treatment Facilities' Institutional Settings

The information and guidelines contained in this document have been developed for Division of Care and Treatment Facilities (DCTF) institution staff to assist in the management of patients (or inmates, in the case of Wisconsin Resource Center) infected with human T-lymphotropic virus type III (HTLV-III), the virus that causes acquired immunodeficiency syndrome (AIDS). The document is intended to provide overall guidance on preventing the transmission of HTLV-III within DCTF institutions, as well as protecting the confidentiality of infected patients and reducing the anxiety and misunderstanding about the disease within the institutions. In addition, the guidelines address general infection control precautions. Adherence to these policies will also reduce the risk of transmission of other viral and bacterial infections in the institutional setting.

The guidelines provided in this document are applicable to all institutions under the jurisdiction of the Division of Care and Treatment Facilities and all institution staff should become thoroughly familiar with the guidelines. Guidelines specific to the Wisconsin Resource Center may require a merging of recommendations noted in this document with recommendations cited in the Department's prison guidelines, because this institution houses patients (inmates) transferred directly from Wisconsin prisons that are under the custody of the Division of Corrections. Although these guidelines address issues specific for the DCTF institutions they may provide a model for administrators of private mental health institutions and residential care facilities that are in the process of developing guidelines.

Section One: Background Information on AIDS/HTLV-III Infections

Acquired immunodeficiency is a severe disease of the immune system caused by the retrovirus human T-lymphotropic virus type III. This virus preferentially infects and destroys T-helper lymphocytes, leaving the host unable to cope with a variety of infectious and neoplastic diseases. For the purposes of epidemiologic surveillance, the Centers for Disease Control (CDC) defines a case of AIDS as an illness characterized by one or more opportunistic diseases that are at least moderately indicative of underlying cellular immunodeficiency occurring in a person with no known cause for diminished resistance to that disease. About 85 percent of the AIDS patients studied have had one or both of two diseases: Pneumocystis carinii pneumonia, an opportunistic parasitic infection of the lungs; and Kaposi's sarcoma, a type of cancer which usually initally appears as a reddish or blue-violet spot on the surface of the skin or in the mouth. The complete CDC case definition of AIDS is included in Appendix A.

The clinical syndrome AIDS is the most severe manifestation of HTLV-III infection; the full clinical spectrum associated with this infection includes a transient mononucleosis-like syndrome, persistent generalized lymphadenopathy, persistent local or systemic symptoms (e.g., fatigue, fever, loss of appetite and weight, chronic or recurrent diarrhea, night sweats, non-productive cough, shortness of breath), acute and chronic neurologic disorders, various hematologic conditions and an asymptomatic virus carrier state. Persons who develop two or more clinical signs or symptoms and two or more laboratory abnormalities related to HTLV-III infection are classified as having AIDS-Related Complex or ARC (a case definition for ARC is included in Appendix B). Studies of the natural history of HTLV-III infection among homosexual men followed for several years have shown that generalized lymphadenopathy or ARC has developed in 25 percent of those infected men and AIDS in 7 to 19 percent; 60 percent of those infected have remained asymptomatic, although their long term prognoses remain unknown.

HTLV-III has been isolated from blood, semen, saliva, tears, urine, vaginal secretions, cerebrospinal fluid and breast milk. However, only intimate exposure to blood and semen appear to be associated with transmission of the virus. While theoretically possible, the evidence to date indicates that casual contact with saliva and tears does not result in transmission of infection. AIDS and HTLV-III infections are transmitted primarily by sexual contact (homosexual or heterosexual) and by the sharing of blood contaminated needles. Transmission may occur less commonly through transfusions of blood or blood products and from mothers to their babies during pregnancy, during birth and possibly through breast milk. Thus, persons at increased risk of acquiring an HTLV-III infection are:

- sexually active homosexual and bisexual men typically with multiple partners (73 percent of the cases of AIDS),
- present and past users of intravenous drugs (17 percent),
- persons with hemophilia (1 percent),

- persons who have received transfusions with blood or blood products (2 percent), and

- heterosexual contacts of someone with AIDS or at risk for HTLV-III infections (1 percent).

Six percent of AIDS cases could not be placed in one of the identified risk categories. These cases included recent Haitian immigrants and immigrants from other developing countries where AIDS is known to exist, persons who could not be or refused to be interviewed and men who gave histories of sexual contact with female prostitutes.

Casual contact with individuals infected with HTLV-III or persons who are at increased risk for acquiring an HTLV-III infection does not place others at risk for getting the infection. Even in the households of over 20,000 AIDS patients in the United States, spread of HTLV-III infection to household contacts has not been detected when the contacts have not been sex partners or have not been infants of infected mothers. Seven studies of family members of patients with HTLV-III infection have failed to demonstrate HTLV-III transmission to adults who are not sexual contacts of the infected patients or to older children who are not likely to have been infected during pregnancy or delivery [1-7]. One recent exception to this is a report of a mother who appears to have acquired her HTLV-III infection as a result of providing direct and extreme care to her child with tranfusion associated AIDS [8]. Even non-sexual household contacts of persons with hemophilia who actively and regularly assist in blood product infusions have not developed evidence of HTLV-III infections [7].

To date, there are no reported cases of AIDS among health care providers in the United State that can be linked to a specific occupational exposure. National studies of 938 health care workers who have inadvertently been exposed to blood or body fluids of AIDS patients (e.g., by accidental needle sticks) have identified only two persons who potentially may have developed an HTLV-III infection through occupational exposure [9]. Both of these cases involved direct inoculation of infected blood via a needle stick injury. One case of apparent transmission of HTLV-III to a health care provider after a needle stick injury has also been reported in England [10]. These studies suggest that the risk of transmission of HTLV-III infection from patients to health care providers is extremely low (see Appendix C). HTLV-III infections appear to be much less transmissible through needle sticks than hepatitis B; nearly 26 percent of persons comparably exposed to a hepatitis B surface antigen positive patient develop hepatitis B virus infection [11].

In March 1985, the U.S. Food and Drug Administration licensed enzyme-linked immunosorbent assay (ELISA) serologic tests to detect antibody to HTLV-III. The ELISA does not confirm the presence of HTLV-III, but rather antibody to it, and is not a direct test for AIDS. The tests are highly (93-98 percent) sensitive (few false negatives) and highly (99.5-99.8 percent) specific (very few false positives). False positives may occur as a result of cross-reactions with antigenically related proteins or testing abnormalities. The specifity of HTLV-III antibody testing may be improved by repeating ELISA tests that are initially reactive and using a test of a different configuration such as a Western blot assay. In the Atlanta Region, American

Red Cross/CDC study of blood donors, strongly reactive (ratio of specimen absorbance to cutoff value of 7.0 or greater) ELISA tests correlated highly with positive Western blot tests (94 percent) and cultures for HTLV-III (56 percent) [12]. Of 220 donors whose tests were initially positive but subsequently negative, and a random sample of 50 specimens with an initially negative ELISA, none had either a positive Western blot or culture.

In individuals from higher prevalence groups, repeatedly reactive ELISA tests, followed by a positive result from the Western blot technique for identifying antibodies to specific proteins associated with HTLV-III is highly predictive of current or prior infection with HTLV-III. A San Francisco study of homosexual men attending a clinic for sexually transmitted diseases found that none of 70 men with negative ELISA tests had a positive culture, while 43 (60 percent) of 72 men with repeatedly reactive tests were culture positive [12]. Of the ELISA positive specimens, 97 percent had positive Western blot tests.

The ELISA tests are useful for detecting antibody to HTLV-III and are extremely important for protecting the nation's blood supply and assisting in research efforts. The sequence of repeated ELISA tests and a Western blot test clearly have important additional clinical applications that benefit the individual and public health applications that benefit the community. When properly used, HTLV-III antibody test information may enhance the educational efforts needed to facilitate changes in behavior which remain, for now, the prinicipal intervention to prevent the transmission of HTLV-III infection.

Section Two: HTLV-III and Hepatitis Infections in Institutional Facilities

The need for institutional control programs to prevent HTLV-III infections depends upon two main factors:

1. The likely frequency of activities or behaviors among patients that potentially could expose persons to blood and body fluid (e.g., intimate heterosexual or male homosexual contact, biting that breaks the skin).

2. The prevalence of HTLV-III infections among patients.

Transmission requires both the presence of the virus in the institution population and opportunities for spread. The risk of transmission of HTLV-III increases as the frequencies of both factors increase.

Little is known about the prevalence of HTLV-III infections or transmission of HTLV-III infection in mental health or long term care and treatment facilities. As of April 1986, no persons with confirmed AIDS have been cared for in Wisconsin DCTF institutions and no serological studies have been conducted to determine the prevalence of HTLV-III infections in these institutions. However, since the epidemiologic features of HTLV-III infection are similar to that of hepatitis B virus infection, much that has been learned about the risk of acquiring hepatitis B can be applied to understanding the risk of HTLV-III transmission in institutional facilities.

Residents of institutions for the mentally retarded have a high prevalence of serologic markers for hepatitis B.* Studies have shown that between 5 and 20 percent of these residents are chronic carriers of hepatitis B surface antigen (HBsAg) and up to 45 percent may have antibody to this surface antigen [13-15]. In a serologic study of the DCTF Centers for Developmentally Disabled conducted in 1983, between 7 and 12 percent of the residents were chronic carriers of HBsAg and an additional 38 to 56 percent had antibody to the surface antigen.

Studies designed to identify risk activities associated with hepatitis B virus transmission in residential institutions for the retarded indicate that the risk is largely due to poor hygiene and frequent close interpersonal contacts [16-18]. Specific risk activities for retarded institutional residents may include self-mutilation with bleeding wounds; bleeding, fissured or hypertrophied gums from phenytoin (Dilantin) therapy; seizures resulting in traumatic bleeding; improper toileting; mouthing and sharing food or objects; excessive drooling or spitting; or biting. Other risk activities that may occur within the institutional setting that may result in exposure of

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* Institutions that have not already done so, should develop a policy regarding hepatitis B. Depending upon the characteristics of the institution and the prevalence of infected persons within the institution, this policy may need to include routine screening and prophylaxis of susceptible individuals. A discussion of hepatitis B vaccine and hepatitis B immune globulin and indications for their use in pre- and post-exposure prophylaxis is included in Appendix D.

individuals to blood, semen or body fluids include intimate sexual contact, physically aggressive behavior, ear piercing and tattooing. The prevalence of these risk activities in the DCTF institutions is not known, and the likelihood of a patient exhibiting risk behavior may vary considerably from patient to patient and from time to time.

Section Three: Development of an AIDS/HTLV-III Education Program in Institutional Facilities

The admission of a patient with AIDS or an HTLV-III infection to an institution may be disruptive to normal institution routine if there is widespread anxiety and misunderstanding about the disease among staff members and patients. Moreover, an individual with an HTLV-III infection is also anxious and must cope with a serious disease. The nonmedical needs of both patients and staff may become so pressing that the medical care of HTLV-III infected persons and other patients may be compromised.

Institutions that develop aggressive education and intervention programs for their patients and staff, including the medical staff, will be successful in minimizing anxiety and disruption. Although educational initiatives need to address communicable diseases in general, specific emphasis should be directed at AIDS and HTLV-III infections. The goal of such an education plan is to combat fear that is based on misinformation or lack of information and to minimize the risk of transmission of HTLV-III by promoting good health practices, including routine use of infection control precautions and eliminating high risk behaviors.

Widespread and open discussion of the issues raised by treating patients with HTLV-III infections are beneficial, especially when that discussion occurs before a patient with AIDS or an HTLV-III infection is actually admitted. Institutions should make special efforts to involve persons from support services, such as the housekeeping, dietary, laboratory and radiology departments, in these discussions. The addition of labor union representatives to these study groups may also be useful. When a broadly based group of employees participates in discussions of what is known and what is not known about this disease, they are likely to respond appropriately when given the opportunity to care for a patient with AIDS or an HTLV-III infection.

Recommendation 1: AIDS Coordinating Group

Each institution should form or designate an AIDS coordinating group, which should have broad educational and supportive responsibilities within the institution. This group should include persons such as an infection control nurse, a social worker, a physician, a psychiatrist, a nursing administrator, training personnel, and a patient advocate, but should not be limited to "experts," or to ranking administrative personnel and should be broadly representative of the institution.

Recommendation 2: Institution Education Program

Each institution should develop and implement an education program that specifically addresses the needs and concerns of their staff and patients regarding infection control precautions and HTLV-III infections. This education program should include information on communicable diseases and infection control precautions in general as well as specific emphasis on HTLV-III infections.

Educational materials should be provided as part of an orientation package for staff beginning employment and as appropriate for a patient entering the institution. Employees and patients should also be provided with periodic information updates as well as continued access to written materials and other information sources. It is also important that several persons at each institution develop an expertise regarding HTLV-III so that they may be available to staff and patients to respond to questions.

Section Four: Personnel Management Issues

Personnel Issues

Optimum patient care depends upon an open, understanding and nonjudgmental attitude by health care providers, an attitude which everyone recognizes is basic to all good patient care. The sick individual (heterosexual or homosexual) deserves the best care the profession has to offer for all physical or mental conditions.

There are risks to the health care provider associated with caring for all sick persons. However, at this time there is no evidence that the risks associated with providing hands-on care to persons with HTLV-III infections are significantly greater than the risks associated with caring for any other sick persons. Despite this fact, some health care providers, including physicians, still may be reluctant to care for patients with AIDS or HTLV-III infections.

Physicians and other health care providers by the nature of their decision to undertake their profession have an ethical and moral responsibility to provide care to all patients to the best of their abilities. In the absence of scientific reasons not to provide care, and providing appropriate infection control precautions are observed, care should not be denied to patients with AIDS or HTLV-III infections. In cases in which an employee refuses outright to perform his or her duties, the issue is an ethical, legal and administrative problem that must be handled on an individual basis.

Physicians who are not employees of the hospital may not be subject to its administrative rules governing provision of care. However, they have an ethical obligation to provide the same standards of professional care to all patients independent of the nature of the individual illness. As noted in the Code of Medical Ethics adopted by the American Medical Association, "Physicians are free to choose whom they will serve. The physician should, however, respond to any request for assistance in an emergency or whenever temperate public opinion expects the service. Once having undertaken a case, the physician should not neglect the patient, nor withdraw from the case without giving notice to the patient, the relatives, or responsible friends sufficiently long in advance of withdrawal to permit another medical attendant to be secured." Therefore, a qualified physician who will not provide necessary care to a given patient has an obligation to arrange for the provision of needed services by another qualified physician. Cases in which a physician refuses to provide care should be brought to the attention of the hospital administration.

Recommendation 3: Refusal to Provide Care

> Otherwise healthy personnel should be expected to care for patients with AIDS or HTLV-III infections, because there is no scientific reason not to do so. If a health care provider or employee simply refuses to perform his or her duties in relation to caring for these patients, the issue should be dealt with through institution administrative policies established for such conditions. The institution Clinical/Medical Director should solicit the advice of DCTF legal counsel in such situations.

There is no increased risk to pregnant personnel from caring for persons with HTLV-III infections. Female employees of childbearing age caring for persons with HTLV-III infections may express concern about the potential for exposure to cytomegalovirus (CMV) excreted by these patients. This is because 2 to 4 percent of women who acquire a primary CMV infection during their pregnancy may give birth to a symptomatic infected infant [19]. However, these employees should be aware that CMV infection is endemic in the community, and that patients within the institutions do not represent their only potential source of exposure. The ubiquity of CMV infection, lack of clinical abnormalities in most cases, persistence of viral shedding and potential for excretion of CMV following reactivation of an existing infection provide many sources through which CMV infections could be acquired. Although little is known regarding how CMV is transmitted in the community, it does not appear to be highly contagious. Acquiring a CMV infection appears to require close or intimate contact with persons who are excreting CMV in their urine, saliva or other secretions. CMV may also be transmitted via blood transfusions, breast milk, sexual intercourse and transplanted organs. High rates of CMV infections have been noted in day care centers, with 20-70 percent of the children shedding virus in their urine [20]. Persons infected with CMV may continue to shed the virus for years. Prior exposure to the virus is so common that 35 to 90 percent of women (depending on race and socioeconomic status) entering their childbearing years have antibody to CMV, and thus, they are not susceptible to primary CMV infection [21]. Although the potential for transmission of CMV virus exists in a patient care setting, hospital-based studies have failed to demonstrate that the risk of transmission within the hospital is significantly greater than the risk of acquiring a CMV infection outside of the patient care setting [19-22]. Preventing exposure to cytomegalovirus in the hospital setting is best accomplished by observance of good personal hygiene and good patient care practices since saliva, urine, cervical secretions, semen and breast milk are all potential sources of cytomegalovirus infection.

Recommendation 4: Pregnant Personnel

> Otherwise healthy female employees of childbearing age and pregnant employees should be expected to provide care to patients with AIDS and HTLV-III infections because there is no scientific reason not to do so.

Precautions to prevent transmission of HTLV-III infection from health care workers to patients.

Although there is no evidence that health care workers infected with HTLV-III have transmitted infection to patients, a risk of transmission of HTLV-III infection from health care workers to patients would theoretically 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 health care worker to the open tissue of a patient, as could occur if the health care worker sustains a needle stick or scalpel injury during an invasive procedure.

Infection control recommendations for health care workers emphasize precautions appropriate for preventing transmission of bloodborne infectious diseases, including HTLV-III and hepatitis B virus (HBV) infections (see Section Seven, "Patient Care Precautions and Practices"). Thus, these

precautions should be enforced routinely, as should other standard infection control precautions, regardless of whether health care workers or patients are known to be infected with HTLV-III or HBV. A discussion of CDC recommendations for preventing transmission of HTLV-III during invasive procedures is included in Appendix E.

Recommendation 5: Precautions for Personnel with HTLV-III Infections

These precautions apply to all health care workers, regardless of whether they perform invasive procedures: (1) all health care workers should wear gloves for direct contact with mucous membranes or nonintact skin of any patient and (2) health care workers who have exposed exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves. In addition to being informed of these precautions, all health care workers, including students and house staff, should be educated regarding the epidemiologic features, modes of transmission and prevention of HTLV-III infection.

Recommendation 6: Work Assignments

Health care workers known to be infected with HTLV-III should not be restricted from work unless they have another infection or illness for which any health care worker should be restricted. If the health care worker who performs invasive procedures is antibody positive, extra precautions should be taken to avoid mucosal or parenteral exposure to a patient (Appendix E). All health care workers 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. The health care worker with an HTLV-III infection should consult with his/her personal physician, the institution's personnel health services and Clinical/Medical Director to determine whether they are physically and mentally competent to perform invasive procedures.

Recommendation 7: Serologic Screening of Personnel

Routine serologic testing of health care workers (including providers of home and prehospital emergency care) is not recommended to prevent transmission of HTLV-III infection. The risk of transmission is extremely low and can be further minimized when routinely recommended infection control precautions are followed. However, serologic testing is available to health care workers who may wish to know their HTLV-III infection status from their physician or a Division of Health sponsored alternate site.

Risk of occupational acquisition of other infectious diseases by health care workers infected with HTLV-III. Health care workers who are known to be infected with HTLV-III 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 precautions are not taken (e.g., tuberculosis).

Recommendation 8: HTLV-III Infected Personnel

Health care workers infected with HTLV-III 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. The health care workers' personal physician(s), in conjunction with their institutions' personnel health services or medical directors, should determine on an individual basis whether the infected health care workers 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 health care workers with live virus vaccines should also be considered.

Wisconsin Statutes Concerning Personnel Management Issues

Unless the state epidemiologist determines and the Secretary of the Department of Health and Social Services declares that individuals who have HTLV-III infections may, through employment, provide a significant risk of transmitting HTLV-III to other individuals, Wisconsin Statute 103.15 (Appendix F) states that no employer or agent of an employer may directly or indirectly:

A. Solicit or require as a condition of employment of any employee or prospective employee a test for the presence of an antibody to HTLV-III.

B. Affect the terms, conditions or privileges of employment or terminate the employment of any employee who obtains a test for the presence of an antibody to HTLV-III.

In addition, any agreement by an employer or agent of the employer and an employee or prospective employee offering employment or any pay or benefit to an employee or prospective employee in return for taking a test for the presence of an antibody to HTLV-III is prohibited, except as provided above.

The Employees' Right to Know Law, set forth in Wisconsin Statutes 101.58-101.599 (Appendix G), is an enactment giving certain rights to employees to be informed about the presence of hazardous substances in the work place. Specifically, the employer must follow the statutory procedures in notifying employees when toxic substances, infectious agents and pesticides are "introduced" by the employer to be "used, studied or produced" in the work place. The statutes also state that the term "infectious agent" does not include such an agent in or on the body of a person who is present in the work place for diagnosis or treatment. Thus, in hospitals, clinics, or other medical facilities where the infected individual is present for the purpose of receiving diagnosis or treatment, the statutory language explicity exempts the situation from the statutory requirements. Additionally, in an office or other place of employment that is not geared to medical treatment where an HTLV-III infected individual is present the statutory requirements would not apply. However, laboratory settings where individuals with HTLV-III infections are not receiving diagnosis or treatment, but where they or their body fluids or tissues are the subject of research, would indeed be subject to the Employees' Right to Know Law procedures.

Section Five: Patient Confidentiality

Institutions should be careful to balance the need to ensure appropriate precautions to prevent spread of disease with the need to ensure appropriate confidentiality to their patients. Patients with AIDS and HTLV-III related infections, like other patients with diseases spread by blood, will need to have laboratory tests performed, and they may need other specialized procedures such as surgical or other invasive procedures. In addition, they may need to be transported within the institution setting for diagnosis or treatment reasons. The institution should develop a procedure that ensures that staff throughout the institution who provide care for these patients know what precautions are to be taken. Because of the legal situation in Wisconsin related to the confidentiality of HTLV-III antibody test results and the publicity that AIDS has received, special care needs to be taken to preserve the dignity and confidentiality of persons with HTLV-III infections at these times. Unless such procedures are outlined, there are dangers that patients will not be appropriately identified, resulting in proper precautions not being taken, or alternatively, confidentiality not being preserved. The general designation "Blood/Body Fluid Precautions," as recommended in the CDC Guideline for Isolation Precautions in Hospitals, should be sufficient, if utilized uniformly throughout the institutions. The precautions, but not the diagnosis, should be clearly identified.

Consent for HTLV-III Antibody Testing and Disclosure of Test Results

The development and licensing in March 1985 of blood tests to detect the presence of antibody to HTLV-III raised a number of issues relative to the use of these tests and access to the test results. Wisconsin Act 73, as enacted November 14, 1985, sets out in statute the procedures to be followed in testing for antibody to HTLV-III as well as the disclosure of these test results (see Appendix F).

The Act protects the rights of individuals to confidentiality concerning their health care while providing the medical community with important health information necessary to provide adequate health care and protect the health and safety of the general public.

The Act protects the rights of the individual by:

1. Requiring the written consent of the subject of the test before performing the blood tests. (A sample of an informed consent form is included in Appendix H.) This written consent requirement for antibody testing is waived:

    a. In the case of organ donations from a person after the person's death to assure the medical acceptability of the donated organ.

    b. For the purpose of research if testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

2. Limiting the disclosure of the antibody test results without consent to the following persons or under the following circumstances:

a. To the subject of the test.

b. To the test subject's health care provider, including those instances in which a health care provider provides emergency care to the subject.

c. To an agent or employee of the test subject's health care provider who provides patient care or handles or processes specimens of body fluids or tissues.

d. To a blood bank, blood center or plasma center that subjects a person to a test.

e. To a health care provider involved in the transplantation of a donated organ.

f. To the state epidemiologist or his or her designee, for the purpose of providing epidemiologic surveillance or investigation or control of communicable disease.

g. To a funeral director or to other persons who prepare the body of a decedent for burial or other disposition.

h. To health care facility staff committees or accreditation or health care services review organizations for the purposes of conducting program monitoring and evaluation and health care services reviews.

i. Under a lawful order of a court of record.

j. To a person who conducts research, for the purpose of research, under conditions specified in the statute.

k. To anyone authorized in writing by the subject of the test.

3. Providing significant civil and criminal liabilities for unauthorized negligent or willful disclosure of test results.

Test results may be disclosed to anyone specified by the test subject or patient, with the subject's written consent. Such written consent to disclose test results may be given at the time, and on the same form as, the subject gives written consent to have the test performed. It may also be given on a separate form at any time subsequent to the test. The form must include the name of the person(s) to whom disclosure may be made, the time period during which the consent to disclosure (beginning and end) is effective, and the date on which the consent to disclosure is signed.

Test results may be included in the medical record. However, they must remain confidential, with disclosure allowed only as provided above. Most of the provisions for disclosure without patient consent, described under item 2, are identical to statutory provisions on disclosure of a medical record without consent (ss. 146.81-.82). However, there are several statutory provisions allowing disclosure of medical records in general which are not repeated in the statutes regarding HTLV-III antibody tests disclosure.

1. Although ss. 146.025 provides for disclosure of HTLV-III antibody test results and mandatory reporting of positive HTLV-III antibody test results to the state epidemiologist, this statute does not allow for disclosure in response to a written response from other state or federal governmental agencies.

2. State statute 146.025 does not provide for disclosure of HTLV-III antibody test results to a county agency investigating elder abuse.

3. State statute 146.025 does not provide for disclosure of HTLV-III antibody test results for the purposes of billing, collection or payment of claims. The issue of whether or not disclosure of the fact that a test has been done, for purposes of billing, is not clearly addressed in the statutes. One method to avoid problems related to disclosure for purposes of billing is to request consent for such disclosure as part of the original consent procedure. The sample consent form included in Appendix H contains a section that deals with disclosure for billing purposes.

Since the DCTF institutions are medical institutions and patients are in the institutions for the primary purpose of receiving treatment, ss. 146.025 (item 2b and 2c on page 14) allows for disclosure of the HTLV-III antibody test result to any DCTF institution employee with a legitimate need to know. The decision on which DCTF employees need to have access to HTLV-III test results for the performance of their duties should be established by the institution Clinical/Medical Director.

Recommendation 9: Confidentiality

All institution employees should be informed of statutory confidentiality provisions regarding disclosure of a patient's HTLV-III antibody test results and the criminal consequences of violating these confidentiality provisions.

Recommendation 10: Informing Health Care Providers of the Need for Infection Control Precautions

All persons having a specific need to know that a patient has an HTLV-III infection for purposes of providing treatment and direct care to the patient that might involve exposure to blood or other body fluids should routinely be informed of the patient's diagnosis and the appropriate infection control procedures to be followed. This includes persons on the patient's treatment team and other persons providing direct hands-on care to the patient. In addition to the direct care staff, other persons responsible for the care and protection of the patient to be notified include the Program Director, Clinical/Medical Director, Infection Control Nurse, Employee Health Nurse and Director of Nursing. Other persons involved less directly in the patient's care (e.g., radiology technicians, housekeeping personnel) should be informed of the need to observe blood and body fluid precautions but do not routinely need to be informed of the patient's diagnosis.

Recommendation 11: Informing Visitors of the Need for Infection Control Precautions

All visitors of patients with HTLV-III infections shall be informed, with the patient's consent, by the patient in the presence of staff or by the staff of the need to observe blood and body fluid precautions. If a patient does not consent to this disclosure, then it may be necessary to supervise or deny the visit using the standard rights denial process (ss. 51.61 (2)).

Recommendation 12: Informing Patients and/or their Guardians of the Need for Infection Control Precautions

Patients routinely should be educated regarding the need to observe general precautions that will minimize their potential exposure to other patient's blood and body fluids. In the case of a minor or an incompetent adult, this information should be explained to the appropriate parent or guardian.

Recommendation 13: Institution Spokesperson

In dealing with the media, patient confidentiality and dignity is of paramount concern. Institutions should designate a knowledgeable and authorative representative to be spokesperson to the media. Other institution staff members should coordinate media communications through that representative.

Section Six: Identification of Patients with HTLV-III Infections

Testing of all patients for antibody to HTLV-III upon admittance or during their treatment stay is not considered likely to be an important means to prevent transmission within the institution, since the usual nonsexual contacts between patients and employees or other patients will not spread infection. However, in some situations testing may be useful in preventing transmission of HTLV-III among patients by (1) alteration of high risk behavior of tested persons after being counseled on ways to prevent transmission or acquisition of infection, or (2) if the behavior cannot be modified, transmission may be prevented by restricting the patients activity. In addition, knowledge of an HTLV-III infection could assist medical staff in the medical management of a patient by enabling more rapid, accurate diagnosis and treatment of intercurrent illness, in determining the need for prophylaxis following exposure to certain infections such as tuberculosis and in serving as a relative contraindication for the use of immunosuppressive agents. Routine systematic testing of persons at the beginning of their treatment stay and perhaps periodically thereafter could be used for surveillance of trends in the incidence of HTLV-III infection and for evaluating the effectiveness of educational and control programs within the institutions.

Information from testing would also facilitate incident management, since the probable infection status of the patient could be established at the time of the incident. However, knowledge that a patient was previously uninfected would not obviate the need to ascertain infection status at the time of an incident, and a delay of several days in determining that the person to whom one was exposed was infected would not importantly influence the ability to document seroconversions in exposed persons. Finally, knowledge of infection status at the time of admission would permit the assignment of appropriate housing for infected persons likely to engage in behavior that might pose a risk of transmission to others.

Recommendation 14: Routine Admission Evaluation

As part of a routine admission evaluation, all newly-admitted patients will routinely be screened to identify individuals with symptomatic or clinically apparent HTLV-III infections. This screening procedure will include (a) a patient interview and record review (preadmission reports, etc.) to identify specific symptoms and risk activities associated with HTLV-III infections, and (b) a physical examination including a careful evaluation of the skin, mouth and pharynx, lymph nodes and rectum for pathology and infectious processes related to HTLV-III infections.

Recommendation 15: HTLV-III Antibody Testing

A. Patients who have a history of symptoms, a physical examination or laboratory studies suggestive of a HTLV-III infection should be counseled regarding the need for further medical evaluation including recommending that the patient voluntarily consent to have a HTLV-III antibody test. Testing shall not be performed without patient consent in this situation.

B. Patients who have a history of high risk activities for HTLV-III infection should be counseled regarding the need for further medical evaluation including recommending that the patient voluntarily consent to have a HTLV-III antibody test. Testing shall not be performed without patient consent in this situation.

C. Patients who have a history of behavior problems that would increase the potential for exposure of others to blood and body fluids (e.g., biting, self-abusive activity, physical or sexual aggressive behavior, sexual contact and seizure disorder not well controlled by medication) should be considered for HTLV-III antibody testing. The decision of whether or not to test these patients with behavior problems should take into consideration factors such as the patient's behavior, a history of activities that would place them at increased risk for an HTLV-III infection, or symptoms, a physical examination or laboratory studies suggestive of a HTLV-III infection. Patients for whom testing is recommended by their attending physician should be counseled regarding the need for further medical evaluation including an HTLV-III antibody test. Patient consent should be sought for this testing, however, for those patients not consenting, the Clinical/Medical Director of the institution will determine whether the testing should be required.

D. HTLV-III antibody testing should only be performed at institutions when counseling (pre- and post-test counseling) can be provided to the patient.

Recommendation 16: Modification of Wisconsin Statutes

Statutory language should be modified to enable the Clinical/Medical Director of a DCTF institution to make a determination when mandatory HTLV-III antibody testing of a patient should occur. Decisions on mandatory testing should be made by the Clinical/Medical Director on a case-by-case basis.

Section Seven: Infection Control Recommendations

In developing specific infection control policies and procedures the following infection control principles need to be considered [from the Infection Control Workshop of the Second National AIDS Forum; Denver, June 1983]:

- Infection control precautions are designed to promote the healthfulness of patients; health care workers; and family, friends and coworkers of patients. Inappropriate and "over-protective" precautions are detrimental to this goal.

- Infection control precautions are established to isolate infectious agents and to interrupt their transmission, rather than isolate the patient.

- Every patient has a right to health care provided in a timely and unbiased manner. This access is not to be abridged in the name of infection control. These services include diagnostic, therapeutic, rehabilitative, nutritional and psychosocial services.

- Principles and policies for HTLV-III infection control should be derived from general infection control concerns such as: (1) the spread of many infections may be associated with body secretions and blood; (2) all patients are at risk of contracting infections as well as spreading them; and (3) dissemination of an agent from infected but asymptomatic patients is of concern to patients, health workers and the community.

- Patients have a right to individual dignity and privacy.

In addition, patients admitted to DCTF institutions have certain statutory rights outlined under Wisconsin Statute 51.61 that need to be considered in developing specific infection control guidelines. Specifically, patients have the right:

- To live in a pleasant physical place, and to be treated with respect.

- To have the least restrictive treatment condition needed to carry out the purpose of their commitment or admission (except for criminally committed persons).

- To be free from physical restraint and isolation except under special conditions.

- To receive prompt and adequate treatment.

- To have confidential conversations with staff and to have all medical and care records kept confidential (s. 51.30).

- Voluntary patients have the right to refuse any form of treatment, but if they do so, they may not be able to stay in the treatment facility as a patient.

- Involuntary patients have the right to refuse any form of treatment before a court hearing or commitment, unless specifically ordered by the court.

Identifying the Patient

The following precautions are advised for persons and specimens from persons with AIDS, ARC, other HTLV-III related conditions, positive HTLV-III antibody tests and persons being evaluated for HTLV-III infections. The precautions are not generalizable to those patients who are at increased risk of HTLV-III infection but have no other clinical evidence suggestive of an HTLV-III infection. It is important to understand that care of a patient with an HTLV-III infection requires blood and body fluid precautions, the same as those for hepatitis B virus infection. If a patient with HTLV-III has another infection or condition requiring additional precautions, then these should be added, according to the CDC Guideline for Isolation Precautions in Hospitals.

Recommendation 17: Physician Responsibilities

It is the responsibility of the attending physician to (a) identify the patient who has an HTLV-III infection or is being evaluated for an HTLV-III infection, and (b) determine, in consultation with the infection control staff, when appropriate infection control precautions should be instituted or discontinued.

Patient Care Precautions and Practices

In general, blood and body fluid precaution measures consistent with those suggested for the prevention of hepatitis B virus infection should be followed. The measures required beyond simple blood and body fluid precautions are dictated by the patient's behavior, symptoms or identified infection. Specific recommendations follow.

Recommendation 18: Room Assignment

Patients with an HTLV-III infection should be placed in a single room in a location where there is the potential to provide maximum supervision and to impose activity restrictions, if necessary.

Recommendation 19: Patient Activities

In general, patients with HTLV-III infections should be allowed access to a full range of recreational activities, work assignments, visitation privileges, showers and bathroom facilities, food services and other program activities. However, to minimize the potential for exposure of other patients and employees, the treatment team should review initially and on a periodic basis the patient's behavior to determine if there is a risk that a particular behavior (e.g., biting, self-abusive activity, physical aggressive behavior, sexual contact and seizures) may expose other persons to the patient's blood or other body fluids. Based on this assessment, the treatment team may need to impose limitations and restrictions on the patient's housing, program activities or work assignments; these limitations should be the least restrictive necessary to provide protection to other persons. Patients with HTLV-III infections that have other infections requiring isolation precaution, should be managed according to existing policy or the Centers for Disease Control's Guideline for Isolation Precautions in Hospitals.

Documentation regarding the management and treatment of all HTLV-III infected patients placed on special restrictions should be submitted to the Clinical/Medical Director monthly for review.

Recommendation 20: Hand Washing

All employees should be instructed in proper techniques of hand washing during their initial employee training. Hands must be washed before and after contact with a patient, both for protection of the employee as well as the patient. This precaution should be observed regardless of the use of gloves. Patients must also be taught to wash their hands regularly, especially after using toilet facilities.

Recommendation 21: Masks

Masks are not routinely necessary for patients with HTLV-III infections. However, they should be worn by any patient with a transmissible respiratory disease or a respiratory disease of unknown etiology when it is necessary for the patient to leave their room. Masks should be worn by visitors and health care workers when in direct and sustained contact with any patient with a transmissible respiratory disease or a respiratory disease of unknown etiology and when an intubated patient is being suctioned. Masks should also be worn by any visitor with a respiratory disease if the patient is immunocompromised.

Recommendation 22: Protective Eye Wear

The use of protective eye wear, such as goggles, is recommended in situations in which splatters with blood, bloody secretions, or other body fluids are possible. This is particularly recommended in the performance of procedures such as endotracheal intubation, bronchoscopy or GI endoscopy. Precautions during other surgical procedures should be judged on an individual basis.

Recommendation 23: Gowns

The use of gowns is recommended only if soiling of clothing with blood or body fluids is anticipated. Gowns should be used once and discarded in an isolation linen hamper or bag.

Recommendation 24: Gloves

Nonsterile gloves should be worn by all persons who are in direct contact with the blood, blood specimens, tissue, any body fluids or secretions of an individual with an HTLV-III infection or being evaluated for an HTLV-III infection, or when having contact with articles or surfaces potentially contaminated by body fluids. This includes persons performing routine venipuncture procedures. This recommendation is especially important for personnel who have cuts or abrasions on their hands.

Recommendation 25: Labeling Clinic Specimens

Blood and other specimens should be labeled prominently with the warning "Blood/Body Fluid Precautions"; the warning label should not mention a specific disease. The label should accompany the specimen through all phases of processing until ultimate disposal. If the outside of the specimen container is visibly contaminated with blood, it should be cleaned with a disinfectant, such as a freshly prepared (once daily) 1:10 dilution of 5.25 percent sodium hypochlorite (household bleach) with water. All blood and other 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.

Recommendation 26: Labeling Charts

A "Blood/Body Fluid Precautions" label should be placed on the outside cover of the chart of individual's with an HTLV-III infection or under evaluation for an HTLV-III infection. This label should not include the reason for the precaution, however, the reason for the precaution should be placed in a readily visible location inside the chart.

Recommendation 27: Labeling Consults

A "Blood/Body Fluid Precautions" label should be placed on all consults and requisitions (Radiology, Nuclear Medicine, etc.) of individuals's with an HTLV-III infection or under evaluation for an HTLV-III infection. For reasons of confidentiality, this label should not include the diagnosis HTLV-III infection, ARC, or AIDS.

Recommendation 28: Needles and Syringes

Needles and syringes should be disposable and should be disposed of in rigid, puncture-resistant containers. Needles should not be recapped and should not be purposely bent or broken by hand, since accidental needle puncture may occur. The use of needle cutting devices is not recommended.

Extraordinary care should be taken to avoid accidental wounds from needles and other sharp instruments. Parenteral injections and blood drawing should be planned to keep these procedures at a minimum; they should be carried out by experienced personnel.

Use needle locking devices or Luer-lok® connections whenever accidental disconnections are likely to produce aerosolization (e.g., infusions pumps).

Recommendation 29: Soiled Clothing and Linens

Soiled linens and other laundry should be bagged, appropriately labeled or color-coded, and processed according to the institution's existing policy regarding linens from patients on isolation precautions.

Recommendation 30: Disposable Items

Disposable items should be incinerated or disposed of in accordance with the institution's policies for disposal of infectious waste.

Recommendation 31: Instruments and Equipment

Disposable equipment should be used whenever possible. Any reusable items that come in contact with blood, secretions, excretions or tissue must be sterilized or disinfected before reuse. Used items should be bagged and labeled "Blood/Body Fluid Precautions" before being sent for decontamination and reprocessing.

Autoclaving should be used for all reusable instruments and equipment that will tolerate heat sterilization.

Lensed instruments, cleaning brushes, biopsy forceps and other accessory items used in endoscopy should be appropriately labeled, cleaned and then sterilized with ethylene oxide or glutaraldehyde after each use on a patient with an HTLV-III infection. Specific decontamination procedures for ophthalomalogic equipment have been developed by the Centers for Disease Control and are included in Appendix I.

Ventilator tubing should be either disposable or sterilized before use.

Personnel reprocessing soiled and presumably contaminated items labeled "Blood/Body Fluid Precautions," should wear disposable aprons, masks and goggles if considerable splatter is likely in initial recleaning.

Recommendation 32: Dishes

No special precautions for dishes are necessary.

Recommendation 33: Blood Spills and Contaminated Surfaces

Blood and body fluid spills should be cleaned up promptly with a disposable towel and surfaces contaminated with blood or other body fluids should be cleaned with a disinfectant such as freshly prepared 1:10 dilution of 5.25 percent hypochlorite solution (household bleach). When a patient with an HTLV-III infection is admitted to a unit, a bottle of disinfectant such as stock hypochlorite solution should be obtained from housekeeping and kept available on the ward. When hypochlorite solution is used a 1:10 dilution of the stock solution in water should be made up fresh for each day's use.

Recommendation 34: Ambulatory Care

Segregated examining rooms for outpatients with HTLV-III infections are neither necessary nor desirable. Outpatients with HTLV-III infections may use the common outpatient waiting room as well as

regular restroom facilities unless the presence of other infections require special precautions.

Recommendation 35: Cardiopulmonary Resuscitation

Resuscitation bags, disposable masks and airways for providing ventilatory support should be readily available at the bedside of all patients with AIDS or HTLV-III infections who are critically ill or who have respiratory distress, where acute cardiorespiratory failure could require immediate resuscitory measures. The employee should use these devices when administering cardiopulmonary resuscitation (CPR).

Recommendation 36: Resuscitation Assessments in AIDS Patients

As with all patients, irrespective of the patient's underlying disease or diseases, it is imperative that the attending staff physician and patient care team initially assess and continue to reassess decisions regarding use of CPR when the patient is terminally ill. Decisions on whether to attempt to resuscitate a terminally ill patient should be discussed fully with the patient, the patient's family, a legal guardian or other designates of the patient. Such decisions should be written in the chart and patient's orders.

Precautions for Patients Undergoing Hemodialysis

Patients requiring hemodialysis are at increased risk for infection with HTLV-III because they may have received multiple transfusions before the initiation of nationwide screening of blood products for HTLV-III antibody. In addition, dialysis patients have an increased rate of falsely positive ELISA tests, presumably due to the exposure of these patients to H9-cell-associated antigens during multiple blood transfusions [24-27]. Currently, there is no evidence that HTLV-III has been transmitted in the dialysis center environment, either from patient to patient or patient to staff member [23,24]. However, since HTLV-III is transmitted in the same manner as hepatitis B (i.e., bloodborne), HTLV-III has the potential for being transmitted in dialysis centers. As a result it has been recommended that dialysis centers use precautions similar to those used for hepatitis B virus carriers when treating patients with validated positive HTLV-III antibody tests [23,24]. Suggested infection-control strategies for HTLV-III range from conservative (separate room and separate machine, as for hepatitis B virus) to less stringent (separate machine only) [23].

There is disagreement over the need to serological screen all dialysis patients for antibody to HTLV-III. The Centers for Disease Control has recommended that screening dialysis patients for antibody to HTLV-III is not necessary [25]; other researchers and clinicians have recommended that patients be screened [26,27]. Researchers agree that physicians considering screening should be aware of the association of a history of multiple blood transfusions and false-positive results from HTLV-III ELISA antibody tests. The following is the recommendation of the Task Force; when additional information regarding HTLV-III transmission and dialysis becomes known, updated recommendations will be made available.

Recommendation 37: Hemodialysis

All persons who require hemodialysis should be tested for antibody to HTLV-III. Those individuals with a validated positive test should be cohorted to the use of a dialysis machine designated for individuals with HTLV-III infections. Maintenance of hemodialysis and peritoneal dialysis equipment used by persons with an HTLV-III infection should be managed in a manner comparable to equipment used by patients who are known to be carriers of hepatitis B surface antigen (HBsAg). Disposable components in dialysis equipment must not be reused.

Precautions in Clinical Laboratories

The precautions to be taken in clinical laboratories are essentially the same as those recommended for processing specimens from patients known to be carriers of hepatitis B surface antigen (HBsAg). 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 persons with HTLV-III infections.

Recommendation 38: Pipetting

Mechanical pipetting devices should be used for the manipulation of all liquids in the laboratory. Mouth pipetting is not to be allowed.

Recommendation 39: Needles and Syringes

Needles and syringes should be handled as stipulated in Recommendation 28.

Recommendation 40: Protective Clothing

Laboratory coats, gowns or uniforms should be worn while working with potentially infectious materials and should be removed and appropriately deposited or disposed of before leaving the laboratory.

Recommendation 41: Gloves

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.

Recommendation 42: Aerosols

All procedures and manipulations of potentially infectious material should be performed carefully to minimize the creation of droplets and aerosols. 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 should also be used in handling materials that might contain concentrated infectious agents or organisms in greater quantities than expected in clinical specimens.

Recommendation 43: Work Surfaces

Laboratory work surfaces should be decontaminated with a disinfectant, such as sodium hypochlorite solution (see Recommendation 33), following any spill of potentially infectious material and at the completion of work activities.

Recommendation 44: Disinfection

All potentially contaminated materials used in laboratory tests should be decontaminated, preferably by autoclaving, before disposal or reprocessing.

Recommendation 45: Hand Washing

All laboratory personnel should be instructed in proper techniques of hand washing during their initial employee training. All personnel should wash their hands following completion of laboratory activities, removal of protective clothing and before leaving the laboratory.

Additional precautions for studies involving experimental animals inoculated with tissues or other potentially infectious materials from individuals with HTLV-III infections are included in Appendix J.

Autopsy and Post-mortem Precautions

The precautions to be followed before, during and after the post-mortem examination are similar to those for hepatitis B.

The following recommendations for autopsy precautions are adapted from the joint recommendations of the Centers for Disease Control and the College of American Pathologists:

Recommendation 46: Identification of the Body

As part of immediate post-mortem care, patients with AIDS or HTLV-III infection should be identified "infectious hazard--blood/body fluid precautions" and that identification should remain with the body whether or not an autopsy is carried out, for delivery to morticians. Wisconsin Statute 146.025 allows disclosure of HTLV-III antibody test results to pathologists, morticians and their assistants.

Recommendation 47: Protective Clothing

All personnel involved in performing an autopsy should wear double gloves, masks, protective eye wear, gowns, waterproof aprons and waterproof shoe coverings.

Recommendation 48: Infection Control and Disinfection

All personnel involved in performing an autopsy should follow appropriate clinical and laboratory precautions previously noted (e.g., disposal of needles, soiled clothing, trash, infectious waste).

Methods that will avoid or minimize aerosol distribution of infectious agents should be used (e.g., bones should be cut with a hand saw rather than an electric saw).

Instruments and surfaces contaminated during the post-mortem examination should be handled as potentially infective items. The following should be decontaminated with 0.5 percent sodium hypochlorite at the conclusion of an autopsy:

a. Autopsy table.

b. All contaminated instruments, for 1 hour before washing and autoclaving.

c. Other contaminated items that cannot be disposed of or autoclaved, including the outside of tissue containers.

Tissue samples should be thoroughly fixed in 10 percent buffered formalin before trimming for histology.

Section Eight: Accidental Exposure to Blood or Body Fluids

The risk of transmission of HTLV-III infection to health care workers is extremely low. Nevertheless, health care workers who have a parenteral (e.g., needle stick or cut) or mucous membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids may wish to have an HTLV-III antibody test themselves and/or to have the source individual tested. Decisions regarding the need for such testing should be individualized to the specific incident based upon factors such as the nature of the exposure, a clinical and epidemiological assessment of the likelihood of the source individual having an HTLV-III infection and the psychological trauma experienced by the exposed person.

Recommendation 49: Unintentional Occupational Exposure to Body Fluids

When a health care worker has a parenteral or mucous membrane exposure to blood or other body fluids, the source patient should be assessed clinically and epidemiologically to determine the likelihood of HTLV-III infection. The source patient should be informed of the incident and strongly encouraged to voluntarily consent to testing; the patient should be given the option of not learning the results of the tests. If the source patient has AIDS or other evidence of HTLV-III infection, declines testing, or has a positive test, the health care worker should be evaluated clinically and serologically for evidence of HTLV-III 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.

If the source patient is seronegative and has no other evidence of HTLV-III infection, the CDC has recommended that no further follow-up of the health care worker is necessary [22]. However, because of the remote possibility that the source patient has been recently exposed to HTLV-III and not yet developed detectable levels of antibody (most infected persons are expected to seroconvert 6-12 weeks after exposure), it may be acceptable and prudent to offer testing to the exposed health care worker. Retesting when possible an antibody negative source at three months would also assist in determining the need to continue serological assessment of the health care worker. In addition, since some individuals may experience considerable anxiety as a result of an exposure to blood or other body fluids of a patient, serial testing for these individuals may result in significant alleviation of their apprehensions.

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.

In cases where the source is antibody positive or later seroconverts, or the health care worker opts to be serially tested following an exposure to a negative or unknown source, the health care worker should be counseled on how s/he may avoid exposure of other individuals during sexual relations, to delay pregnancy until successful completion of the recommended series of examinations, to avoid sharing needles or other implements that may be contaminated with blood (e.g., razors, toothbrushes), and to inform dental and medical personnel of the potential exposure so that appropriate precautions could be taken in providing health care to the individual (e.g., protection of health care workers, contraindications for use of immunosuppressive drugs or live virus vaccines).

Health care workers who routinely have direct blood exposures when caring for patients and who work with sharp instruments or needles contaminated with blood may be at higher risk than other health care workers of acquiring an HTLV-III infection and transmitting the infection to those in their care. Examples of health care workers who may be at higher risk are surgeons, dentists, dental hygienests, hemodialysis nurses and others who perform invasive procedures. There is evidence of hepatitis B virus transmission from health care workers in situations in which they exhibited high concentrations of hepatitis B virus in their blood and sustained a puncture would while performing traumatic procedures on patients, or had exudative or weeping lesions that allowed viral contamination of instruments or entrance of the hepatitis B virus into open wounds of the patients. The risk of hepatitis B virus transmission in health care settings, however, exceeds the risk of HTLV-III transmission. To date there is no evidence of an infected health care worker having transmitted HTLV-III to a patient. A theoretical risk exists in situations where there is a high degree of trauma to a patient and access of blood or serous fluid from the infected health care worker to the open tissue of the patient.

In the event that a patient has mucous membrane or parenteral exposure to body fluids of a health care worker, the patient may wish to know the antibody status of the health care worker. The patient should be informed of the incident and the health care worker should be encouraged to be tested. The follow-up protocols should be the same as those recommended for the exposed health care worker.

Recommendation 50: Patient Exposure to a Potentially Infected Health Care Worker

If a patient sustains mucous membrane or parenteral exposure to body fluid of a health care worker, the patient should be informed of the incident. The health care worker should be strongly encouraged to voluntarily consent to testing and clinical evaluation, and should have the option of not learning the results of the tests. The testing protocols and precautions to be taken are discussed in Recommendation 49.

Section Nine: Reporting Requirements for HTLV-III Infections

Confirmed and suspect cases of AIDS are reportable to the Division of Health and have been since August 1983 under Wisconsin Statute 143.04. Wisconsin Act 73 does not affect statute 143.04 as it relates to reporting of suspected or diagnosed cases of AIDS. Cases should be reported to the Division of Health utilizing the DOH case report form (see Appendix K). Case reports meeting the CDC definition for a case of AIDS (see Appendix A) are forwarded to the CDC with individual case identifying information removed.

Recommendation 51: Reporting Confirmed and Suspect Cases of AIDS

> Health care providers should report all confirmed and suspected cases of AIDS, in accordance with Wisconsin Statute 143.04, to the Division of Health utilizing the AIDS case report form DOH 4264.

Wisconsin Act 73 requires that all validated positive HTLV-III antibody test results be reported to the state epidemiologist. A copy of the state epidemiologist's definition of a validated positive test for the presence of antibody to HTLV-III is included in Appendix L and a copy of the report form is included in Appendix M.

Specifically, the Wisconsin Statute 146.025 requires that:

1. When a positive, validated test result for the presence of antibody to HTLV-III is obtained from a test subject, the health care provider, blood bank, blood center or plasma center that maintains a record of the test results must report directly to the state epidemiologist the following information:

    a. The name and address of the reporting health care provider, blood bank, blood center or plasma center.

    b. The name and address of the subject's health care provider, if known.

    c. The name, address, telephone number, age or date of birth, race and ethnicity, sex and county of residence of the test subject, if known.

    d. The date on which the test was performed.

    e. The test result.

    f. Any additional information required on the report form by the state epidemiologist for the purpose of exercising surveillance, control and prevention of HTLV-III infections.

2. The report of an HTLV-III antibody may <u>not</u> include any of the following.

    a. Information with respect to the sexual orientation of the test subject.

    b. The identity of persons with whom the test subject may have had sexual contact.

Recommendation 52: Reporting of HTLV-III Antibody Positive Test Results

Case information regarding a positive HTLV-III test result should be reported, in accordance with Wisconsin Statute 146.025, directly to the state epidemiologist utilizing the HTLV-III antibody test report form DOH 4338.

Section Ten: Referral Services and Discharge Planning

At the time of discharge, the characteristics and needs of individuals with HTLV-III infections may vary greatly depending upon the nature of the symptoms and physical or neurological disabilities. Even following discharge, their health status, level of functioning and basic service needs (medical, housing, social services and social/psychological support) may continue to fluctuate. The Division of Health has developed the following materials which should assist persons in identifying community services available to persons with HTLV-III infections.

- Organizations providing service to persons at risk for AIDS.
- Care for the chronically ill: Services for people with AIDS in Wisconsin.
- Applying for Social Security benefits: The basic facts for persons with AIDS.

These materials may be requested from the Division of Health by writing or calling:

AIDS/HTLV-III Activity
Bureau of Community Health and Prevention
Wisconsin Division of Health
P O BOX 309
MADISON WI 53701-0309
608/267-5287

Recommendation 53: Discharge Planning

The institution social service department should identify and establish contacts with appropriate community resources for persons with HTLV-III infections. The institution social service department should be involved with establishing a discharge plan for persons with HTLV-III infections prior to the date of discharge. The discharge plan should address the four basic service needs of a person with an HTLV-III infection: medical, housing, social services and social/psychological support.

Recommendation 54: Disclosure of Medical Information at Discharge

All patients with HTLV-III infections should be encouraged to sign a consent for disclosure of their HTLV-III infection diagnosis prior to their discharge so that appropriate persons in their new living setting may be informed. If a patient is discharged to live in a group setting, the fact that a patient has an HTLV-III infection should be disclosed to the medical director of that new setting. If there is no health care provider serving this setting (e.g., group home), the administrator of this setting should be informed of the need for all persons to observe blood and body fluid precautions regarding this patient. The patient's actual diagnosis may only be released to non-health care providers with the patient's specific consent for that disclosure.

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Appendix A

The Case Definition of AIDS Used by CDC for National Reporting (CDC Reportable AIDS) August 1, 1985

For the limited purposes of national reporting of some of the severe late manifestations of infection with human T-cell lymphotropic virus type III/ lymphadenopathy-associated virus (HTLV-III/LAV) in the United States, CDC defines a case of "acquired immunodeficiency syndrome" (AIDS) as an illness characterized by:

I. One or more of the opportunistic diseases listed below (diagnosed by methods considered reliable) that are at least moderately indicative of underlying cellular immunodeficiency, and

II. Absence of all known underlying causes of cellular immunodeficiency (other than HTLV-III/LAV infection) and absence of all other causes of reduced resistance reported to be associated with at least one of those opportunistic diseases.

Despite having the above, patients are excluded as AIDS cases if they have negative result(s) on testing for serum antibody to HTLV-III/LAV*, do not have a positive culture for HTLV-III/LAV, and have both a normal or high number of T-helper (OKT4 or LEU3) lymphocytes and a normal or high ratio of T-helper to T-suppressor (OKT8 or LEU2) lymphocytes. In the absence of test results, patients satisfying all other criteria in this definition are included as cases.

This general case definition may be made more explicit by specifying:

I. The particular diseases considered at least moderately indicative of cellular immunodeficiency, which are used as indicators of AIDS, and

II. The known causes of cellular immunodeficiency, or other causes of reduced resistance reported to be associated with particular diseases, which would disqualify a patient as an AIDS case.

This specification is as follows:

I. <u>Diseases at least moderately indicative of underlying cellular immunodeficiency</u>:

In the following list of diseases, the required diagnostic methods with positive results are shown in parentheses. "Microscopy" may include cytology.

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* A single negative test for HTLV-III/LAV may be applied here if it is an antibody test by ELISA, immunofluorescent, or Western blot methods, because such tests are very sensitive. Viral cultures are less sensitive but more specific, and so may be relied on if positive but not if negative. If multiple antibody tests have inconsistent results, the result applied to the case definition should be that of the majority. A positive culture, however, would overrule negative antibody tests.

A. Protozoal and Helminthic Infections:

1. Cryptosporidiosis, intestinal, causing diarrhea for over 1 month (on histology or stool microscopy).

2. Pneumocystis carinii pneumonia (on histology, or microscopy of a "touch" preparation, bronchial washings, or sputum).

3. Strongyloidosis, causing pneumonia, central nervous system infection, or infection disseminated beyond the gastrointestinal tract (on histology).

4. Toxoplasmosis, causing infection in internal organs other than liver, spleen, or lymph nodes (on histology or microscopy of a "touch" preparation).

B. Fungal Infections:

1. Candidiasis, causing esophagitis (on histology, or microscopy of a "wet" preparation from the esophagus, or endoscopic or autopsy findings of white plaques on an erythematous mucosal base, but not by culture alone).

2. Cryptococcosis, causing central nervous system or other infection disseminated beyond lungs and lymph nodes (on culture, antigen detection, histology, or India ink preparation of CSF).

C. Bacterial Infections:

1. Mycobacterium avium or intracellulare (Mycobacterium avium complex), or Mycobacterium kansasii, causing infection disseminated beyond lungs and lymph nodes (on culture).

D. Viral Infections:

1. Cytomegalovirus, causing infection in internal organs other than liver, spleen, or lymph nodes (on histology or cytology, but not by culture or serum antibody titer).

2. Herpes simplex virus, causing chronic mucocutaneous infection with ulcers persisting more than 1 month, or pulmonary, gastrointestinal tract (beyond mouth, throat, or rectum), or disseminated infection (but not encephalitis alone) (on culture, histology, or cytology).

3. Progressive multifocal leukoencephalopathy (presumed to be caused by Papovavirus) (on histology).

E. Cancer:

1. Kaposi's sarcoma (on histology).

2. Lymphoma limited to the brain (on histology).

F. Other Opportunistic Infections With Positive Test For HTLV-III/LAV*:

In the absence of the above opportunistic diseases, any of the following diseases is considered indicative of AIDS if the patient had a positive test for HTLV-III/LAV*:

1. Disseminated histoplasmosis (on culture, histology, or cytology).

2. Bronchial or pulmonary candidiasis (on microscopy or visualization grossly of characteristic white plaques on the bronchial mucosa, but not by culture alone).

3. Isosporiasis, causing chronic diarrhea (over 1 month) (on histology or stool microscopy).

G. Chronic Lymphoid Interstitial Pneumonitis:

In the absence of the above opportunistic diseases, a histologically confirmed diagnosis of chronic (persisting over 2 months) lymphoid interstitial pneumonitis in a child (under 13 years of age) is indicative of AIDS unless test(s) for HTLV-III/LAV are negative.* The histologic examination of lung tissue must show diffuse interstitial and peribronchiolar infiltration by lymphocytes, plasma cells with Russell bodies, plasmacytoid lymphocytes and immunoblasts. Histologic and culture evaluation must not identify a pathogenic organism as the cause of this pneumonia.

H. Non-Hodgkin's Lymphoma With Positive Test For HTLV-III/LAV*:

If the patient had a positive test for HTLV-III/LAV*, then the following histologic types of lymphoma are indicative of AIDs, regardless of anatomic site:

1. Small noncleaved lymphoma (Burkitt's tumor or Burkitt-like lymphoma), but not small cleaved lymphoma.

2. Immunoblastic sarcoma (or immunoblastic lymphoma) of B-cell or unknown immunologic phenotype (not of T-cell type). Other terms which may be equivalent include: diffuse undifferentiated non-Hodgkin's lymphoma, large cell lymphoma (cleaved or noncleaved), diffuse histiocytic lymphoma, reticulum cell sarcoma, and high-grade lymphoma.

Lymphomas should not be accepted as indicative of AIDS if they are described in any of the following ways: low grade, of T-cell type (immunologic phenotype), small cleaved lymphoma, lymphocyte lymphoma (regardless of whether well or poorly differentiated), lymphoblastic lymphoma, plasmacytoid lymphocytic lymphoma, lymphocytic leukemia (acute or chronic), or Hodgkin's disease (or Hodgkin's lymphoma).

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* A positive test for HTLV-III/LAV may consist of a reactive test for antibody to HTLV-III/LAV or a positive culture (isolation of HTLV-III/LAV from a culture of the patient's peripheral blood lymphocytes). If multiple antibody tests have inconsistent results, the result applied to the case definition should be that of the majority done by the ELISA, immunofluorescent, or Western blot methods. A positive culture, however, would overrule negative antibody tests.

II. Known Causes of Reduced Resistance:

Known causes of reduced resistance to diseases indicative of immunodeficiency are listed in the left column, while the diseases that may be attributable to these causes (rather than to the immunodeficiency caused by HTLV-III/LAV infection) are listed on the right:

Known Causes of Reduced Resistance	Diseases Possibly Attributable to the Known Causes of Reduced Resistance
1. Systemic corticosteroid therapy	Any infection diagnosed during or within 1 month after discontinuation of the corticosteroid therapy, unless symptoms specific for an infected anatomic site (e.g., dyspnea for pneumonia, headache for encephalitis, diarrhea for colitis) began before the corticosteroid therapy or any cancer diagnosed during or within 1 month after discontinuation of more than 4 months of long term corticosteroid therapy, unless symptoms specific for the anatomic sites of the cancer (as described above) began before the long term corticosteroid therapy
2. Other immunosuppressive or cytotoxic therapy	Any infection diagnosed during or within 1 year after discontination of the immunosuppressive therapy, unless symptoms specific for an infected anatomic site (as described above) began before the therapy or any cancer diagnosed during or within 1 year after discontinuation of more than 4 months of long term immunosuppressive therapy, unless symptoms specific for the anatomic sites of the cancer (as described above) began before the long term therapy
3. Cancer of lymphoreticular or histiocytic tissue such as lymphoma (except for lymphoma localized to the brain), Hodgkin's disease, lymphocytic leukemia, or multiple myeloma	Any infection or cancer, if diagnosed after or within 3 months before the diagnosis of the cancer of lymphoreticular or histiocytic tissue

Known Causes of Reduced Resistance	Diseases Possibly Attributable to the Known Causes of Reduced Resistance
4. Age 60 years or older at diagnosis	Kaposi's sarcoma, but not if the patient has a positive test for HTLV-III/LAV
5. Age under 28 days (neonatal) at diagnosis	Toxoplasmosis or herpes simplex virus infection, as described above
6. Age under 6 months at diagnosis	Cytomegalovirus infection, as described above
7. An immunodeficiency atypical of AIDS, such as one involving hypogammaglobulinemia or angioimmunoblastic lymphadenopathy; or an immunodeficiency of which the cause appears to be a genetic or developmental defect, rather than HTLV-III/LAV infection	Any infection or cancer diagnosed during such immunodeficiency
8. Exogenous malnutrition (starvation due to food deprivation, not malnutrition due to malabsorption or illness)	Any infection or cancer diagnosed during or within 1 month after discontinuation of starvation

Appendix B

Definition of AIDS Related Complex (ARC)

At least two of the following clinical signs/symptoms lasting three of more months PLUS two or more of the following laboratory abnormalities, occurring in a patient in a cohort at increased risk for developing AIDS and having no underlying infectious cause for the symptoms.

Clinical

1. Fever: > 100° F, intermittent or continuous, for at least 3 months, in the absence of other identifiable cause.

2. Weight Loss: 10 percent normal body weight or ≥ 15 pounds.

3. Lymphadenopathy: persistent over at least 3 months, involving ≥ 2 extrainguinal node-bearing areas.

4. Diarrhea: intermittent or continous, ≥ 3 months, in the absence of other identifiable cause.

5. Fatigue: to the point of decreased physical or mental function.

6. Night Sweats: intermittent or continuous, ≥ 3 months, in the absence of other identifiable cause.

Laboratory

1. Depressed helper T-cells (≥ 2 standard deviations below the mean).

2. Depressed helper/supressor ratio (≥ 2 standard deviations below the mean).

3. At least one of the following: leukopenia, thrombocytopenia, absolute lymphopenia or anemia.

4. Elevated serum globulins.

5. Depressed blastogenesis (Pokeweed, phytohemagglutinin [PHA] mitogens).

6. Abnormal intradermal tests for delayed cutaneous hypersensitivity (using Multi-Test or equivalent).

Reprinted by The Wisconsin Division of Health
from MMWR, September 27, 1985

Update: Evaluation of Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus Infection in Health-Care Personnel — United States

The occurrence of the acquired immunodeficiency syndrome (AIDS) in intravenous (IV) drug users, blood transfusion recipients, and persons with hemophilia indicates that parenteral transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV) occurs via infectious blood or blood products (*1*). Currently available practices have nearly eliminated these risks for transfusion recipients and persons with hemophilia (*2,3*). Because health-care personnel may be inadvertently exposed to the blood of AIDS patients, several studies have been conducted to determine the prevalence of HTLV-III/LAV antibodies in health-care personnel who have cared for these patients (*4-10*). Combining published results with data reported to CDC shows that, to date, 1,758 health-care workers participating in such studies have been tested for antibodies to HTLV-III. Twenty-six (1.5%) were seropositive, and all but three of these persons belonged to groups recognized to be at increased risk for AIDS. Epidemiologic information is not available for one of these three health-care workers who was tested anonymously. Because of the high level of interest in these studies and in the potential for occupational transmission of HTLV-III/LAV through parenteral and mucosal routes, the case histories for these two health-care workers are reported below.

Patient 1. A female health-care worker was tested for serum antibodies to HTLV-III in November 1984 as part of a study of hospital personnel. She had sustained accidental needlestick injuries in November 1983 and March 1984 (12 months and 8 months before) while drawing blood from patients with AIDS . At the time of enrollment in the study, serum antibodies to HTLV-III were detected by enzyme immunoassay (EIA) and Western blot techniques. No serum obtained before or within 12 months after the needlesticks was available for testing. She was in good health until June 1984, when she developed mild but persistent lymphadenopathy, most marked in the axilla. Beginning in August 1984, she experienced intermittent diarrhea. When interviewed by a physician, the patient denied IV drug use or blood transfusions and reported being heterosexually monogamous since 1981. Her long-term sex partner denied homosexual activity, IV drug use, or other known risk factors when interviewed separately. Although repeatedly antibody negative by EIA and Western blot methods over an 8-month period, HTLV-III was recovered from his peripheral lymphocytes in April 1985 but could not be recovered from lymphocytes obtained several months later.

Patient 2. A male laboratory worker was discovered to be lymphopenic after he volunteered to be tested in conjunction with a study in April 1985. At that time, he had serum antibodies to HTLV-III by EIA and Western blot methods. No previous blood samples were available for testing. As part of his job, he processed platelets pooled from individual donors for transfusion. In December 1983, he sustained an accidental cut on the hand while processing blood from a patient with leukemia. He also sustained an accidental needlestick injury in August 1984 while processing a unit of pooled platelets. Both incidents resulted in parenteral exposure to blood from other persons. It is not known whether any of the individual platelet donors or the patient with leukemia had HTLV-III infection. The health-care worker is asymptomatic, although he had transient cervical lymphadenopathy during early 1985. HTLV-III was recovered from his peripheral blood lymphocytes in September 1985. During three independent interviews, he denied any homosexual activity, IV drug use, foreign travel, or blood transfusions. He described himself as heterosexual and was not aware that any of his approximately 12 lifetime sex partners had AIDS or were at increased risk for HTLV-III/LAV infection.

Reported by J Nadler, MD, S Landesman, MD, D Rechtman, MD, S Holman, MS, New York City, New York; J Groopman, MD, Boston, G Seage, MPH, Boston Dept of Health and Hospitals, G Grady, MD, Massachusetts Dept of Health; J Gerberding, MD, San Francisco, California; Environmental Epidemiology Br, Laboratory of Tumor Cell Biology, National Cancer Institute, National Institutes of Health; Hospital Infections Program, AIDS Br, Div of Viral Diseases, Center for Infectious Diseases, CDC.

Editorial Note: These two health-care workers probably represent occupational transmission of HTLV-III/LAV due to parenteral exposure, although in neither was a preexposure serum sample available to date the onset of infection. Although not reported during investigations of these two cases, it is difficult to totally assure that additional risk factors for AIDS were absent. For purposes of epidemiologic surveillance, a case of occupationally acquired HTLV-III/LAV infection should ideally include all the following features: a worker with no identifiable risk factors for AIDS whose serum, obtained within several days of the date of a possible occupational exposure, is negative for antibody to HTLV-III/LAV but whose follow-up serum, in absence of interim exposure to other risk factors, is positive for antibody to HTLV-III/LAV. The two cases reported here do not fully meet these ideal criteria. However, there is one published report from England of a nurse who developed HTLV-III/LAV antibody following an accidental needlestick injury (*11*). Her serum was negative for antibody to HTLV-III/LAV at the time of exposure. This nurse reportedly had none of the recognized risk factors for AIDS and was asymptomatic at the time the report was published.

The two cases reported here represent the only known evidence of probable occupational transmission of HTLV-III/LAV in the United States. This confirms that the risk of transmission of HTLV-III/LAV infection to health-care workers from patients is extremely low (*4-10*). HTLV-III/LAV infections appear to be much less transmissible through needlesticks than hepatitis B; nearly 26% of persons comparably exposed to a hepatitis B surface antigen-positive patient develop infection (*12*). Nonetheless, personnel should follow recommendations designed to minimize the risk of exposure to parenteral or mucosal (e.g., blood spatter on conjunctiva) contact with potentially infectious materials from patients with AIDS or suspected AIDS (*13,14*).

Epidemiologic studies of needlestick injuries in hospital personnel indicate that over 40% of the accidents are potentially preventable if recommended precautions are followed when handling used needles or other sharp objects (*6*). Educational programs to familiarize health-care workers with the basic practices in infection control are essential to the prevention of AIDS and other infections. Health-care workers and others should become familiar with and follow recommended precautions when handling specimens, secretions, and excretions from persons known to be infected with HTLV-III/LAV. Health-care personnel whose serum is positive for HTLV-III/LAV antibody should follow the precautions that have been published for health-care workers with AIDS (*15*).

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REPRINTED FROM
MORBIDITY AND MORTALITY WEEKLY REPORT
June 7, 1985 / Vol. 34 / No. 22
Pages 313-324 & 329-335

Recommendation of the Immunization Practices Advisory Committee (ACIP)

Recommendations for Protection Against Viral Hepatitis

*The following statement updates all previous recommendations on use of immune globulins for protection against viral hepatitis (*MMWR *1981;30:423-35) and use of hepatitis B vaccine and hepatitis B immune globulin for prophylaxis of hepatitis B (*MMWR *1982;31:317-28 and* MMWR *1984;33:285-90).*

INTRODUCTION

The term "viral hepatitis" is commonly used for several clinically similar diseases that are etiologically and epidemiologically distinct (*1*). Two of these, hepatitis A (formerly called infectious hepatitis) and hepatitis B (formerly called serum hepatitis) have been recognized as separate entities since the early 1940s and can be diagnosed with specific serologic tests. The third, currently known as non-A, non-B hepatitis, is probably caused by at least two different agents, and lacking specific diagnostic tests, remains a disease diagnosed by exclusion. It is an important form of acute viral hepatitis in adults and currently accounts for most posttransfusion hepatitis in the United States. An epidemic type of non-A, non-B hepatitis, which is probably spread by the fecal-oral route and is different from the types seen in the United States, has been described in parts of Asia and North Africa (*2*).

A fourth type of hepatitis, delta hepatitis, has recently been characterized as an infection dependent on hepatitis B virus. It may occur as a coinfection with acute hepatitis B infection or as superinfection of a hepatitis B carrier (*3*).

HEPATITIS SURVEILLANCE

Approximately 21,500 cases of hepatitis A, 24,300 cases of hepatitis B, 3,500 cases of non-A, non-B hepatitis, and 7,100 cases of hepatitis type unspecified were reported in the United States in 1983. Most cases of each type occur among young adults. Since reporting from many localities is incomplete, the actual number of hepatitis cases occurring annually is thought to be several times the reported number.

IMMUNE GLOBULINS

Immune globulins used in medical practice are sterile solutions of antibodies (immunoglobulins) from human plasma. They are prepared by cold ethanol fractionation of large plasma pools and contain 10%-18% protein. In the United States, plasma is primarily obtained from professional donors. Only plasma shown to be free of hepatitis B surface antigen (HBsAg) is used to prepare immune globulins.

Immune globulin (IG) (formerly called "immune serum globulin," ISG, or "gamma globulin") produced in the United States contains antibodies against the hepatitis A virus (anti-HAV) and the hepatitis B surface antigen (anti-HBs). Tests of IG lots prepared since 1977 indicate that both types of antibody have uniformly been present. Hepatitis B immune globulin (HBIG) is an IG prepared from plasma containing high titers of anti-HBs.

Neither IG nor HBIG commercially available in the United States transmits hepatitis or other viral infections. There is no evidence that the causative agent of AIDS (human T-lymphotropic virus type III/lymphadenopathy-associated virus [HTLV-III/LAV]) has been transmitted by IG or HBIG (*4*).

Serious adverse effects from immune globulins administered as recommended have been exceedingly rare. Standard immune globulins are prepared for intramuscular use and should not be given intravenously. Two preparations for intravenous use in immunodeficient and other selected patients have recently become available in the United States but are not recommended for hepatitis prophylaxis. Immune globulins are not contraindicated for pregnant women.

HEPATITIS A

Hepatitis A is caused by the hepatitis A virus (HAV), a 27-nm ribonucleic acid (RNA) agent that is a member of the picornavirus family. The illness caused by HAV characteristically has an abrupt onset with fever, malaise, anorexia, nausea, abdominal discomfort, and jaundice. Severity is related to age. In children, most infections are asymptomatic, and illness is usually not accompanied by jaundice. Most infected adults become symptomatically ill with jaundice. Fatality among reported cases is infrequent (about 0.6%).

Hepatitis A is primarily transmitted by person-to-person contact, generally through fecal contamination. Transmission is facilitated by poor personal hygiene, poor sanitation, and intimate (intrahousehold or sexual) contact. Common-source epidemics from contaminated food and water also occur. Sharing utensils or cigarettes or kissing are not believed to transmit the infection.

The incubation period of hepatitis A is 15-50 days (average 28-30). High concentrations of HAV (10^8 particles/g) are found in stools of infected persons. Fecal virus excretion reaches its highest concentration late in the incubation period and early in the prodromal phase of illness, and diminishes rapidly once jaundice appears. Greatest infectivity is during the 2-week period immediately before the onset of jaundice. Viremia is of short duration; virus has not been found in urine or other body fluids. A chronic carrier state with HAV in blood or feces has not been demonstrated. Transmission of HAV by blood transfusion has occurred but is rare.

The diagnosis of acute hepatitis A is confirmed by finding IgM-class anti-HAV in serum collected during the acute or early convalescent phase of disease. IgG-class anti-HAV, which appears in the convalescent phase of disease and remains detectable in serum thereafter, apparently confers enduring protection against disease. Commercial tests are available to detect IgM anti-HAV and total anti-HAV in serum.

Although the incidence of hepatitis A in the United States has decreased over the last 15 years, it is still a common infection in older children and young adults. About 38% of reported hepatitis cases in this country are attributable to hepatitis A.

Recommendations for IG prophylaxis of hepatitis A. Numerous field studies conducted in the past 4 decades confirm that IG given before exposure or during the incubation period of hepatitis A is protective against clinical illness (*5-7*). Its prophylactic value is greatest (80%-90%) when given early in the incubation period and declines thereafter (*7*).

Preexposure prophylaxis. The major group for whom preexposure prophylaxis is recommended is international travelers. The risk of hepatitis A for U.S. citizens traveling abroad varies with living conditions, incidence of hepatitis A infection in areas visited, and length of stay (*8,9*). In general, travelers to developed areas of western Europe, Japan, and Australia are at no greater risk of infection than in the United States. In contrast, travelers to developing countries may be at significant risk of infection. In such areas, the best way to prevent hepatitis A and other enteric diseases is to avoid potentially contaminated water or food. Drinking water (or beverages with ice) of unknown purity and eating uncooked shellfish or uncooked fruits or vegetables that are not peeled (or prepared) by the traveler should be avoided.

IG is recommended for travelers to developing countries if they will be eating in settings of poor or uncertain sanitation (some restaurants or homes) or will be visiting extensively with local persons, especially young children, in settings with poor sanitary conditions. Persons who plan to reside in developing areas for long periods should receive IG regularly if they anticipate exposure as described above or will be living in rural areas with poor sanitation.

For such travelers, a single dose of IG of 0.02 ml/kg is recommended if travel is for less than 2 months. For prolonged travel, 0.06 ml/kg should be given every 5 months. For persons who require repeated IG prophylaxis, screening for total anti-HAV antibodies before travel may be useful to define susceptibility and eliminate unnecessary doses of IG in those who are immune.

Postexposure prophylaxis. A serologic test for the diagnosis of acute hepatitis A is now widely available. Since only 38% of acute hepatitis cases in the United States result from hepatitis A, serologic confirmation of hepatitis A in the index case is recommended before treatment of contacts. Serologic screening of contacts for anti-HAV before giving IG is not recommended because screening is more costly than IG and would delay its administration.

IG should be given as soon as possible after exposure; giving IG more than 2 weeks after exposure is not indicated.

Specific recommendations for IG prophylaxis of hepatitis A depend on the nature of the HAV exposure:

1. *Close personal contact.* IG is recommended for all household and sexual contacts of persons with hepatitis A.
2. *Day-care centers.* Day-care facilities with children in diapers can be important settings for HAV transmission (*10-12*). IG should be administered to all staff and attendees of day-care centers or homes if: (a) one or more hepatitis A cases are recognized among children or employees; or (b) cases are recognized in two or more households of center attendees. When an outbreak (hepatitis cases in three or more families) occurs, IG should also be considered for members of households whose diapered children attend. In centers not enrolling children in diapers, IG need only be given to classroom contacts of an index case.
3. *Schools.* Contact at elementary and secondary schools is usually not an important means of transmitting hepatitis A. Routine administration of IG is not indicated for pupils and teachers in contact with a patient. However, when epidemiologic study clearly shows the existence of a school- or classroom-centered outbreak, IG may be given to those who have close personal contact with patients.
4. *Institutions for custodial care.* Living conditions in some institutions, such as prisons and facilities for the developmentally disabled, favor transmission of hepatitis A. When outbreaks occur, giving IG to residents and staff who have close contact with patients with hepatitis A may reduce the spread of disease. Depending on the epidemiologic circumstances, prophylaxis can be limited in extent or can involve the entire institution.
5. *Hospitals.* Routine IG prophylaxis for hospital personnel is not indicated. Rather, sound hygienic practices should be emphasized. Staff education should point out the risk of exposure to hepatitis A and emphasize precautions regarding direct contact with potentially infective materials (*13*).

   Outbreaks of hepatitis A among hospital staff occur occasionally, usually in association with an unsuspected index patient who is fecally incontinent. Large outbreaks have occurred among staff and family contacts of infected infants in neonatal intensive-care units. In outbreaks, prophylaxis of persons exposed to feces of infected patients may be indicated.
6. *Offices and factories.* Routine IG administration is not indicated under the usual office or factory conditions for persons exposed to a fellow worker with hepatitis A. Experience shows that casual contact in the work setting does not result in virus transmission.
7. *Common-source exposure.* IG might be effective in preventing foodborne or waterborne hepatitis A if exposure is recognized in time. However, IG is not recommended for persons exposed to a common source of hepatitis infection after cases have begun to occur in those exposed, since the 2-week period during which IG is effective will have been exceeded.

   If a foodhandler is diagnosed as having hepatitis A, common-source transmission is possible but uncommon. IG should be administered to other foodhandlers but is usually not recommended for patrons. However, IG administration to patrons may be considered if (a) the infected person is directly involved in handling, without gloves, foods that will not be cooked before they are eaten; (b) the hygienic practices of the foodhandler are deficient; and (c) patrons can be identified and treated within 2 weeks of exposure. Situations where repeated exposures may have occurred, such as in institutional cafeterias, may warrant stronger consideration of IG use.

   For postexposure IG prophylaxis, a single intramuscular dose of 0.02 ml/kg is recommended.

HEPATITIS B

Hepatitis B virus (HBV) infection is a major cause of acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma worldwide. The frequency of HBV infection and patterns of transmission vary markedly in different parts of the world. In the United States, western Europe, and Australia, it is a disease of low endemicity, with only 0.1%-0.5% of the population being virus carriers and infection occurring primarily during adulthood. In contrast, HBV infection is highly endemic in China and Southeast Asia, sub-Saharan Africa, most Pacific islands, and the Amazon Basin; in these areas,

5%-15% of the population carry the virus, and most persons acquire infection at birth or during childhood. In other parts of the world, HBV is moderately endemic, and 1%-4% of persons are HBV carriers. Recommendations for prophylaxis of hepatitis B will vary in accordance with local patterns of HBV transmission. The recommendations that follow are intended for use in the United States.

Hepatitis B infection is caused by the HBV, a 42-nm, double-shelled deoxyribonucleic acid (DNA) virus. Several well-defined antigen-antibody systems have been associated with HBV infection (Table 1). HBsAg, formerly called "Australia antigen" or "hepatitis-associated antigen," is found on the surface of the virus and on accompanying 22-nm spherical and tubular forms. HBsAg can be identified in serum 30-60 days after exposure to HBV and persists for variable periods. The various subtypes (adr, adw, ayw, ayr) of HBsAg provide useful epidemiologic markers. Antibody against HBsAg (anti-HBs) develops after a resolved infection and is responsible for long-term immunity. Anti-HBc, the antibody to the core antigen (an internal component of the virus), develops in all HBV infections and persists indefinitely. IgM anti-HBc appears early in infection and persists for 6 or more months; it is a reliable marker of acute or recent HBV infection. The hepatitis B e antigen (HBeAg) is a third antigen, presence of which correlates with HBV replication and high infectivity. Antibody to HBeAg (anti-HBe) develops in most HBV infections and correlates with lower infectivity.

The onset of acute hepatitis B is generally insidious. Clinical symptoms and signs include various combinations of anorexia, malaise, nausea, vomiting, abdominal pain, and jaundice. Skin rashes, arthralgias, and arthritis can also occur. Overall fatality rates for reported cases generally do not exceed 2%. The incubation period of hepatitis B is long—45-160 days (average 60-120).

HBV infection in the United States. The estimated lifetime risk of HBV infection in the United States varies from almost 100% for the highest-risk groups to approximately 5% for the population as a whole. An estimated 200,000 persons, primarily young adults, are infected each year. One-quarter become ill with jaundice; more than 10,000 patients require hospitalization; and an average of 250 die of fulminant disease each year. Between 6% and 10% of young adults with HBV infection become carriers. The United States currently contains an estimated pool of 500,000-1,000,000 infectious carriers. Chronic active hepatitis develops in over 25% of carriers and often progresses to cirrhosis. Furthermore, HBV carriers have a risk of developing primary liver cancer that is 12-300 times higher than that of other persons. It is estimated that 4,000 persons die from hepatitis B-related cirrhosis each year in this country and that more than 800 die from hepatitis B-related liver cancer.

The role of the HBV carrier is central in the epidemiology of HBV transmission. A carrier is defined as a person who is HBsAg-positive on at least two occasions at least 6 months apart. Although the degree of infectivity is best correlated with HBeAg-positivity, any person positive for HBsAg is potentially infectious. The likelihood of developing the carrier state varies inversely with the age at which infection occurs. During the perinatal period, HBV transmitted from HBeAg-positive mothers results in HBV carriage in up to 90% of infected infants, whereas 6%-10% of acutely infected adults become carriers.

Carriers and persons with acute infection have highest concentrations of HBV in the blood and serous fluids; less is present in other body fluids, such as saliva and semen. Transmission occurs via percutaneous or permucosal routes. Infective blood or body fluids can be introduced by contaminated needles or through sexual contact. Infection can occur in settings of continuous close personal contact, such as in households or among children in institutions for the mentally retarded, presumably via inapparent or unnoticed contact of infectious secretions with skin lesions or mucosal surfaces. Transmission of infection by transfusion of contaminated blood or blood products has been greatly reduced since the advent of routine screening with highly sensitive tests for HBsAg. HBV is not transmitted via the fecal-oral route or by contamination of food or water.

Serologic surveys demonstrate that, although HBV infection is uncommon among adults in the general population, it is highly prevalent in certain groups. Those at risk, based on the prevalence of serologic markers of infection, are described in Table 2. Immigrants/refugees and their descendants from areas of high HBV endemicity are at high risk of acquiring HBV infection. Homosexually active men and users of illicit injectable drugs are among the highest-risk groups, acquiring infection soon after adopting these lifestyles (10%-20%/year). Inmates of prisons have high prevalence of HBV markers usually because of prior parenteral drug abuse; actual risk of transmission in prisons is also asso-

TABLE 1. Hepatitis nomenclature

Abbreviation	Term	Comments
	Hepatitis A	
HAV	Hepatitis A virus	Etiologic agent of "infectious" hepatitis; a picornavirus; single serotype.
Anti-HAV	Antibody to HAV	Detectable at onset of symptoms; lifetime persistence.
IgM anti-HAV	IgM class antibody to HAV	Indicates recent infection with hepatitis A; positive up to 4-6 months after infection.
	Hepatitis B	
HBV	Hepatitis B virus	Etiologic agent of "serum" or "long-incubation" hepatitis; also known as Dane particle.
HBsAg	Hepatitis B surface antigen	Surface antigen(s) of HBV detectable in large quantity in serum; several subtypes identified.
HBeAg	Hepatitis B e antigen	Soluble antigen; correlates with HBV replication, high titer HBV in serum, and infectivity of serum.
HBcAg	Hepatitis B core antigen	No commercial test available.
Anti-HBs	Antibody to HBsAg	Indicates past infection with and immunity to HBV, passive antibody from HBIG, or immune response from HBV vaccine.
Anti-HBe	Antibody to HBeAg	Presence in serum of HBsAg carrier suggests lower titer of HBV.
Anti-HBc	Antibody to HBcAg	Indicates past infection with HBV at some undefined time.
IgM anti-HBc	IgM class antibody to HBcAg	Indicates recent infection with HBV; positive for 4-6 months after infection.
	Delta hepatitis	
δvirus	Delta virus	Etiologic agent of delta hepatitis; may only cause infection in presence of HBV.
δ-Ag	Delta antigen	Detectable in early acute delta infection.
Anti-δ	Antibody to delta antigen	Indicates past or present infection with delta virus.
	Non-A, non-B hepatitis	
NANB	Non-A, non-B hepatitis	Diagnosis of exclusion. At least two candidate viruses; epidemiology parallels that of hepatitis B.
	Epidemic non-A, non-B hepatitis	
Epidemic NANB	Epidemic non-A, non-B hepatitis	Causes large epidemics in Asia, North Africa; fecal-oral or waterborne.
	immune globulins	
IG	Immune globulin (previously ISG, immune serum globulin, or gamma globulin)	Contains antibodies to HAV, low titer antibodies to HBV.
HBIG	Hepatitis B immune globulin	Contains high titer antibodies to HBV.

ciated with parenteral drug abuse in prisons. Patients and staff in custodial institutions for the mentally retarded are also at increased risk of having HBV infection. Classroom contacts, particularly teachers or instructors, of some deinstitutionalized carriers may also be at higher risk than the general population. Household contacts and sexual partners of HBV carriers are at increased risk, as are hemodialysis patients and recipients of certain pooled plasma products.

There is increased risk for medical and dental workers and related laboratory and support personnel who have contact with blood. Employment in a hospital without exposure to blood carries no greater risk than that for the general population.

Hepatitis B prophylaxis. Two types of products are available for prophylaxis against hepatitis B. Hepatitis B vaccine, licensed in 1981, provides active immunization against HBV infection, and its use is recommended for both pre- and postexposure prophylaxis. IG products provide temporary, passive protection and are indicated only in certain postexposure settings.

IG and HBIG. IG and HBIG contain different amounts of anti-HBs. IG is prepared from plasma that is not preselected for anti-HBs content. Since 1977, all lots tested have contained anti-HBs at a titer of at least 1:100 by radioimmunoassay (RIA). HBIG is prepared from plasma preselected for high-titer anti-HBs. In the United States, HBIG has an anti-HBs titer of higher than 1:100,000 by RIA. There is no evidence that the causative agent of AIDS (HTLV-III/LAV) has been transmitted by IG or HBIG (*4*).

Hepatitis B vaccine. Hepatitis B vaccine licensed in the United States is a suspension of inactivated, alum-adsorbed 22-nm surface antigen particles that have been purified from human plasma by a combination of biophysical (ultracentrifugation) and biochemical procedures. Inactivation is a threefold process using 8M urea, pepsin at pH 2, and 1:4000 formalin. These treatment steps have been shown to inactivate representatives of all classes of viruses found in human blood, including the causative agent of AIDS (HTLV-III/LAV) (*14*). HB vaccine contains 20 μg/ml of HBsAg protein.

After a series of three intramuscular doses of hepatitis B vaccine, over 90% of healthy adults develop protective antibody (*15,16*). A course of three 10-μg doses induces antibody in virtually all infants and children from birth through 9 years of age. The deltoid (arm) is the recommended site for

TABLE 2. Prevalence of hepatitis B serologic markers in various population groups

Population group	Prevalence of serologic markers of HBV infection	
	HBsAg (%)	All markers (%)
High risk		
Immigrants/refugees from areas of high HBV endemicity	13	70-85
Clients in institutions for the mentally retarded	10-20	35-80
Users of illicit parenteral drugs	7	60-80
Homosexually active men	6	35-80
Household contacts of HBV carriers	3-6	30-60
Patients of hemodialysis units	3-10	20-80
Intermediate risk		
Health-care workers—frequent blood contact	1-2	15-30
Prisoners (male)	1-8	10-80
Staff of institutions for the mentally retarded	1	10-25
Low risk		
Health-care workers—no or infrequent blood contact	0.3	3-10
Healthy adults (first-time volunteer blood donors)	0.3	3-5

hepatitis B vaccination in adults; immunogenicity of vaccine in adults is significantly lower when injections are given in the buttock (81%) (*17*). The immunogenicity of the intradermal route has not yet been clearly established.

Field trials of the U.S.-manufactured vaccine have shown 80%-95% efficacy in preventing infection or hepatitis among susceptible persons (*16,18*). Protection against illness is virtually complete for persons who develop adequate antibody levels* after vaccination. The duration of protection and need for booster doses are not yet defined. However, only 10%-15% of persons who develop adequate antibody after three vaccine doses will lose antibody within 4 years, and among those who lose antibody, protection against viremic infection and liver inflammation appears to persist. Immunogenicity and efficacy of the licensed vaccine in hemodialysis patients is much lower than in normal adults; protection may last only as long as adequate antibody levels persist (*19*).

Vaccine usage. Primary vaccination consists of three intramuscular doses of vaccine, with the second and third doses given 1 and 6 months, respectively, after the first. Adults and older children should be given 20 μg (1.0 ml) per dose, while children under 10 years should receive 10 μg (0.5 ml) per dose. For patients undergoing hemodialysis and for other immunosuppressed patients, a 40-μg (2.0-ml) dose should be used. Vaccine doses administered at longer intervals provide equally satisfactory protection, but optimal protection is not conferred until after the third dose. Hepatitis B vaccine should only be given in the deltoid muscle in adults and children or in the anterolateral thigh muscle in infants and neonates. Since hepatitis B vaccine is an inactivated (noninfective) product, it is presumed that there will be no interference with other simultaneously administered vaccines.

Data are not available on the safety of the vaccine for the developing fetus. Because the vaccine contains only noninfectious HBsAg particles, there should be no risk to the fetus. In contrast, HBV infection in a pregnant woman may result in severe disease for the mother and chronic infection for the newborn. Pregnancy should not be considered a contraindication to the use of this vaccine for persons who are otherwise eligible.

Vaccine storage. Vaccine should be stored at 2 C-8 C (36 F-46 F) but not frozen. *Freezing destroys the potency of the vaccine.*

Side effects and adverse reactions. The most common side effect observed in prevaccination trials was soreness at the injection site. Among an estimated 750,000 vaccinees, approximately 100 episodes of severe illness have been reported after receipt of vaccine. These have included arthralgias, neurologic reactions (such as Guillain-Barré syndrome), and other illnesses. The rate of Guillain-Barré syndrome following HB vaccine does not appear to be significantly increased above that observed in normal adults. Such temporally associated illnesses are not considered to be etiologically related to hepatitis B vaccine.

Effect of vaccination on carriers and immune persons. The vaccine produces neither therapeutic nor adverse effects in HBV carriers (*20*). Vaccination of individuals who possess antibodies against HBV from a previous infection is not necessary but will not cause adverse effects. Such individuals will have a postvaccination increase in their anti-HBs levels. Passively acquired antibody, whether from HBIG or IG administration or from the transplacental route, will not interfere with active immunization (*21*).

Prevaccination serologic screening for susceptibility. The decision to screen potential vaccine recipients for prior infection depends on three variables: (1) the cost of vaccination; (2) the cost of testing for susceptibility; and (3) the expected prevalence of immune individuals in the group. Figure 1 shows the relative cost-effectiveness of screening, given different costs of screening tests and the expected prevalence of immunity. In constructing the figure, the assumption was made that the cost of three doses of vaccine is $100 and that there are additional costs for administration. For any combination of screening costs and immunity to hepatitis, the cost-effectiveness can be estimated. For example, if the expected prevalence of serologic markers for HBV is over 20%, screening is cost-effective if costs of screening are no greater than $30 per person. If the expected prevalence of markers is less than 8%, and if the costs of screening are greater than $10 per person, vaccination without screening is cost-effective.

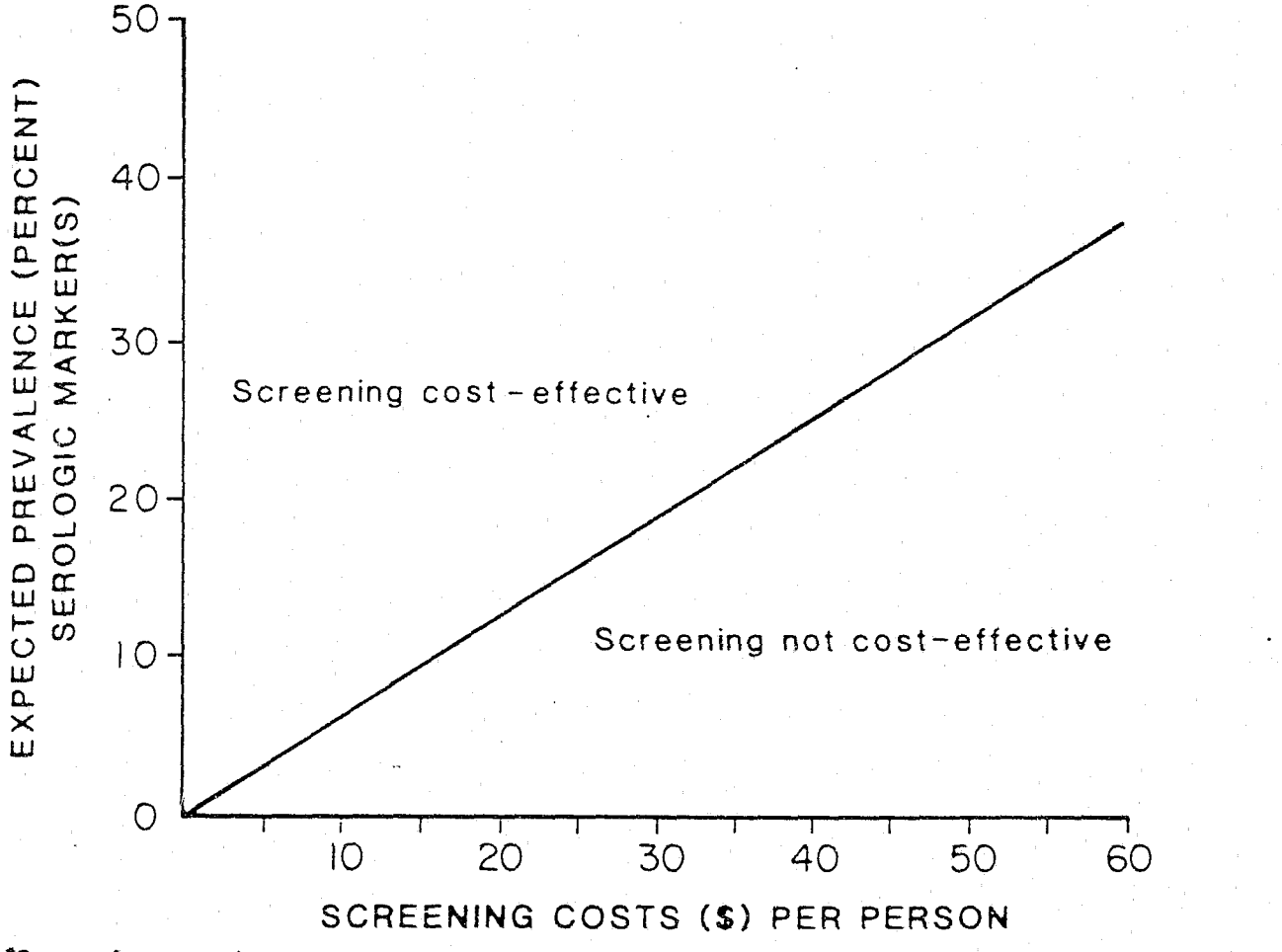
*Adequate antibody is 10 or more sample ratio units (SRU) by RIA or positive by enzyme immunoassay.

Screening in groups with the highest risk of HBV infection (Table 2) will be cost-effective unless testing costs are extremely high. For groups at intermediate risk, cost-effectiveness of screening may be marginal, and vaccination programs may or may not utilize screening. For groups with a low expected prevalence of HBV serologic markers, such as health professionals in their training years, screening will not be cost-effective.

For routine screening, only one antibody test, either anti-HBc or anti-HBs, need be used. Anti-HBc will identify all previously infected persons, both carriers and noncarriers, but will not discriminate between members of the two groups. Anti-HBs will identify those previously infected, except carriers. For groups expected to have carrier rates of under 2%, such as health-care workers, neither test has a particular advantage. For groups with higher carrier rates, anti-HBc may be preferred to avoid unnecessary vaccination of carriers. If the RIA anti-HBs test is used for screening, a minimum of 10 RIA sample ratio units should be used to designate immunity (2.1 is the usual designation of a positive test). If enzyme immunoassay (EIA) is used, the manufacturers' recommended positive is appropriate.

Serologic confirmation of postvaccination immunity and revaccination of nonresponders. When given in the deltoid, hepatitis B vaccine produces protective antibody (anti-HBs) in more than 90% of healthy persons. Testing for immunity following vaccination is not recommended routinely but is advised for persons whose subsequent management depends on knowing their immune status, such as dialysis patients and staff, and for persons in whom a suboptimal response may be anticipated, such as those who have received vaccine in the buttock.

FIGURE 1. Cost-effectiveness of prevaccination screening of hepatitis B virus vaccine candidates*



*See text for assumptions.

Revaccination of persons who do not respond to primary series (nonresponders) produces adequate antibody in only one-third when the primary vaccination has been given in the deltoid. Therefore, revaccination of nonresponders to deltoid injection is not recommended routinely. For persons who did not respond to a primary vaccine series given in the buttock, preliminary data from two small studies suggest that revaccination in the arm induces adequate antibody in over 75%. Revaccination should be strongly considered for such persons.

Preexposure vaccination. Persons at substantial risk of acquiring HBV infection who are demonstrated or judged likely to be susceptible should be vaccinated. They include:

1. *Health-care workers.* The risk of health-care workers acquiring HBV infection depends on the frequency of exposure to blood or blood products and on the frequency of needlesticks. These risks vary during the training and working career of each individual but are often highest during the professional training period. For this reason, it is recommended that vaccination be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions.

   The risk of HBV infection for hospital personnel can vary both among hospitals and within hospitals. In developing specific immunization strategies, hospitals should use available published data about the risk of infection (*22-24*) and may wish to evaluate their own clinical and institutional experience with hepatitis B. Studies in urban centers have indicated that occupational groups with frequent exposure to blood and/or needles have the highest risk of acquiring HBV infection, including (but not limited to) the following groups: medical technologists, operating room staff, phlebotomists and intravenous therapy nurses, surgeons and pathologists, and oncology and dialysis unit staff. Groups shown to be at increased risk in some hospitals include: emergency room staff, nursing personnel, and staff physicians.

   Other health-care workers based outside hospitals who have frequent contact with blood or blood products are also at increased risk of acquiring HBV infection. These include (but are not limited to): dental professionals (dentists, oral surgeons, dental hygienists), laboratory and blood bank technicians, dialysis center staff, emergency medical technicians, and morticians.
2. *Clients and staff of institutions for the mentally retarded.* Susceptible clients and staff who work closely with clients of institutions for the mentally retarded should be vaccinated. Risks for staff are comparable to those for health-care personnel in other high-risk environments. However, the risk in institutional environments is associated, not only with blood exposure, but also with bites and contact with skin lesions and other infective secretions. Susceptible clients and staff who live or work in smaller (group) residential settings with known HBV carriers should also receive hepatitis B vaccine.
3. *Hemodialysis patients.* Numerous studies have established the high risk of HBV transmission in hemodialysis units. Although recent data have shown not only a decrease in the rate of HBV infection in hemodialysis units but also a lower vaccine efficacy in these patients, vaccination is recommended for susceptible patients. Environmental control measures and regular serologic screening (based on immune status) of patients should be maintained.
4. *Homosexually active men.* Susceptible homosexually active men should be vaccinated regardless of their ages or duration of their homosexual practices. It is important to vaccinate persons as soon as possible after their homosexual activity begins. Homosexually active women are not at increased risk of sexually transmitted HBV infection.
5. *Users of illicit injectable drugs.* All users of illicit injectable drugs who are susceptible to HBV should be vaccinated as early as possible after their drug use begins.
6. *Recipients of certain blood products.* Patients with clotting disorders who receive clotting factor concentrates have an elevated risk of acquiring HBV infection. Vaccination is recommended for these persons and should be initiated at the time their specific clotting disorder is identified. Screening is recommended for patients who have already received multiple infusions of these products.
7. *Household and sexual contacts of HBV carriers.* Household contacts of HBV carriers are at high risk of acquiring HBV infection. Sexual contacts appear to be at greatest risk. When HBV carriers are identified through routine screening of donated blood, diagnostic testing in hospitals,

prenatal screening, screening of refugees, or other screening programs, they should be notified of their status and their susceptible household contacts vaccinated.

Families accepting orphans or unaccompanied minors from countries of high HBV endemicity should have the child screened for HBsAg, and if positive, family members should be vaccinated.

8. *Other contacts of HBV carriers.* Persons in casual contact with carriers at schools, offices, etc., are at minimal risk of acquiring HBV infection, and vaccine is not routinely recommended for them. However, classroom contacts of deinstitutionalized mentally retarded HBV carriers who behave aggressively or have special medical problems that increase the risk of exposure to their blood or serous secretions may be at risk. In such situations, vaccine may be offered to classroom contacts.
9. *Special high-risk populations.* Some American populations, such as Alaskan Eskimos, native Pacific islanders, and immigrants and refugees from areas with highly endemic disease (particularly eastern Asia and sub-Saharan Africa) have high HBV infection rates. Depending on specific epidemiologic and public health considerations, more extensive vaccination programs should be considered.
10. *Inmates of long-term correctional facilities.* The prison environment may provide a favorable setting for the transmission of HBV because of the frequent use of illicit injectable drugs and homosexual practices. Moreover, it provides an access point for vaccination of parenteral drug abusers. Prison officials should consider undertaking screening and vaccination programs directed at those who abuse drugs before or while in prison.
11. *Heterosexually active persons.* Heterosexually active persons with multiple sexual partners are at increased risk of acquiring HBV infection; risk increases with increasing sexual activity. Vaccination should be considered for persons who present for treatment of sexually transmitted diseases and who have histories of sexual activity with multiple partners.
12. *International travelers.* Vaccination should be considered for persons who plan to reside more than 6 months in areas with high levels of endemic HBV and who will have close contact with the local population. Vaccination should also be considered for short-term travelers who are likely to have contact with blood from or sexual contact with residents of areas with high levels of endemic disease. Hepatitis B vaccination of travelers ideally should begin 6 months before travel in order to complete the full vaccine series; however, a partial series will offer some protection against HBV infection.

Postexposure prophylaxis for hepatitis B. Prophylactic treatment to prevent hepatitis B infection after exposure to HBV should be considered in the following situations: perinatal exposure of an infant born to an HBsAg-positive mother; accidental percutaneous or permucosal exposure to HBsAg-positive blood; or sexual exposure to an HBsAg-positive person.

Recent studies have established the relative efficacies of immune globulins and/or hepatitis B vaccine in various exposure situations. For perinatal exposure to an HBsAg-positive, HBeAg-positive mother, a regimen combining one dose of HBIG at birth with the hepatitis B vaccine series started soon after birth is 85%-90% effective in preventing development of the HBV carrier state (*25,27*). Regimens involving either multiple doses of HBIG alone, or the vaccine series alone, have 70%-75% efficacy, while a single dose of HBIG alone has only 50% efficacy (*28*).

For accidental percutaneous exposure or sexual exposure, only regimens including HBIG and/or IG have been studied. A regimen of two HBIG doses, one given after exposure and one a month later, is about 75% effective in preventing hepatitis B following percutaneous exposure; a single dose of HBIG has similar efficacy when used following sexual exposure (*29-31*). IG may have some effect in preventing clinical hepatitis B following percutaneous exposures and can be considered as an alternative to HBIG when it is not possible to obtain HBIG.

Recommendations on postexposure prophylaxis are based on the efficacy data discussed above and on the likelihood of future HBV exposure of the person requiring treatment. In perinatal exposure and percutaneous exposure of high-risk health-care personnel, a regimen combining HBIG with hepatitis B vaccine will provide both short- and long-term protection, will be less costly than the two-dose HBIG treatment alone, and is the treatment of choice.

Perinatal exposure. One of the most efficient modes of HBV transmission is from mother to infant during birth. If the mother is positive for both HBsAg and HBeAg, about 70%-90% of infants will become infected, and up to 90% of these infected infants will become HBV carriers. If the HBsAg-positive carrier mother is HBeAg-negative, or if anti-HBe is present, transmission occurs less frequently and rarely leads to the HBV carrier state. However, severe acute disease, including fatal fulminant hepatitis in the neonate, has been reported (*32,33*). Prophylaxis of infants from all HBsAg-positive mothers is recommended, regardless of the mother's HBeAg or anti-HBe status.

The efficacy of a combination of HBIG plus the hepatitis B vaccine series has been confirmed in recent studies. Although the following regimen is recommended (Table 3), other schedules have also been effective (*25-27,34*). The major consideration for all these regimens is the need to give HBIG as soon as possible after delivery.

HBIG (0.5 ml [10 μg]) should be administered intramuscularly after physiologic stabilization of the infant and preferably within 12 hours of birth. Hepatitis B vaccine should be administered intramuscularly in three doses of 0.5 ml (10 μg) each. The first dose should be given concurrently with HBIG but at a different site. If vaccine is not available at birth, the first vaccine dose may be given within 7 days of birth. The second and third doses should be given 1 month and 6 months, respectively, after the first. Testing for HBsAg and anti-HBs is recommended at 12-15 months to monitor the final success or failure of therapy. If HBsAg is not detectable, and anti-HBs is present, the child has been protected. Testing for anti-HBc is not useful, since maternal anti-HBc may persist for more than 1 year; the utility of testing for IgM anti-HBc is currently being evaluated. HBIG administered at birth should not interfere with oral polio and diphtheria-tetanus-pertussis vaccines administered at 2 months of age.

Maternal screening. Since efficacy of the treatment regimen depends on administering HBIG on the day of birth, it is vital that HBsAg-positive mothers be identified before delivery. Mothers belonging to groups known to be at high risk of acquiring HBV infection (Table 4) should be tested routinely for HBsAg during a prenatal visit. If a mother belonging to a high-risk group has not been screened prenatally, HBsAg screening should be done at the time of delivery, or as soon as possible thereafter, and the infant treated as above if the mother is HBsAg-positive. If the mother is identified as HBsAg-positive more than 1 month after giving birth, the infant should be screened for HBsAg, and if negative, treated with hepatitis B vaccine and HBIG.

The appropriate obstetric and pediatric staff should be notified directly of HBsAg-positive mothers, so the staff may take appropriate precautions to protect themselves and other patients from infectious material, blood, and secretions, and so the neonate may receive therapy without delay after birth.

Acute exposure to blood that contains (or might contain) HBsAg. For accidental percutaneous or permucosal exposure to blood that is known to contain or might contain HBsAg, the decision to provide prophylaxis must take into account several factors: (1) the hepatitis B vaccination status of

TABLE 3. Hepatitis B virus postexposure recommendations

	HBIG		Vaccine	
Exposure	Dose	Recommended timing	Dose	Recommended timing
Perinatal	0.5 ml IM	Within 12 hours	0.5 ml (10 μg) IM of birth	Within 12 hours of birth*; repeat at 1 and 6 months
Sexual	0.06 ml/kg IM	Single dose within 14 days of sexual contact	†	—

*The first dose can be given the same time as the HBIG dose but at a different site.

†Vaccine is recommended for homosexual men and for regular sexual contacts of HBV carriers and is optional in initial treatment of heterosexual contacts of persons with acute HBV.

the exposed person; (2) whether the source of blood is known or unknown; and (3) whether the HBsAg status of the source is known or unknown. Such exposures usually occur in persons who are candidates for hepatitis B vaccine; for any exposure in a person not previously vaccinated, hepatitis B vaccination is recommended.

The following outline and table summarize prophylaxis for percutaneous (needlestick or bite), ocular, or mucous-membrane exposure to blood according to the source of exposure and vaccination status of the exposed person (Table 5). For greatest effectiveness, passive prophylaxis with HBIG (or IG) should be given as soon as possible after exposure (its value beyond 7 days of exposure is unclear).

1. *Exposed person not previously vaccinated.* Hepatitis B vaccination should be considered the treatment of choice. Depending on the source of the exposure, HBsAg testing of the source and additional prophylaxis of the exposed person may be warranted (see below). Screening the exposed person for immunity should be considered if such screening is cost-effective (as discussed in preexposure prophylaxis) and if this will not delay treatment beyond 7 days.

TABLE 4. Women for whom prenatal HBsAg screening is recommended

1. Women of Asian, Pacific island, or Alaskan Eskimo descent, whether immigrant or U.S.-born.
2. Women born in Haiti or sub-Saharan Africa.
3. Women with histories of:
   a. Acute or chronic liver disease.
   b. Work or treatment in a hemodialysis unit.
   c. Work or residence in an institution for the mentally retarded.
   d. Rejection as a blood donor.
   e. Blood transfusion on repeated occasions.
   f. Frequent occupational exposure to blood in medico-dental settings.
   g. Household contact with an HBV carrier or hemodialysis patient.
   h. Multiple episodes of venereal diseases.
   i. Percutaneous use of illicit drugs.

TABLE 5. Recommendations for hepatitis B prophylaxis following percutaneous exposure

Source	Exposed person: Unvaccinated	Exposed person: Vaccinated
HBsAg-positive	1. HBIG x 1 immediately* 2. Initiate HB vaccine† series.	1. Test exposed person for anti-HBs.§ 2. If inadequate antibody,¶ HBIG (x1) immediately plus HB vaccine booster dose.
Known source		
High-risk HBsAg-positive	1. Initiate HB vaccine series 2. Test source for HBsAg. If positive, HBIG x 1.	1. Test source for HBsAg only if exposed is vaccine nonresponder; if source is HBsAg-positive, give HBIG x 1 immediately plus HB vaccine booster dose
Low-risk HBsAg-positive	Initiate HB vaccine series.	Nothing required.
Unknown source	Initiate HB vaccine series.	Nothing required.

*HBIG dose 0.06 ml/kg IM.

†HB vaccine dose 20 μg IM for adults; 10 μg IM for infants or children under 10 years of age. First dose within 1 week; second and third doses, 1 and 6 months later.

§ See text for details.

¶Less than 10 SRU by RIA, negative by EIA.

a. *Source known HBsAg-positive.* A single dose of HBIG (0.06 ml/kg) should be given as soon as possible after exposure and within 24 hours, if possible. The first dose of hepatitis B vaccine (20 μg) should be given intramuscularly at a separate site within 7 days of exposure, and the second and third doses given 1 month and 6 months later (Table 5).† If HBIG cannot be obtained, IG in an equivalent dosage (0.06 ml/kg) may provide some benefit.

b. *Source known, HBsAg status unknown.* The following guidelines are suggested based on the relative probability that the source is HBsAg-positive and on the consequent risk of HBV transmission:

(1) *High risk that the source is HBsAg-positive, such as patients with a high risk of HBV carriage (Table 2) or patients with acute or chronic liver disease (serologically undiagnosed).* The exposed person should be given the first dose of hepatitis B vaccine (20 μg) within 1 week of exposure and vaccination completed as recommended. The source person should be tested for HBsAg. If positive, the exposed person should be given HBIG (0.06 ml/kg) if within 7 days of exposure.

(2) *Low risk that the source is positive for HBsAg.* The exposed person should be given the first dose of hepatitis B vaccine (20 μg) within 1 week of exposure and vaccination completed as recommended. Testing of the source person is not necessary.

c. *Source unknown.* The exposed person should be given the first dose of hepatitis B vaccine (20 μg) within 7 days of exposure and vaccination completed as recommended.

2. *Exposed person previously vaccinated against hepatitis B.* For percutaneous exposures to blood in persons who have previously received one or more doses of hepatitis B vaccine, the decision to provide additional prophylaxis will depend on the source of exposure and on whether the vaccinated person has developed anti-HBs following vaccination.

a. *Source known HBsAg-positive.* The exposed person should be tested for anti-HBs unless he/she has been tested within the last 12 months. If the exposed person has adequate§ antibody, no additional treatment is indicated.

(1) If the exposed person has not completed vaccination and has inadequate levels of antibody, one dose of HBIG (0.06 ml/kg) should be given immediately and vaccination completed as scheduled.

(2) If the exposed person has inadequate antibody on testing or has previously not responded to vaccine, one dose of HBIG should be given immediately and a booster dose of vaccine (1 ml or 20 μg) given at a different site.

(3) If the exposed person shows inadequate antibody on testing but is known to have had adequate antibody in the past, a booster dose of hepatitis B vaccine (1 ml or 20 μg) should be given.

b. *Source known, HBsAg status unknown.*

(1) *High risk that the source is HBsAg-positive.* Additional prophylaxis is necessary only if the exposed person is a known vaccine nonresponder. In this circumstance, the source should be tested for HBsAg and, if positive, the exposed person treated with one dose of HBIG (0.06 ml/kg) immediately and a booster dose of vaccine (1 ml or 20 μg) at a different site. In other circumstances, screening of the source for HBsAg and the exposed person for anti-HBs is not routinely recommended, because the actual risk of HBV infection is very low (less than 1 per 1,000).¶

(2) *Low risk that the source is HBsAg-positive.* The risk of HBV infection is minimal. Neither testing of the source for HBsAg, nor testing of the exposed person for anti-HBs, is recommended.

c. *Source unknown.* The risk of HBV infection is minimal. No treatment is indicated.

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†For persons who are not given hepatitis B vaccine, a second dose of HBIG should be given 1 month after the first dose.

§Adequate antibody is 10 SRU or more by RIA or positive by EIA.

¶Estimated by multiplying the risk of vaccine nonresponse in the exposed person (.10) by the risk of the needle source being HBsAg-positive (.05) by the risk of HBV infection in a susceptible person having an HBsAg-positive needle-stick injury (.20).

Sexual contacts of persons with acute HBV infection. Sexual contacts of HBsAg-positive persons are at increased risk of acquiring HBV infection, and HBIG has been shown to be 75% effective in preventing such infections (*31*). Because data are limited, the period after sexual exposure during which HBIG is effective is unknown, but extrapolation from other settings makes it unlikely that this period would exceed 14 days. Prescreening sexual partners for susceptibility before treatment is recommended if it does not delay treatment beyond 14 days after last exposure. Testing for anti-HBc is the most efficient prescreening test to use in this population group.

A single dose of HBIG (0.06 ml/kg) is recommended for susceptible individuals who have had sexual contact with an HBsAg-positive person, if HBIG can be given within 14 days of the last sexual contact, and for persons who will continue to have sexual contact with an individual with acute hepatitis B before loss of HBsAg in that individual. In exposures between heterosexuals, hepatitis B vaccination may be initiated at the same time as HBIG prophylaxis; such treatment may improve efficacy of postexposure treatment. However, since 90% of persons with acute HBV infection become HBsAg-negative within 15 weeks of diagnosis, the potential for repeated exposure to HBV is limited. Hepatitis B vaccine is, therefore, optional in initial treatment for such exposures. If vaccine is not given, a second dose of HBIG should be given if the index patient remains HBsAg-positive for 3 months after detection. If the index patient is a known carrier or remains positive for 6 months, hepatitis B vaccine should be offered to regular sexual contacts. For exposures among homosexual men, the hepatitis B vaccine series should be initiated at the time HBIG is given, since hepatitis B vaccine is recommended for all susceptible homosexual men. Additional doses of HBIG are unnecessary if vaccine is given. IG is an alternative to HBIG when it is not possible to obtain HBIG.

Household contacts of persons with acute HBV infection. Prophylaxis for other household contacts of persons with acute HBV infection is not indicated unless they have had identifiable blood exposure to the index case, such as by sharing toothbrushes or razors. Such exposures should be treated similarly to sexual exposures. If the index patient becomes a hepatitis B carrier, all household contacts should be given hepatitis B vaccine.

DELTA HEPATITIS

The delta virus (also known as hepatitis D virus [HDV] by some investigators) is a defective virus that may only cause infection in the presence of active HBV infection. The delta virus has been characterized as a particle of 35-37 nm in size, consisting of RNA (mw 500,000) as genetic material and an internal protein antigen (delta-antigen), coated with HBsAg as the surface protein (*3*). Infection may occur as either coinfection with hepatitis B or superinfection of a hepatitis B carrier, each of which usually cause an episode of acute hepatitis. Coinfection usually resolves, while superinfection frequently causes chronic delta infection and chronic active hepatitis. Both types of infection may cause fulminant hepatitis.

Delta infection may be diagnosed by detection of delta-antigen in serum during early infection and by the appearance of delta antibody during or after infection. Routes of delta transmission appear to be similar to those of hepatitis B. In the United States, delta infection occurs most commonly among persons at high risk of acquiring HBV infection, such as drug addicts and hemophilia patients.

A test for detection of delta antibody is expected to be commercially available soon. Other tests (delta antigen, IgM anti-delta) are available only in research laboratories.

Since the delta virus is dependent on hepatitis B for replication, prevention of hepatitis B infection, either preexposure or postexposure, will suffice to prevent delta infection in a person susceptible to hepatitis B. Known episodes of perinatal, sexual, or percutaneous exposure to sera or persons positive for both HBV and delta virus should be treated exactly as such exposures to hepatitis B alone.

Persons who are HBsAg carriers are at risk of delta infection, especially if they participate in activities that put them at high risk of repeated exposure to hepatitis B (parenteral drug abuse, homosexuality). However, at present there are no products available that might prevent delta infection in HBsAg carriers either before or after exposure.

NON-A, NON-B HEPATITIS

United States. Non-A, non-B hepatitis that presently occurs in the United States has epidemiologic characteristics similar to those of hepatitis B, occurring most commonly following blood transfusion and parenteral drug abuse. Multiple episodes of non-A, non-B hepatitis have been observed in

the same individuals and may be due to different agents. Chronic hepatitis following acute non-A, non-B hepatitis infection varies in frequency from 20% to 70%. Experimental studies in chimpanzees have confirmed the existence of a carrier state, which may be present in up to 8% of the population.

Although several studies have attempted to assess the value of prophylaxis with IG against non-A, non-B hepatitis, the results have been equivocal, and no specific recommendations can be made (*35,36*). However, for persons with percutaneous exposure to blood from a patient with non-A, non-B hepatitis, it may be reasonable to administer IG (0.06 ml/kg) as soon as possible after exposure.

Epidemic (fecal-oral) non-A, non-B hepatitis. In recent years, epidemics of non-A, non-B hepatitis spread by water or close personal contact have been reported from several areas of Southeast Asia (Indian subcontinent, Burma) and north Africa (*2*). Such epidemics generally affect adults and cause unusually high mortality in pregnant women. The disease has been transmitted to experimental animals, and candidate viruses have been identified; however, no serologic tests have yet been developed (*37*).

Epidemic non-A, non-B hepatitis has not been recognized in the United States or western Europe, and it is unknown whether the causative agent is present in these areas.

Travelers to areas having epidemic non-A, non-B hepatitis may be at some risk of acquiring this disease by close contact or by contaminated food or water. The value of IG in preventing this infection is unknown. The best prevention of infection is to avoid potentially contaminated food or water, as with hepatitis A and other enteric infections.

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CENTERS FOR DISEASE CONTROL

MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

April 11, 1986 / Vol. 35 / No. 14

Current Trends

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.
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.

*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.

Appendix E

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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STATE OF WISCONSIN

1985 Assembly Bill 487

Date of enactment: November 14, 1985
Date of publication*: November 22, 1985

1985 Wisconsin Act 73

AN ACT *to amend* 20.435 (1) (a); *to repeal and recreate* 103.15, 146.025 and 631.90; and *to create* 146.023 and 619.12 (1) (e) of the statutes, *relating to* restricting the use of a test for an antibody to the virus that causes acquired immunodeficiency syndrome, requiring certain blood testing, providing penalties and making an appropriation.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 20.435 (1) (a) of the statutes is amended to read:

20.435 (1) (a) *General program operations.* The amounts included in the schedule for general program operations; including health services regulation, administration and field services. Of the amounts appropriated under this paragraph, unless the department has expended all federal moneys available for provision of these services:

1. In state fiscal year 1985-86 $75,000 may not be expended and in state fiscal year 1986-87 $150,000 may not be expended for the provision of in-person counseling services and laboratory testing services for the presence of an antibody to HTLV-III at alternate testing sites.

2. In state fiscal year 1985-86 $41,400 may not be expended and in state fiscal year 1986-87 $83,000 may not be expended to fund department administrative costs and a total of 1.5 full-time equivalent general purpose revenue positions to assist in responding to the epidemic of acquired immunodeficiency syndrome and HTLV-III infections.

SECTION 2. 103.15 of the statutes, as created by 1985 Wisconsin Act 29, is repealed and recreated to read:

103.15 Restrictions on use of a test for an antibody to HTLV-III. (1) In this section:

(a) "HTLV-III" means the human T-cell lymphotropic virus-type III that causes acquired immunodeficiency syndrome.

(b) "HTLV-III infection" means the pathological state produced by a human body in response to the presence of HTLV-III.

(c) "State epidemiologist" means the individual designated by the secretary of health and social services as the individual in charge of communicable disease control for this state.

(2) Notwithstanding ss. 227.01 (9) and 227.011 (1) unless the state epidemiologist determines and the secretary of health and social services declares under s. 140.05 (1) that individuals who have HTLV-III infections may, through employment, provide a significant risk of transmitting HTLV-III to other individuals, no employer or agent of an employer may directly or indirectly:

(a) Solicit or require as a condition of employment of any employe or prospective employe a test for the presence of an antibody to HTLV-III.

(b) Affect the terms, conditions or privileges of employment or terminate the employment of any employe who obtains a test for the presence of an antibody to HTLV-III.

(3) Any agreement by an employer or agent of the employer and an employe or prospective employe offering employment or any pay or benefit to an employe or prospective employe in return for taking a test for the presence of an antibody to HTLV-III is prohibited, except as provided under sub. (2) (intro.).

SECTION 2m. 146.023 of the statutes is created to read:

146.023 Blood tests for antibody to virus that causes acquired immunodeficiency syndrome. (1) Except as provided under sub. (3), any blood bank, blood center or plasma center in this state that purchases or receives voluntarily donated whole blood, blood

* Section 991.11, WISCONSIN STATUTES 1983-84: **Effective date of acts.** "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication as designated" by the secretary of state [the date of publication may not be more than 10 working days after the date of enactment].

plasma, a blood product or a blood derivative shall, prior to its distribution or use, subject that blood, plasma, product or derivative to a test approved by the federal food and drug administration and the department for the presence of an antibody to the human T-cell lymphotropic virus-type III that causes acquired immunodeficiency syndrome.

(2) If performance of a validated test as defined under s. 146.025 (1) (g) yields a result positive for the presence of an antibody to the human T-cell lymphotropic virus-type III, the whole blood, blood plasma, blood product or blood derivative so tested with this result may not be distributed or used except for purposes of research.

(3) If a medical emergency, including a threat to the preservation of life of a potential donee, exists under which whole blood, blood plasma, a blood product or a blood derivative that has been subjected to testing under sub. (1) is unavailable, the requirement of sub. (1) shall not apply.

(4) Subsections (1) and (2) do not apply to the extent that federal law or regulations require that a blood bank, blood center or plasma center test whole blood, blood plasma, a blood product or a blood derivative.

SECTION 3. 146.025 of the statutes, as created by 1985 Wisconsin Act 29, is repealed and recreated to read:

146.025 Restrictions on use of a test for an antibody to HTLV-III. (1) DEFINITIONS. In this section:

(a) "Health care provider" has the meaning given under s. 146.81 (1).

(b) "HTLV-III" means the human T-cell lymphotropic virus-type III that causes acquired immunodeficiency syndrome.

(c) "HTLV-III infection" means the pathological state produced by a human body in response to the presence of HTLV-III.

(d) "Informed consent for testing or disclosure" means consent in writing on an informed consent for testing or disclosure form by a person to the administration of a test to him or her for the presence of an antibody to HTLV-III or to the disclosure to another specified person of the results of a test administered to the person consenting.

(e) "Informed consent for testing or disclosure form" means a printed document on which a person may signify his or her informed consent for testing for the presence of an antibody to HTLV-III or authorize the disclosure of any test results obtained.

(f) "State epidemiologist" means the individual designated by the secretary of health and social services as the individual in charge of communicable disease control for this state.

(g) "Validated test result" means a result of a test for the presence of an antibody to HTLV-III that meets the validation requirements determined to be necessary by the state epidemiologist.

(2) INFORMED CONSENT FOR TESTING OR DISCLOSURE. (a) No health care provider, blood bank, blood center or plasma center may subject a person to a test for the presence of an antibody to HTLV-III unless the subject of the test first provides informed consent for testing or disclosure as specified under par. (b), except that consent to testing is not required for any of the following:

1. A health care provider who procures, processes, distributes or uses a human body part donated for a purpose specified under s. 155.06 (3) may, without obtaining consent to the testing, test for the presence of an antibody to HTLV-III in order to assure medical acceptability of the gift for the purpose intended.

2. The department, a laboratory certified under s. 143.15 (4) or a health care provider, blood bank, blood center or plasma center may, for the purpose of research and without first obtaining written consent to the testing, subject any body fluids or tissues to a test for the presence of an antibody to HTLV-III if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

(b) The health care provider, blood bank, blood center or plasma center that subjects a person to a test for the presence of an antibody to HTLV-III under par. (a) shall provide the potential test subject with an informed consent form for testing or disclosure that shall contain the following information and shall obtain the potential test subject's signature on the form:

1. The name of the potential test subject who is giving consent and whose test results may be disclosed.

2. A statement of explanation to the potential test subject that the test results may be disclosed as specified under sub. (5) (a) and either a listing that duplicates the persons or circumstances specified under sub. (5) (a) 2 to 10 or a statement that the listing is available upon request.

3. Spaces specifically designated for the following purposes:

a. The signature of the potential test subject providing informed consent for the testing and the date on which the consent is signed.

b. The name of a person to whom the potential test subject authorizes that disclosure of test results be made, if any, the date on which the consent to disclosure is signed, and the time period during which the consent to disclosure is effective.

(3) WRITTEN CONSENT TO DISCLOSURE. A person who receives a test for the presence of an antibody to HTLV-III under sub. (2) (b) may authorize in writing a health care provider, blood bank, blood center or plasma center to disclose his or her test results to anyone at any time subsequent to providing informed consent for disclosure under sub. (2) (b) and a record of this consent shall be maintained by the health care

provider, blood bank, blood center or plasma center so authorized.

(4) RECORD MAINTENANCE. A health care provider, blood bank, blood center or plasma center that obtains from a person a specimen of body fluids or tissues for the purpose of testing for the presence of an antibody to HTLV-III shall:

(a) Obtain from the subject informed consent for testing or disclosure, as provided under sub. (2).

(b) Maintain a record of the consent received under par. (a).

(c) Maintain a record of the test results obtained.

(5) CONFIDENTIALITY OF TEST. (a) The results of a test for the presence of an antibody to HTLV-III may be disclosed only to the following persons or under the following circumstances, except that the person who receives a test may under sub. (2) (b) or (3) authorize disclosure to anyone:

1. To the subject of the test.

2. To the test subject's health care provider, including those instances in which a health care provider provides emergency care to the subject.

3. To an agent or employe of the test subject's health care provider under subd. 2 who provides patient care or handles or processes specimens of body fluids or tissues.

4. To a blood bank, blood center or plasma center that subjects a person to a test under sub. (2) (a), for any of the following purposes:

a. Determining the medical acceptability of blood or plasma secured from the test subject.

b. Notifying the test subject of the test results.

c. Investigating HTLV-III infections in blood or plasma.

5. To a health care provider who procures, processes, distributes or uses a human body part donated for a purpose specified under s. 155.06 (3), for the purpose of assuring medical acceptability of the gift for the purpose intended.

6. To the state epidemiologist or his or her designee, for the purpose of providing epidemiologic surveillance or investigation or control of communicable disease.

7. To a funeral director, as defined under s. 445.01 (5) or to other persons who prepare the body of a decedent for burial or other disposition.

8. To health care facility staff committees or accreditation or health care services review organizations for the purposes of conducting program monitoring and evaluation and health care services reviews.

9. Under a lawful order of a court of record.

10. To a person who conducts research, for the purpose of research, if the researcher:

a. Is affiliated with the test subject's health care provider under subd. 3.

b. Has obtained permission to perform the research from an institutional review board.

c. Provides written assurance to the person disclosing the test results that use of the information requested is only for the purpose under which it is provided to the researcher, the information will not be released to a person not connected with the study, and the final research product will not reveal information that may identify the test subject unless the researcher has first received informed consent for disclosure from the test subject.

(b) A private pay patient may deny access to disclosure of his or her test results granted under par. (a) 10 if he or she annually submits to the maintenance of his or her test results under sub. (4) (c) a signed, written request that denial be made.

(6) EXPANDED DISCLOSURE OF TEST RESULTS PROHIBITED. No person to whom the results of a test for the presence of an antibody to HTLV-III have been disclosed under sub. (5) (a) may disclose the test results except as authorized under sub. (5) (a).

(7) REPORTING OF POSITIVE TEST RESULTS. (a) Notwithstanding ss. 227.01 (9) and 227.011 (1), for the purposes of this subsection, the state epidemiologist shall determine, based on the preponderance of available scientific evidence, the procedures necessary in this state to obtain a validated test result for the presence of an antibody to HTLV-III and the secretary of health and social services shall so declare under s. 140.05 (1). The state epidemiologist shall revise this determination if, in his or her opinion, changed available scientific evidence warrants a revision, and the secretary of health and social services shall declare the revision under s. 140.05 (1).

(b) If a positive, validated test result for the presence of an antibody to HTLV-III is obtained from a test subject, the health care provider, blood bank, blood center or plasma center that maintains a record of the test results under sub. (4) (c) shall report to the state epidemiologist the following information:

1. The name and address of the health care provider, blood bank, blood center or plasma center reporting.

2. The name and address of the subject's health care provider, if known.

3. The name, address, telephone number, age or date of birth, race and ethnicity, sex and county of residence of the test subject, if known.

4. The date on which the test was performed.

5. The test result.

6. Any other medical or epidemiological information required by the state epidemiologist for the purpose of exercising surveillance, control and prevention of HTLV-III infections.

(c) A report made under par. (b) may not include any of the following:

1. Information with respect to the sexual orientation of the test subject.

2. The identity of persons with whom the test subject may have had sexual contact.

(d) This subsection does not apply to the reporting of information under s. 143.04 with respect to persons for whom a diagnosis of acquired immunodeficiency syndrome has been made.

(8) CIVIL LIABILITY. (a) Any person violating sub. (2), (5) (a), (6) or (7) (c) is liable to the subject of the test for actual damages and costs, plus exemplary damages of up to $1,000 for a negligent violation and up to $5,000 for an intentional violation.

(b) The plaintiff in an action under par. (a) has the burden of proving by a preponderance of the evidence that a violation occurred under sub. (2), (5) (a), (6) or (7) (c). A conviction under sub. (2), (5) (a), (6) or (7) (c) is not a condition precedent to bringing an action under par. (a).

(9) CRIMINAL PENALTY. Whoever intentionally discloses the results of a blood test in violation of sub. (5) (a) and thereby causes bodily harm or psychological harm to the subject of the test may be fined not more than $10,000 or imprisoned not more than 9 months or both.

SECTION 4. 619.12 (1) (e) of the statutes is created to read:

619.12 (1) (e) A notice of rejection or cancellation of coverage from one insurer and evidence of a positive test for the presence of an antibody to the human T-cell lymphotropic virus-type III that causes acquired immunodeficiency syndrome.

SECTION 5. 631.90 of the statutes, as created by 1985 Wisconsin Act 29, is repealed and recreated to read:

631.90 Restrictions on use of a test for an antibody to HTLV-III. (1) In this section, "HTLV-III" means the human T-cell lymphotropic virus-type III that causes acquired immunodeficiency syndrome.

(2) With regard to policies issued or renewed on and after July 20, 1985, an insurer may not do any of the following:

(a) Require or request directly or indirectly any individual to reveal whether the individual has obtained a test for the presence of an antibody to HTLV-III or what the results of this test, if obtained by the individual, were.

(b) Condition the provision of insurance coverage on whether an individual has obtained a test for the presence of an antibody to HTLV-III or what the results of this test, if obtained by the individual, were.

(c) Consider in the determination of rates or any other aspect of insurance coverage provided to an individual whether an individual has obtained a test for the presence of an antibody to HTLV-III or what the results of this test, if obtained by the individual, were.

(3) (a) Subsection (2) does not apply with regard to any test or series of tests for use in the underwriting of individual life, accident and health insurance policies that the person designated by the secretary of health and social services as the state epidemiologist finds medically significant and sufficiently reliable for the presence of an antibody to HTLV-III and that the commissioner finds and designates by rule as sufficiently reliable for use in the underwriting of individual life, accident and health insurance policies.

(b) Paragraph (a) does not authorize the use of any test or series of tests for the presence of an antibody to HTLV-III to discriminate in violation of s. 628.34 (3).

SECTION 6. **Appropriation changes; health and social services.** (1) The appropriation to the department of health and social services under section 20.435 (1) (a) of the statutes, as affected by the acts of 1985, is increased by $75,000 for fiscal year 1985-86 and by $150,000 for fiscal year 1986-87 to fund provision of in-service counseling services and laboratory testing services for the presence of an antibody to HTLV-III at alternate testing sites designated by the department.

(2) The appropriation to the department of health and social services under section 20.435 (1) (a) of the statutes, as affected by the acts of 1985, is increased by $41,400 for fiscal year 1985-86 and by $83,000 for fiscal year 1986-87 to fund department administrative costs and a total of 1.5 FTE GPR positions to assist in responding to the epidemic of acquired immunodeficiency syndrome and HTLV-III infections. The department shall reallocate a total of 1.5 FTE existing positions to assist in responding to the epidemic.

SECTION 7. **Program responsibility changes.** In the sections of the statutes listed in Column A, the program responsibilities references shown in Column B are deleted and the program responsibilities references shown in Column C are inserted:

A	B	C
Statute Sections	References Deleted	References Inserted
15.191 (intro.)	none	103.15 (2), 631.90 (3)(a)

SECTION 8. **Cross-reference changes.** In the sections of the statutes listed in Column A, the cross-references shown in Column B are changed to the cross-references shown in Column C:

A	B	C
Statute Sections	Old Cross-References	New Cross-References
103.20, as affected by 1985 Wis. Act 29	103.15	103.15 (2) or (3)

SECTION 9. **Initial applicability.** The treatment of section 631.90 (3) of the statutes by this act first applies to policies issued or renewed on the effective date of this SECTION.

SECTION 10. **Effective dates.** (1) Except as provided in subsection (2), this act takes effect on the day following publication.

(2) The treatment of section 146.023 of the statutes takes effect on January 1, 1986.

101.58 Employes' right to know. (1) SHORT TITLE. Sections 101.58 to 101.599 shall be known as the "Employes' Right to Know Law".

(2) DEFINITIONS. In ss. 101.58 to 101.599:

(a) "Agricultural employer" means any person, including the state and its political subdivisions, who engages the services of any employe to perform agricultural labor. If any employe is present at the workplace of an agricultural employer under an agreement between that agricultural employer and another agricultural employer or employer, "agricultural employer" means the agricultural employer with control or custody of a pesticide. An agricultural employer who engages some employes to perform agricultural labor and other employes for other purposes is only an agricultural employer with respect to the employes engaged to perform agricultural labor.

(b) "Agricultural labor" has the meaning provided in s. 108.02 (2).

(c) "Employe" means any person whose services are currently or were formerly engaged by an employer or an agricultural employer, or any applicant at the time an employer or agricultural employer offers to engage his or her services.

(d) "Employe representative" means an individual or organization to whom an employe gives written authorization to exercise his or her rights to request information under s. 101.583, 101.585 or 101.586, a parent of a minor employe or a recognized or certified collective bargaining agent.

(e) "Employer" means any person, except an agricultural employer, with control or custody of any employment or workplace who engages the services of any employe. "Employer" includes the state and its political subdivisions. If any employe is present at the workplace of an employer under an agreement between that employer and another employer or agricultural employer, "employer" means the employer with control or custody of a toxic substance or infectious agent. An employer who engages some employes to perform agricultural labor and other employes for other purposes is only considered an employer with respect to the employes engaged for other purposes.

(f) "Infectious agent" means a bacterial, mycoplasmal, fungal, parasitic or viral agent identified by the department by rule as causing illness in humans or human fetuses or both, which is introduced by an employer to be used, studied or produced in the workplace. "Infectious agent" does not include such an agent in or on the body of a person who is present in the workplace for diagnosis or treatment.

(g) "Legal holiday" has the meaning provided in s. 895.20.

(h) "Overexposure" means any chronic or acute exposure to a toxic substance or infectious agent which results in illness or injury.

(i) "Pesticide" means any substance or mixture of substances which is registered with the federal environmental protection agency under 7 USC 136 to 136y or the department of agriculture, trade and consumer protection under ch. 94, and which is labeled, designed or intended to prevent, destroy, repel or mitigate any pest or as a plant regulator, defoliant or desiccant.

(j) 1. "Toxic substance" means any substance or mixture containing a substance regulated by the federal occupational safety and health administration under title 29 of the code of federal regulations part 1910, subpart z, which is introduced by an employer to be used, studied or produced in the workplace.

2. "Toxic substance" does not include:

a. Any article, including but not limited to an item of equipment or hardware, which contains a substance regulated by the federal occupational safety and health administration under title 29 of the code of federal regulations part 1910, subpart z, if the substance is present in a solid form which does not cause any acute or chronic health hazard as a result of being handled by an employe.

b. Any mixture containing a substance regulated under title 29 of the code of federal regulations part 1910, subpart z, if the substance is less than one percent, or, if the substance is an impurity, less than 2%, of the product.

c. Any consumer product packaged for distribution to and used by the general public, for which the employe's exposure during use is not significantly greater than the consumer's exposure occurring during the principal use of the product.

d. Any substance received by an employer in a sealed package and subsequently sold or transferred in that package, if the seal remains intact while the substance is in the employer's workplace.

e. Any waste material regulated under the federal resource conservation and recovery act, P.L. 94-580.

f. Lutefisk.

(k) "Workplace" means any location where an employe performs a work-related duty in the course of his or her employment, except a personal residence.

(3) RELATIONSHIP TO FEDERAL REGULATIONS. (a) If the federal occupational safety and health administration promulgates a hazards communication regulation which, with respect to toxic substances, has requirements comparable to those in s. 101.583, 101.59 or 101.597 (1), and has time periods no less stringent than s. 101.589 and confidentiality requirements no less stringent than s. 101.592, an employer, manufacturer or supplier may apply to the department for an exemption from s. 101.583, 101.59 or 101.597 (1).

(b) An employer applying to the department for an exemption under par. (a) shall provide a copy of the application to appropriate certified collective bargaining agents and shall post a statement at the place where notices to employes are normally posted. The posted statement shall summarize the application, specify a place where employes may examine it and inform employes of their right to request a hearing on it.

(c) Upon receipt of a written request from an affected employer, manufacturer, supplier, employe or employe representative, the department shall hold a hearing on the application. If a hearing has been requested, the department is prohibited from approving the application until a hearing has been held. In no case may the department approve the application within less than 60 days after receiving it.

History: 1981 c. 364, 391; 1983 a. 189 s. 329 (28); 1983 a. 192 s. 304.

Wisconsin's new "right to know" law. McCauley. WBB Jan. 1983.

101.581 Notice requirements. (1) EMPLOYER. An employer who uses, studies or produces a toxic substance, infectious agent or pesticide shall post in every workplace at the location where notices to employes are usually posted a sign which informs employes that the employer is required, upon request, to provide an employe or employe representative with all of the following:

(a) The identity of any toxic substance or infectious agent which an employe works with or is likely to be exposed to.

(b) A description of any hazardous effect of the toxic substance or infectious agent.

(c) Information regarding precautions to be taken when handling the toxic substance or infectious agent.

(d) Information regarding procedures for emergency treatment in the event of overexposure to the toxic substance or infectious agent.

(e) Access to the information contained on the label of any pesticide with which the employe works or to which the employe is likely to be exposed.

(2) AGRICULTURAL EMPLOYER. An agricultural employer who uses pesticides shall post in a prominent place in the workplace a sign which informs employes that the agricultural employer is required, upon request, to provide an employe or employe representative with access to the information contained on the label of any pesticide with which the employe works or to which the employe is likely to be exposed.

(3) MINOR EMPLOYE. If an employe is a minor, an employer or agricultural employer shall send to the employe's parent or guardian, at the address provided by the employe, notice of the employe's rights under sub. (1) or (2).

History: 1981 c. 364; 1983 a. 392.

Further details of the Employes' Right to Know Statute are included in Wisconsin s. 101.583-101.599.

Consent Form A

Patient Consent Form To Test For HTLV-III Antibody

I _____ of _____
(patient name) (city, state)

have been advised that my physician(s) at _____ recommend for me the performance of a blood test to detect antibody to HTLV-III, the virus that causes acquired immunodeficiency syndrome (AIDS). I have also been advised that the procedure, which involves the withdrawal by needle of a small amount of blood for laboratory testing (about 1 1/2 tablespoons), may cause some slight discomfort at the site of entry of the needle, and that the procedure has minimal risks, such as bruising, soreness and a slight risk of infection. I have received and read a copy of "Information for Individuals about the Test for Antibodies to the HTLV-III Virus," which explains AIDS and the HTLV-III antibody test, and I have been given an opportunity to ask questions regarding this information and have my questions answered. I have been informed by my physician(s) that the test, in his/her (their) opinion, is important both to my health care and to ensure that appropriate evaluation can be undertaken and adequate precautions taken to prevent transmission of the virus to others.

I have been informed by my physician(s) that if my test results are positive, it may be necessary to take infectious disease precautions. I can ask my physician to provide me with more detailed information about infection control precautions. I have been informed that if I decline permission for this test, decisions whether to take infectious disease precautions will be made on the basis of other medical information concerning me. I have been informed that if I refuse permission for the HTLV-III antibody test, my health care, including diagnosis and treatment, may be adversely affected.

My physician(s) have informed me that if I consent to have the test done, it is important, both for my health care and for the health of others who will be providing care to me, that the test results be placed in my medical record, and that the medical record is the most accurate way for all health care providers involved in a patient's care to be fully informed of the patient's diagnosis and treatment. Therefore, if I agree to have the test done, the results of the test will be recorded in my medical record and persons involved in my health care will have access to that information.

I have been informed that the HTLV-III test results are considered confidential. I have been informed by my physicians that the test results in my medical record shall not be released without my written permission, except to the individuals and organizations that have been given access by state law.

I have been informed that the results of a test for the presence of an antibody to HTLV-III may be disclosed only to the following persons or under the following circumstances:

1. Subject of the test.

2. The subject's health care provider, including a health care provider who provides emergency care to the subject.

3. To an agent or employee of the test subject's health care provider, who provides patient care or handles or processes specimen's of body fluids or tissues.

4. To a blood bank, blood center or plasma center that subjects a person to a test.

5. To a health care provider who procures, processes, distributes or uses a donated human body part, for the purpose of assuring medical acceptability of the gift for the purpose intended.

6. To the State Epidemiologist or his/her designee, for the purpose of providing epidemiologic surveillance or investigation or control of communicable diseases.

7. To a funeral director, or to other persons who prepare the body of a decedent for burial or other disposition.

8. To health care facility staff committees or accreditation or health care services review organizations for the purpose of conducting program monitoring and evaluation and health care services reviews.

9. Under lawful order of a court of record.

10. To a person who conducts research, for the purpose of research, if the researcher:

    a. Is affiliated with the test subject's health care provider.

    b. Has obtained permission to perform the research from an institutional review board.

    c. Provides written assurance that the use of the information requested is only for the purpose under which it is provided to the researcher, the information will not be released to a person not connected with the study, and the final research product will not reveal information that may identify the test subject unless the researcher has first received informed consent for disclosure from the test subject.

    A private pay patient may deny researchers access to disclosure of his/her test results if he/she annually submits to the maintainer of his/her test results a signed written request that denial be made.

I have been informed that all of these individuals and organizations are also required by state law to keep my medical record information confidential.

Any questions I have regarding this test and the consequences of placing the test results in my medical record have been answered to my satisfaction.

If I do not consent to the HTLV-III antibody test, I agree to assume all risks that may result from my refusal to consent. I also agree not to hold my physician(s) or any other personnel responsible for any adverse results that may arise from my refusal to consent to the HTLV-III antibody test.

I do _____ do not _____ (check one) consent to the performance of the HTLV-III antibody test.

_____ _____
Signature of Patient Date

PATIENT'S BILLING CONSENT FOR HTLV-III TESTING
(Select one option below)

1. _____ I authorize the forwarding of the name of the test(s) and charges to my insurance company.

2. _____ I consent to allow the disclosure of my name, address, birthdate, name of the test(s) and the charge to Medicare or Medical Assistance.

Patient's full name: _____ Birthdate: _____

Address: _____ Medicare #: _____

_____ Medicaid #: _____

3. _____ I do not give my consent to release the name of the test(s) to my insurance company, Medicare or Medical Assistance. I will pay the bill myself.

Signature _____

I also authorize the following persons or agencies access to my HTLV-III antibody test results:

_____ _____ to _____
Name of Person/Agency Date Valid

_____ _____ to _____
Name of Person/Agency Date Valid

_____ _____ to _____
Name of Person/Agency Date Valid

_____ _____
Signature of Patient Date

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Patient Consent Form To Test For HTLV-III Antibody

I _____ of _____
(patient name) (city, state)

have been advised that my physician(s) at _____ recommend for me the performance of a blood test to detect antibody to HTLV-III, the virus that causes acquired immunodeficiency syndrome (AIDS). I have also been advised that the procedure, which involves the withdrawal by needle of a small amount of blood for laboratory testing (about 1 1/2 tablespoons), may cause some slight discomfort at the site of entry of the needle, and that the procedure has minimal risks, such as bruising, soreness and a slight risk of infection. I have received and read a copy of "Information for Individuals about the Test for Antibodies to the HTLV-III Virus," which explains AIDS and the HTLV-III antibody test, and I have been given an opportunity to ask questions regarding this information and have my questions answered. I have been informed by my physician(s) that the test, in his/her (their) opinion, is important both to my health care and to ensure that appropriate evaluation can be undertaken and adequate precautions taken to prevent transmission of the virus to others.

I have been informed by my physician(s) that if my test results are positive, it may be necessary to take infectious disease precautions. I can ask my physician to provide me with more detailed information about infection control precautions. I have been informed that if I decline permission for this test, decisions whether to take infectious disease precautions will be made on the basis of other medical information concerning me. I have been informed that if I refuse permission for the HTLV-III antibody test, my health care, including diagnosis and treatment, may be adversely affected.

My physician(s) have informed me that if I consent to have the test done, it is important, both for my health care and for the health of others who will be providing care to me, that the test results be placed in my medical record, and that the medical record is the most accurate way for all health care providers involved in a patient's care to be fully informed of the patient's diagnosis and treatment. Therefore, if I agree to have the test done, the results of the test will be recorded in my medical record and persons involved in my health care will have access to that information.

I have been informed that the HTLV-III test results are considered confidential. I have been informed by my physicians that the test results in my medical record shall not be released without my written permission, except to the individuals and organizations that have been given access by state law. A list of individuals and organizations to whom my HTLV-III antibody test results may be disclosed was made available to me. I have been informed that all of these individuals and organizations are also required by state law to keep my medical record information confidential.

Any questions I have regarding this test and the consequences of placing the test results in my medical record have been answered to my satisfaction.

If I do not consent to the HTLV-III antibody test, I agree to assume all risks that may result from my refusal to consent. I also agree not to hold my physician(s) or any other personnel responsible for any adverse results that may arise from my refusal to consent to the HTLV-III antibody test.

I do _____ do not _____ (check one) consent to the performance of the HTLV-III antibody test.

_____ _____

Signature of Patient Date

PATIENT'S BILLING CONSENT FOR HTLV-III TESTING
(Select one option below)

1. _____ I authorize the forwarding of the name of the test(s) and charges to my insurance company.

2. _____ I consent to allow the disclosure of my name, address, birthdate, name of the test(s) and the charge to Medicare or Medical Assistance.

Patient's full name: _____ Birthdate: _____

Address: _____ Medicare #: _____

_____ Medicaid #: _____

3. _____ I do not give my consent to release the name of the test(s) to my insurance company, Medicare or Medical Assistance. I will pay the bill myself.

Signature _____

I also authorize the following persons or agencies access to my HTLV-III antibody test results:

_____ _____ to _____

Name of Person/Agency Date Valid

_____ _____ to _____

Name of Person/Agency Date Valid

_____ _____ to _____

Name of Person/Agency Date Valid

_____ _____

Signature of Patient Date

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The results of a test for the presence of an antibody to HTLV-III may be disclosed only to the following persons or under the following circumstances:

1. Subject of the test.

2. The subject's health care provider, including a health care provider who provides emergency care to the subject.

3. To an agent or employee of the test subject's health care provider, who provides patient care or handles or processes specimen's of body fluids or tissues.

4. To a blood bank, blood center or plasma center that subjects a person to a test.

5. To a health care provider who procures, processes, distributes or uses a human body part, for the purpose of assuring medical acceptability of the gift for the purpose intended.

6. To the State Epidemiologist or his/her designee, for the purpose of providing epidemiologic surveillance or investigation or control of communicable diseases.

7. To a funeral director, or to other persons who prepare the body of a decedent for burial or other disposition.

8. To health care facility staff committees or accreditation or health care services review organizations for the purpose of conducting program monitoring and evaluation and health care services reviews.

9. Under lawful order of a court of record.

10. To a person who conducts research, for the purpose of research, if the researcher:

    a. Is affiliated with the test subject's health care provider.

    b. Has obtained permission to perform the research from an institutional review board.

    c. Provides written assurance that the use of the information requested is only for the purpose under which it is provided to the researcher, the information will not be released to a person not connected with the study, and the final research product will not reveal information that may identify the test subject unless the researcher has first received informed consent for disclosure from the test subject.

A private pay patient may deny researchers access to disclosure of his/her test results if he/she annually submits to the maintainer of his/her test results a signed written request that denial be made.

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CENTERS FOR DISEASE CONTROL

MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

August 30, 1985 / Vol 34 / No. 34

Current Trends

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 [illegible]
   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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1. Fujikawa LS, Salahuddin SZ, Palestine AG, et al. Isolation of human T-cell leukemia/lymphotropic virus type III (HTLV-III) from the tears of a patient with acquired immunodeficiency syndrome (AIDS). Lancet (in press).
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Appendix I

Reprinted by
The Wisconsin Division of Health
from *MMWR*, Nov. 6, 1982, Vol. 31, No. 43, pp. 577-80

Current Trends

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.

Appendix K

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) CASE REPORT

DOH 4264 (Rev. 6/86)
ss. 143.04

Mail in an envelope marked "CONFIDENTIAL" to:

Jeffrey P. Davis, M.D.
Wisconsin Division of Health
P O Box 309
MADISON WI 53701-0309
Phone: 608/266-5287

DEMOGRAPHIC DATA

A. Case Identification:
Last Name | First Name | M.I. | Date of Birth (Mo. Day Yr.) | Age | ☐ Married ☐ Single | Gender ☐ M ☐ F

Address (Street of RFD) | Telephone No. ( ) -

City | State | Zip | County of residence

Usual Occupation:

Race: ☐ White ☐ Black ☐ Am. Indian ☐ Asian or Pacific Islander ☐ Other (Specify): _____

Ethnic Origin: ☐ Hispanic ☐ Not Hispanic

Current Status: ☐ Alive ☐ Dead ☐ Unknown Date of Death ___/___/___

	Yes	No	Unk	
Was patient born in U.S. (50 states, Washington, DC)?	☐	☐	☐	If no, date of arrival in U.S. Month ☐☐ Year ☐☐

If patient was born outside U.S., what was country/territory of birth? ☐ Canada ☐ Dominican Republic ☐ Haiti ☐ Mexico ☐ Puerto Rico ☐ Other (Specify country/territory) _____

What is the sexual orientation of the patient? ☐ Heterosexual ☐ Homosexual ☐ Bisexual ☐ None ☐ Unk

Did the patient ever use needles for self-injection of drugs not prescribed by a physician? ☐ Yes ☐ No ☐ Unk

SINCE 1978 AND PRECEDING THE DIAGNOSIS OF AIDS, DID THIS PATIENT:

Work in a health care or clinical laboratory setting? ☐ Yes ☐ No ☐ Unk If yes, specify occupation: _____

Receive any blood products (i.e., Factor VIII or IX, cryoprecipitate, or fibrinogen) for the treatment of a coagulation disorder? ☐ Yes ☐ No ☐ Unk

If yes, specify disorder: ☐ Hemophilia A (Factor VIII) ☐ Hemophilia B (Factor IX) ☐ Other, specify _____

	Yes	No	Unk		Yes	No	Unk
Have sexual relations with a male partner?	☐	☐	☐	Receive hepatitis B immune globulin (HBIG)?	☐	☐	☐
Have sexual relations with a female partner?	☐	☐	☐	Receive other immune globulin?	☐	☐	☐
Have heterosexual relations with a person with a risk factor for AIDS?	☐	☐	☐	Receive blood or blood components, e.g., packed red cells, platelets or plasma? If yes, when _____	☐	☐	☐
Receive hepatitis B vaccine?	☐	☐	☐	Undergone hemodialysis?	☐	☐	☐

Did this patient:	Yes	No	Unk
Have any other medical condition which may cause immunodeficiency? If yes, specify: _____	☐	☐	☐
Receive systemic corticosteroid therapy within 1 month before diagnosis of the earliest opportunistic disease?	☐	☐	☐
Receive other systemic immunosuppressive or cytotoxic therapy within 1 year before diagnosis of the earliest opportunistic disease?	☐	☐	☐
If the answer is Yes to either of the above two questions, did symptoms specifically related to the opportunistic disease precede the immunosuppressive therapy?	☐	☐	☐

CLINICAL INFORMATION PRODROMAL TO AIDS

Signs and Symptoms Persistent for at Least One Month:
(Check all that apply)

- ☐ None
- ☐ Fever
- ☐ Night Sweats
- ☐ Weight Loss
- ☐ Diarrhea
- ☐ Malaise/Fatigue
- ☐ Lymphadenopathy
- ☐ Candidiasis, oral (thrush)
- ☐ Herpes zoster
- ☐ Neurological signs
- ☐ Persistent Cough
- ☐ Bruising, Bleeding
- ☐ _____
- ☐ _____
- ☐ Unknown

Approximate date of onset of first sign/symptom: ___/___/___

Where was this patient living at that time? _____ City _____ State _____ County

CURRENT CLINICAL INFORMATION

DISEASES AT LEAST MODERATELY INDICATIVE OF CELLULAR IMMUNODEFICIENCY AND AIDS:
(Check all that apply)

	Date of Specimen or Diagnosis	Method of Diagnosis*
☐ Kaposi's sarcoma	___/___/___	☐
☐ Pneumocystis carinii pneumonia	___/___/___	☐
☐ Toxoplasmosis (exclude if only in liver, spleen, muscle or lymph nodes) ☐ Brain/CNS ☐ Other Site	___/___/___	☐
☐ Cryptosporidiosis with diarrhea persisting > 1 month	___/___/___	☐
☐ Cytomegalovirus infection histopathologically documented (exclude if only in liver, nodes, or mononucleosis syndrome, or diagnosis by serology or culture alone)	___/___/___	☐
☐ Primary lymphoma of brain	___/___/___	☐
☐ Progressive multifocal leukoencephalopathy (Papovavirus infection, brain)	___/___/___	☐
☐ Candida esophagitis	___/___/___	☐
☐ Atypical (nontuberculosis) mycobacterial infection, disseminated, e.g., bone marrow or multiple organ involvement (exclude if only pulmonary and/or lymph node infection)	___/___/___	☐
Species: ☐ M. avium-intracellulare ☐ Other, (specify): _____		
☐ Cryptococcal infection (exclude pulmonary only)	___/___/___	☐
☐ Meningitis ☐ Other internal organ ☐ Blood		
☐ Chronic mucocutaneous herpes simplex infection persisting > 1 month	___/___/___	☐

* METHODS OF DIAGNOSIS: (Not all methods are appropriate or acceptable for all diseases)

1 = Microscopy: cytology, histology
2 = Culture/microbiologic techniques
3 = Endoscopy: bronchoscopy, sigmoidoscopy, etc.
4 = Serology: antibody titer
5 = Antigen detection, any technique
6 = Physical examination
7 = X-ray, fluoroscopy, etc.
8 = Ultrasound, CAT scan, etc.
9 = Unknown

OTHER DISEASES PRECEDING OR COEXISTING WITH THIS PATIENT'S SYMPTOMS: (Check all that apply)

- ☐ None
- ☐ Unknown
- ☐ Herpes Simplex (chronic or persistent):
  - ☐ Mouth/Pharynx ☐ Genital ☐ Anal/Rectal
  - ☐ Other _____
- ☐ Herpes Zoster: ☐ Localized ☐ Disseminated
- ☐ Candida infection: ☐ Colo/Rectal ☐ Oral/Pharyngeal ☐ Bronchial/Pulmonary
- ☐ Isosporiasis
- ☐ Idiopathic/Autoimmune thrombocytopenic purpura
- ☐ Autoimmune hemolytic anemia
- ☐ Hepatitis (chronic)
- ☐ Sexually transmitted disease; specify _____
- ☐ Disseminated histoplasmosis
- ☐ Leukemia or lymphoma _____
- ☐ Bleeding disorder _____
- ☐ Tuberculosis
- ☐ Other significant diseases _____

Other clinical comments:

	Date of serum	ELISA result	Western blot result
a.	___/___/___	☐ Pos. ☐ Neg.	☐ Pos. ☐ Neg. ☐ Not done
b.	___/___/___	☐ Pos. ☐ Neg.	☐ Pos. ☐ Neg. ☐ Not done
c.	___/___/___	☐ Pos. ☐ Neg.	☐ Pos. ☐ Neg. ☐ Not done

☐ Thrombocytopenia
☐ Hypergammaglobulinemia
☐ Anemia
☐ Lymphopenia
☐ Anergy
☐ ↓ T4 cell count, if decreased, specify count _____
☐ ↓ T4:T8 ratio, if decreased, specify ratio _____
☐ Other _____

Virus isolation (specify souce of specimen--blood, semen, saliva, etc.)

	Result	Mo. Day Yr.
_____	☐ Pos. ☐ Neg.	___/___/___
_____	☐ Pos. ☐ Neg.	___/___/___

Since 1978, has patient donated blood or plasma? ☐ Yes ☐ No ☐ Unk If yes, complete next section

Blood/plasma center(s) of most recent donation(s): Approximate Date(s) of Donation

Name of Center	City	State	Mo. Day Yr.
_____	_____	_____	___/___/___
_____	_____	_____	___/___/___

FOR WOMEN: Has the patient delivered a live-born infant since 1978? ☐ Yes ☐ No ☐ Unk

Is the patient currently pregnant? ☐ Yes ☐ No ☐ Unk

HOSPITAL/CLINIC WHERE DIAGNOSIS OF AIDS ESTABLISHED:

Name _____

City _____ State _____

Other pertinent information, e.g., other hospitalizations (if more room is needed, use reverse side) _____

_____

Attending physician: _____

address: _____

telephone: _____

Person or agency reporting: _____

address: _____

telephone: _____

Date of report: ___/___/___

For hospitalized patient, how was infection control practitioner notified of diagnosis (check all that apply):

☐ Attending Physician
☐ Laboratory (e.g., microbiology, pathology) specify _____
☐ Service (e.g., immunology, dermatology) specify _____
☐ Isolation Records
☐ Medical Records Discharge Coding
☐ Pharmacy
☐ Admissions or Transferring Institution
☐ Other (specify) _____

REPORTING OF CONFIRMED AND SUSPECT CASES OF AIDS

Confirmed or suspect cases of acquired immunodeficiency syndrome (AIDS) are reportable to the Division of Health under Wisconsin Statute 143.04. These cases should be reported to the Division of Health utilizing the "AIDS Case Report (DOH 4264)." Copies of this report form may be obtained by calling 608/267-5287.

CORRESPONDENCE/MEMORANDUM

STATE OF WISCONSIN

Date: December 13, 1985 *File Ref:*

To: Linda Reivitz, Secretary
Department of Health and Social Services

From: Jeffrey P. Davis, M.D.
State Epidemiologist and Chief
Section of Acute and Communicable Disease Epidemiology

Subject: VALIDATED POSITIVE TEST FOR ANTIBODY TO HUMAN T-CELL LYMPHOTROPIC VIRUS TYPE III (HTLV-III)*

Wisconsin Statute 146.025 (7) requires that the "state epidemiologist shall determine, based on the preponderance of available scientific data, the procedures necessary in this state to obtain a validated test result for the presence of antibody to HTLV-III..." The statutes further require that case information regarding a positive, validated test result be reported to the state epidemiologist. Pursuant to Wis. Stat. 146.025 (7) for the purposes of surveillance and case reporting (but not for the purposes of defining HTLV-III antibody testing procedures to be utilized in underwriting insurance policies) I determine a validated positive test for the presence of antibody to HTLV-III to be defined as:

1. A single serum or plasma specimen which is reactive by Western blot procedure for bands 24 and/or 41, regardless of the reproducibility of a Food and Drug Administration (FDA) licensed enzyme-linked immunoassay (ELISA) HTLV-III antibody test result.

OR

2. A single serum or plasma specimen which is reactive at least twice using one or more FDA licensed ELISA for antibody to HTLV-III for which no Western blot procedure has been performed.

It is recognized that criterion two is less specific and it is hoped that there will be few people in this category, since the Western blot procedure is available and should be used to test all specimens that are repeatably ELISA reactive.

---

* The International Committee on the Taxonomy of Viruses has proposed the name human immunodeficiency virus (HIV) for this virus.

DECLARATION

Pursuant to 146.025 (7) Wis. Stats. and the powers vested in me by 140.05 Wis. Stats., I hereby declare that a validated positive test for antibody to Human T-cell Lymphotropic Virus Type III (HTLV-III) is defined as the procedures determined to be valid by the State Epidemiologist on _____.

Signed this _____ day of October 1986.

Linda Reivitz
Secretary

DOH 4338 (Rev. 6/86)
ss. 146.025 & 143.04

Appendix M

Mail in an envelope marked "CONFIDENTIAL" to:

Jeffrey P. Davis, M.D.
State Epidemiologist
Wisconsin Division of Health
P O Box 309
MADISON WI 53701-0309
Phone: 608/267-5287

POSITIVE HTLV-III/HIV ANTIBODY TEST CASE REPORT

CASE IDENTIFICATION DEMOGRAPHIC DATA

A. Case Identification:
Last Name _____ First Name _____ M.I. ___ Date of Birth (Mo. Day Yr.) ___ Age ___ ☐ Married ☐ Single Gender ☐ M ☐ F

Address (Street of RFD) _____ Telephone No. ( ) -

City _____ State _____ Zip _____ County of residence _____

Usual Occupation: _____

Race: ☐ White ☐ Black ☐ Am. Indian ☐ Asian or Pacific Islander ☐ Other (Specify): _____

Ethnic Origin: ☐ Hispanic ☐ Not Hispanic

CLINICAL INFORMATION

B. Signs and Symptoms Persistent For at Least One Month:

☐ None ☐ Fever ☐ Night Sweats ☐ Weight Loss ☐ Diarrhea
☐ Malaise/Fatigue ☐ Lymphadenopathy ☐ Candidiasis (oral) ☐ Herpes zoster ☐ Neurological Signs
☐ Persistent Cough ☐ Bruising, Bleeding ☐ _____ ☐ _____ ☐ Unknown

Approximate date of onset of first sign/symptom: ___/___/___

Other clinical comments:

C. Laboratory Abnormalities:

☐ Thrombocytopenia ☐ Hypergammaglobulinemia ☐ ↓ T4 cell count _____ ☐ ↓ T4:T8 ratio _____ ☐ Other _____
☐ Anemia ☐ Lymphopenia ☐ Anergy

D. Opportunistic Infections/Malignancies:

☐ Pneumocystic carinii pneumonia
☐ Kaposi's sarcoma
☐ Other _____

HTLV-III/HIV ANTIBODY TESTS

E.	Date of serum	ELISA result	Western blot result
a.	___/___/___	☐ Pos. ☐ Neg.	☐ Pos. ☐ Neg. ☐ Not done
b.	___/___/___	☐ Pos. ☐ Neg.	☐ Pos. ☐ Neg. ☐ Not done
c.	___/___/___	☐ Pos. ☐ Neg.	☐ Pos. ☐ Neg. ☐ Not done

REPORTING SOURCE

F. Attending physician: _____ Date of report: ___/___/___

hospital or clinic: _____

address: _____

telephone: _____

Agency and/or person reporting: _____

address: _____

telephone: _____

This report is authorized by Wis. Statute 146.025 (see back of form)

REPORTING OF CONFIRMED AND SUSPECT CASES OF AIDS

Confirmed or suspect cases of acquired immunodeficiency syndrome (AIDS) are reportable to the Division of Health under Wisconsin Statute 143.04. These cases should be reported to the Division of Health utilizing the "AIDS Case Report Form (DOH 4264)." Copies of this report form may be obtained by calling 608/267-5287.

REPORTING VALIDATED POSITIVE HTLV-III ANTIBODY TEST RESULTS

Wisconsin Statute 146.025 (7) requires that:

When a positive, validated test result for the presence of antibody to HTLV-III is obtained from a test subject, the health care provider, blood bank, blood center or plasma center that maintains a record of the test results must report directly to the state epidemiologist the following information:

a. The name and address of the reporting health care provider, blood bank, blood center or plasma center.

b. The name and address of the subject's health care provider, if known.

c. The name, address, telephone number, age or date of birth, race and ethnicity, sex and county of residence of the test subject, if known.

d. The date on which the test was performed.

e. The test result.

f. Any additional information required on the report form by the state epidemiologist for the purpose of exercising surveillance, control and prevention of HTLV-III infections.

The initial report of an HTLV-III antibody test may <u>not</u> include any of the following.

a. Information with respect to the sexual orientation of the test subject.

b. The identity of persons with whom the test subject may have had sexual contact.

VALIDATED POSITIVE TEST FOR ANTIBODY TO HTLV-III

Pursuant to Wisconsin Statute 146.025 (7) for the purposes of surveillance and case reporting a validated positive test for the presence of antibody to HTLV-III is to be defined as:

1. A single serum or plasma specimen which is reactive by Western blot procedure for bands 24 and/or 41, regardless of the reproducibility of a Food and Drug Administration (FDA) licensed enzyme-linked immunoassay (ELISA) HTLV-III antibody test result.

OR

2. Specifically, when the Abbott ELISA for antibody to HTLV-III is used, a single serum or plasma specimen which is strongly reactive (test reactivity to test cutoff ratio is greater than or equal to 6) at least twice regardless of the Western blot result.

OR

3. A single serum or plasma specimen which is reactive at least twice using one or more FDA licensed ELISA for antibody to HTLV-III for which no Western blot procedure has been performed.

It is recognized that criteria three is the least specific of the three criteria and it is hoped that there will be few people in this category, since the Western blot procedure is available and should be used to test all specimens that are repeatably ELISA reactive.