VIRGINIA
EPIDEMIOLOGY BULLETIN

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Licensure of Screening Tests for Antibody to Human T-Lymphotropic Virus Type I

Screening tests for antibody to human T-lymphotropic virus type I (HTLV-I), the first-recognized human retrovirus, have been licensed by the Food and Drug Administration (FDA). These tests have been recommended by the FDA for screening of blood and cellular components donated for transfusion. They have also been approved as diagnostic tests, which may be useful in evaluating patients with clinical diagnoses of adult T-cell leukemia/lymphoma (ATL) and tropical spastic paraparesis (TSP)/HTLV-I—associated myelopathy (HAM), both of which have been associated with HTLV-I infection. Because licensure will probably result in widespread use of these tests, the information presented below is provided for physicians and public health officials who may need to interpret HTLV-I test results and to counsel persons whose serum specimens are reactive in these tests. **Users of the new HTLV-I screening tests are cautioned that additional, more specific tests are necessary to confirm that serum specimens that are repeatably reactive in these screening tests are truly positive for HTLV-I antibody.** Users should also be aware that neither the screening tests nor more specific tests can distinguish between antibody to HTLV-I and antibody to the closely related human retrovirus, human T-lymphotropic virus type II (HLTV-II).

HTLV-I does not cause AIDS, and the finding of HTLV-I antibody in human blood does not imply infection with human immunodeficiency virus (HIV) or a risk of developing acquired immunodeficiency syndrome (AIDS).

Background: HTLV-I

HTLV-I was isolated in 1978 and first reported in 1980 (*1*). Although a member of the family of retroviruses, HTLV-I is *not* closely related to HIV, the virus that causes AIDS. HTLV-I does not cause depletion of T-helper lymphocytes, and it is not generally associated with immunosuppression.

HTLV-I differs from HIV in its morphologic and genetic structure and in that HTLV-I antigens should not cross-react with the antigens of HIV. The HTLV-I genome contains four major genes: *gag,* which encodes core proteins of 15,000 (p15), 19,000 (p19), and 24,000 (p24) daltons; *pol,* which encodes a polymer-

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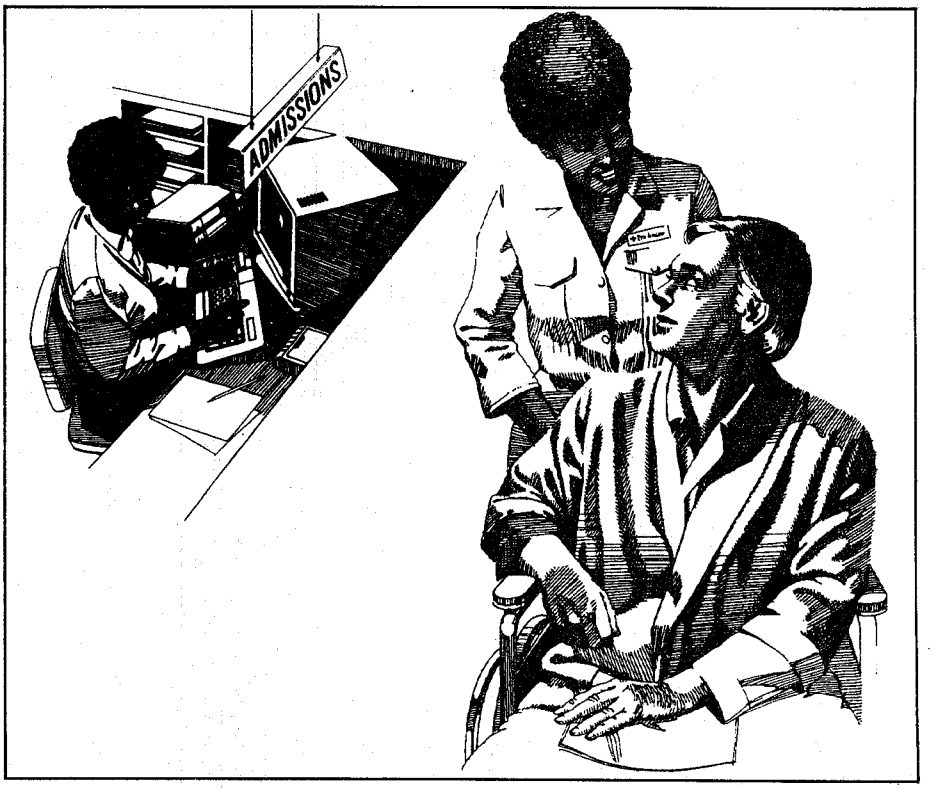

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ase (reverse transcriptase) protein of 96,000 daltons; *env,* which encodes envelope glycoproteins of 21,000 (gp21) and 46,000 (gp46) daltons; and *tax,* which encodes a transactivator protein of 40,000 daltons (p40x).

Seroprevalence

HTLV-I infection is endemic primarily in southwestern Japan, the Caribbean, and some areas of Africa (*2*). Seroprevalence in well-characterized areas appears to increase with patient age, with rates in females markedly higher than those in males beginning in the 20–30-year age range. Seroprevalence rates as high as 15% in the general population and 30% in older age groups have been reported in some areas of Japan (*3*). In the Caribbean islands, rates may be as high as 5% in the general population and 15% in older age groups (*4*).

In the United States, HTLV-I infection has been identified mainly in intravenous-drug users (IVDUs), with seroprevalence rates ranging from 7% to 49% (*5,6*). Elevated rates have also been reported in female prostitutes (in whom IV-drug use is a major risk factor) (*7*) and in recipients of multiple blood transfusions (*8*). Seropositivity is rare among homosexual men and among patients in sexually transmitted disease clinics (*9,10*), and it appears to be nonexistent in hemophilic men without other risk factors (*11*). Systematic determination of HTLV-I seroprevalence in the general population of the United States has not been undertaken. However, in a study of 39,898 random blood donors in eight U.S. cities, 10 (0.025%) were seropositive for HTLV-I (*12*).

Transmission

Transmission of HTLV-I infection by blood transfusion is well documented in Japan, with a seroconversion rate of 63% in recipients of the *cellular* components of contaminated units (whole blood, red blood cells, and platelets) (*13*). Transmission by the plasma fraction of contaminated units has not resulted in infection; this finding has been attributed to the fact that HTLV-I is highly cell-associated. Transmission among IVDUs is presumed to occur by sharing of needles and syringes contaminated with infectious blood.

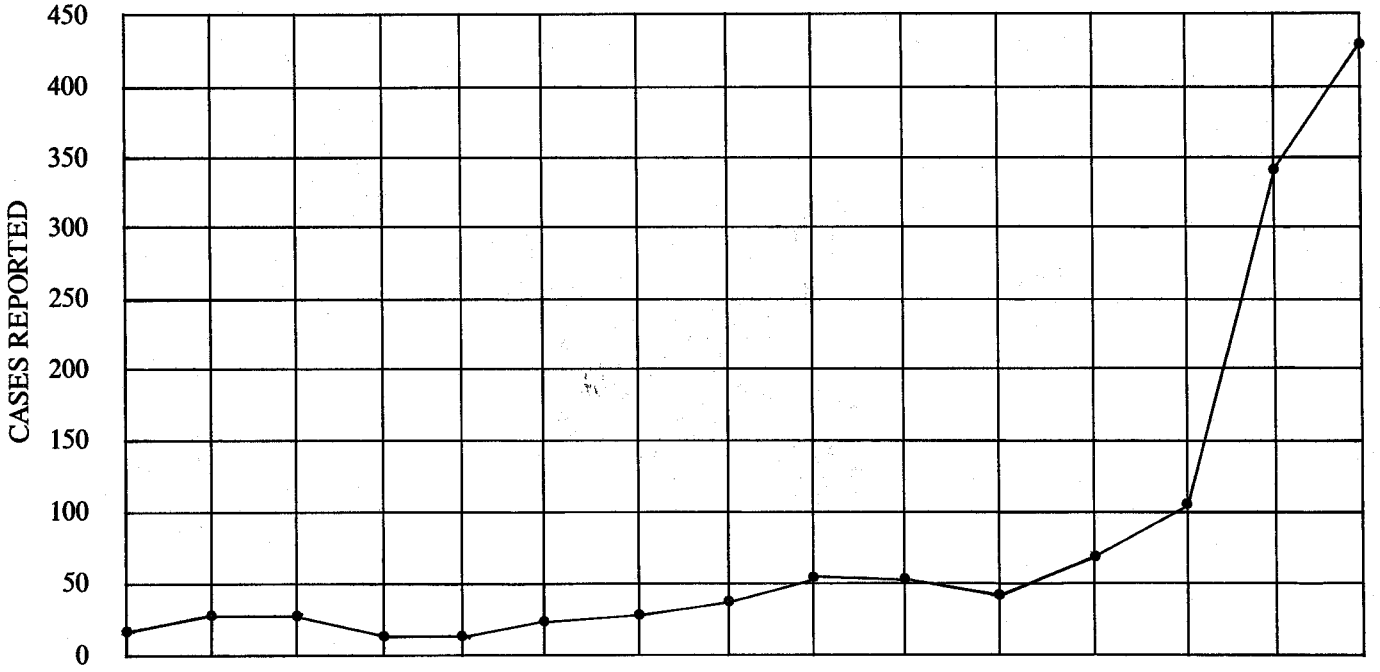
Transmission from mother to child occurs through breastfeeding; breastfed infants of seropositive mothers have an approximately 25% probability of becoming infected (*14*). However, infection has also occurred in infants who are not breastfed, suggesting that intrauterine and/or perinatal transmission may occur.

Sexual transmission of HTLV-I appears to be relatively inefficient (*15*). Transmission from male to female, however, appears to be more efficient than from female to male (*16*).

Disease Associations

HTLV-I has been etiologically associated with adult T-cell leukemia/lymphoma (ATL), a malignancy of mature T-lymphocytes characterized by skin lesions, visceral involvement, circulating abnormal lymphocytes, hypercalcemia, and lytic bone lesions (*17*). ATL has been recognized in Japan, the Caribbean,

Influenza Activity in Virginia 1988–89
Reported by 37 Sentinel Physicians



Graph represents cases of influenza-like illnesses reported by sentinel physicians from October 20th through February 1. Both influenza B/Victoria and influenza A have been isolated during the outbreak.

and Africa. No systematic attempt has been made to record cases of ATL in the United States, but 74 cases were reported to the National Institutes of Health between 1980 and 1987 (*18*). Approximately half of these cases occurred in persons of Japanese or Caribbean ancestry; most of the remainder were in blacks from the southeastern United States. ATL tends to occur equally in men and women, with peak occurrence in persons 40–60 years of age.

It is thought that a person must be infected with HTLV-I for years to decades before ATL develops. The lifetime risk of ATL among HTLV-I–infected persons has been estimated to be approximately 2% in two studies in Japan (*19,20*). In Jamaica, the lifetime risk of ATL among persons infected before the age of 20 years was estimated to be 4% (*21*).

Because of the long latent period of ATL, the risk of this disease among persons infected by blood transfusion (many of whom are elderly and may not survive their underlying disease) is not thought to be substantial. In fact, no cases of ATL associated with blood transfusion have been reported.

HTLV-I has also been associated with a degenerative neurologic disease known as tropical spastic paraparesis (TSP) in the Caribbean and as HTLV-I–associated myelopathy (HAM) in Japan (*22,23*). TSP/HAM is characterized by progressive difficulty in walking, lower extremity weakness, sensory disturbances, and urinary incontinence. Although most cases have been reported from countries in which HTLV-I is endemic, a few cases have occurred in the United States (*24*). TSP/HAM occurs in persons of all age groups, with peak occurrence in ages 40–49 years. Rates are higher in females than in males. The lifetime risk of TSP/HAM among persons infected with HTLV-I is unknown but appears to be very low. The latent period for this disease appears to be less than for ATL, and the disease probably can be caused by blood transfusion. Of 420 Japanese patients with HAM from whom information was available, 109 (26%) gave a history of blood transfusion; the mean interval between transfusion and onset of neurologic symptoms was estimated to be 4 years (M. Osame, unpublished data).

HTLV-I does not cause AIDS, and the finding of HTLV-I antibody in human blood does not imply infection with HIV or a risk of developing AIDS.

Background: HTLV-II

HTLV-II is closely related to HTLV-I. The genome of HTLV-II encodes viral proteins that are similar to those of HTLV-I, and there is extensive serologic cross-reactivity among proteins from HTLV-I and HTLV-II.

No specific information is available regarding the seroepidemiology or the modes of transmission of HTLV-II. There is some evidence that some of the HTLV-I seropositivity in the United States, especially in IVDUs, may be caused by HTLV-II (*5*).

Two cases of disease have been associated with HTLV-II infection. HTLV-II was first isolated from a patient with a rare T-lymphocytic hairy cell leukemia (*25*). In the second case, HTLV-II was isolated from a patient who had the more common B-lymphocytic form of hairy cell leukemia and who also suffered from a T-suppressor lymphoproliferative disease (*26*). No serologic evidence of HTLV-II infection has been found in 21 additional cases of hairy cell leukemia (*27*). Thus, the disease associations of HTLV-II are unclear, and nothing is known regarding lifetime risk of disease among infected persons.

Serologic Tests For HTLV-I

Interpretation

The screening tests that have been licensed by the FDA are enzyme immunoassays (EIAs) to detect HTLV-I antibody in human serum or plasma. Specimens with absorbance values greater than or equal to the cutoff value determined by the manufacturer are defined as initially reactive. Initially reactive specimens must be retested in duplicate to minimize the chance that reactivity is due to technical error. Specimens that do not react in either of the duplicate repeat tests are considered nonreactive. **Additional, more specific serologic tests are necessary to confirm that serum specimens repeatably reactive in the screening tests are positive for HTLV-I antibody. Users of the screening tests must have available to them additional, more specific tests to properly interpret repeatably reactive screening tests.** Such tests are available in research institutions, industry, and some diagnostic laboratories. No such tests have been licensed by the FDA.

Tests used to confirm HTLV-I seropositivity must be inherently capable of identifying antibody to the core (*gag*) and envelope (*env*) pro-

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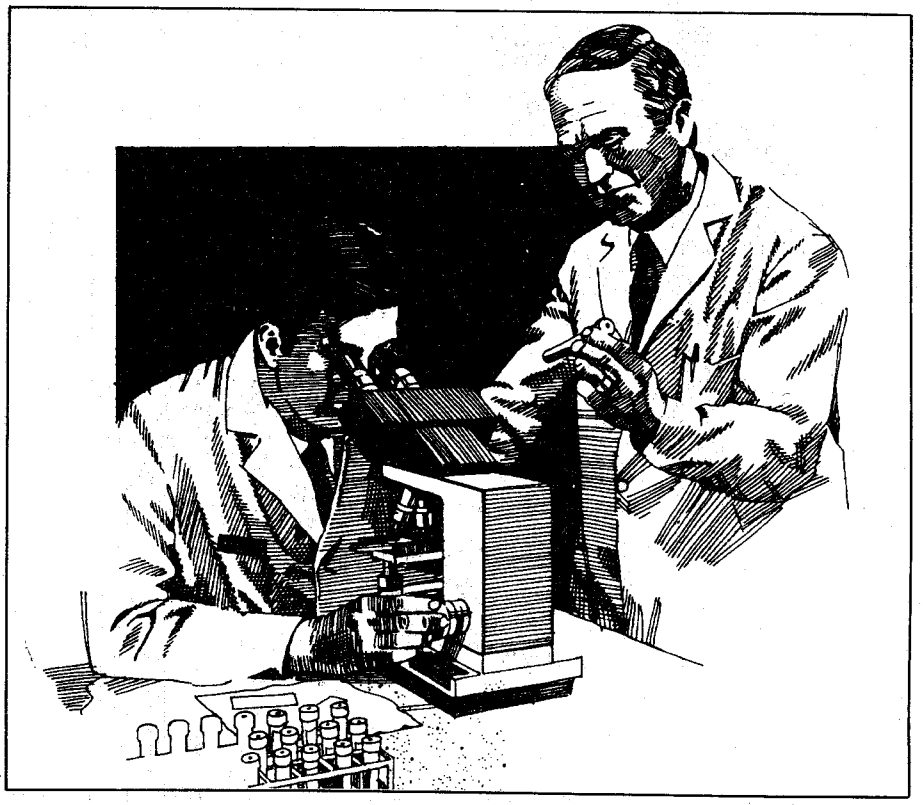

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teins of HTLV-I. (The immunoreactivities of the polymerase [*pol*] and transactivator [*tax*] proteins of HTLV-I have not been well-defined in current test systems.) Specific tests include Western immunoblot (WIB) and radioimmunoprecipitation assay (RIPA). Indirect fluorescent antibody (IFA) testing for HTLV-I has been used in some laboratories, but IFA does not detect antibody to specific HTLV-I gene products.

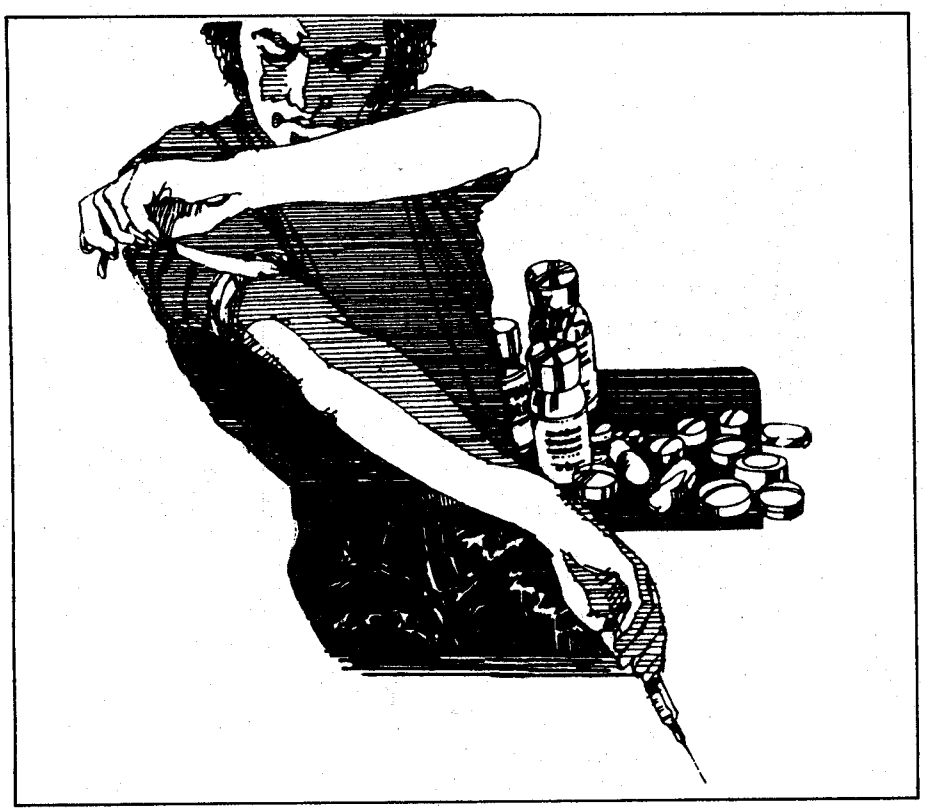
WIB appears to be the most sensitive of the more specific tests for antibody to *gag* protein products p19, p24, and (*gag*-derived) p28, whereas RIPA appears to be most sensitive for antibody to the *env* glycoproteins gp46 and (*env* precursor) gp61/68. Based on experience with these tests in several laboratories, the following confirmatory criteria for HTLV-I seropositivity have been adopted by the Public Health Service Working Group: a specimen must demonstrate immunoreactivity to the *gag* gene product p24 and to an *env* gene product (gp46 and/or gp61/68) to be considered "positive." Serum specimens not satisfying these criteria but having immunoreactivities to at least one suspected HTLV-I gene product (such as p19 only, p19 and p28, or p19 and *env*) are designated "indeterminate." Serum specimens with no immunoreactivity to any HTLV-I gene products in additional, more specific tests are designated "negative." **Both WIB and RIPA may be required to determine whether a serum specimen is positive, indeterminate, or negative.**

Although additional, more specific tests have been somewhat standardized, the quantities and the molecular weights of HTLV-I proteins produced by various cell lines vary considerably. Hence, the cell of origin for HTLV-I antigens used in either WIB or RIPA, as well as the method of antigen preparation, may markedly influence test sensitivity and interpretation of immunoreactivity against individual HTLV-I proteins. Laboratories performing these tests, however, should be able to detect antibody to the *gag* and *env* gene products of HTLV-I in WIB and/or RIPA.

Sensitivity, Specificity, and Predictive Value

Using the WIB and RIPA available in research laboratories and the confirmatory criteria described above to define the presence of HTLV-I antibody, the sensitivities of the three EIAs that have been licensed by the FDA have been estimated from the performance of the tests on a reference panel of 137 antibody-positive serum specimens. All three EIAs were repeatably reactive for 137 of 137 panel serum specimens, yielding an estimated sensitivity of 97.3%–100% by the binomial distribution at 95% confidence. Specificity* of the EIAs was estimated for each test from screening of at least 5000 normal U.S. blood donors in nonendemic areas. Estimated specificities ranged from 99.3% to 99.9% by the binomial distribution at 95% confidence. However, a specificity >99% but <100% may still yield a low positive predictive value when the screening test is used in a low-prevalence population. For example, in the study of U.S. blood donors cited above, 68 donors were repeat reactors in the screening test, but only 10 (15%) were determined to be HTLV-I–seropositive in more specific testing. This relatively low positive predictive value emphasizes the need for additional, more specific testing of specimens repeatably reactive in the EIA.

Neither the EIAs nor the additional, more specific tests can distinguish between antibodies to HTLV-I and HTLV-II. More sophisticated techniques, such as virus isolation and gene amplification (polymerase chain reaction [PCR]) are required to differentiate HTLV-I from HTLV-II infection.



Use Of HTLV-I Screening Tests In Blood Banks

The FDA recommends that whole blood and cellular components donated for transfusion be screened for HTLV-I antibody using a licensed EIA screening test. The FDA further recommends that units that are repeatably reactive by EIA be quarantined, then destroyed, unless otherwise stipulated by the FDA. Source plasma (obtained from plasma donors) intended for use in further manufacturing need not be screened for HTLV-I antibody.

Donor Deferral And Notification

FDA recommends permanent deferral of donors whose sera are repeatably reactive in EIA and confirmed as positive for HTLV-I antibody by additional, more specific testing. Such donors should be notified and counseled accordingly.

**Specificity was calculated as follows: (total donations screened minus total number repeatably reactive in EIA) divided by (total donations screened minus number confirmed as positive by additional testing).*

Donors whose serum specimens are repeatably reactive in the EIA but not confirmed as positive for HTLV-I antibody need not be notified on the first occasion. Although the donated units must be destroyed, the donors remain eligible for future donation. If, however, the donors test repeatably reactive in the EIA on a subsequent donation, they should be deferred indefinitely as donors and notified and counseled accordingly.

Guidelines For Counseling

Counseling should be considered a routine adjunct depending on the results of HTLV-I testing. Given some of the uncertainties related to testing, e.g., the inability to distinguish between antibodies to HTLV-I and HTLV-II, and the low probability that disease will occur in seropositive persons, every effort should be made to minimize the anxiety provoked by a repeatably reactive screening test, particularly one that is not confirmed as HTLV-I–seropositive by additional testing.

Persons confirmed as seropositive for HTLV-I should be notified that they have antibody to HTLV-I and are likely infected with HTLV-I or HTLV-II. They should be given information concerning disease associations and possible modes of transmission. In addition, they should be advised that they have been permanently deferred as blood donors and should neither give blood for transfusion nor share needles that have been used for percutaneous injection or infusions with other persons. Breastfeeding of infants should be discouraged. The paucity of data concerning sexual transmission of HTLV-I/HTLV-II does not permit a firm recommendation concerning sex practices; specific recommendations, such as the use of condoms to reduce the potential risk of sexual transmission, should be developed in consultation with a health-care professional.

Persons whose serum specimens are repeatably reactive on more than one occasion in the EIA but not confirmed as positive for HTLV-I antibody in more specific testing should be informed that they have inconclusive test results that do not necessarily imply infection with HTLV-I or HTLV-II. Nevertheless, they should be notified that they have been deferred indefinitely as donors and should not donate blood for transfusion. Periodic follow-up of such donors with EIA, more specific serologic tests, and possibly sophisticated techniques such as virus isolation and/or PCR may provide more reliable information regarding the presence of viral infection.

Reported by: Public Health Service Working Group.†

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Reprinted from MMWR 1988;37:736–740, 745–747.

Notices to Readers

Fourth National Environmental Health Conference

On June 20–23, 1989, the Center for Environmental Health and Injury Control, CDC; the Agency for Toxic Substances and Disease Registry (ATSDR); and the Association of State and Territorial Health Officials will cosponsor the Fourth National Environmental Health Conference. The conference will be held in San Antonio, Texas, and is directed toward federal, state, and local health and environment officials, physicians, and the environmental community.

The theme of the 1989 conference is "Environmental Issues: Today's Challenge for the Future." The conference will address environmental problems that have the greatest importance to public health, review topical scientific findings, and discuss prevention strategies. Plenary sessions will cover radon; medical, municipal, and hazardous waste; air pollution; lead in the environment; and dioxin. Twenty workshops will be held on topics of interest to states, academic institutions, and federal agencies, including health assessments at National Priority List (NPL) and Resource Conservation and Recovery Act (RCRA) sites, emergency responding, radiation, birth defects, risk communication, and indoor air pollution and respiratory disease.

For further information, call CDC at (404) 488-4700 or (404) 488-4682 or ATSDR at (404) 488-4881.

Have an Idea for the *Bulletin?*

The editor welcomes any reports of cases, outbreaks, or public health problems of interest to the Bulletin's *readers. Such accounts and any other comments or suggestions regarding the* Bulletin *should be addressed to: Editor,* Epidemiology Bulletin, *Office of Epidemiology, Room 700, 109 Governor Street, Richmond, Virginia 23219.*

Health Hints for the International Traveler—AIDS and HIV Infection

Editor's comment: This is the first of several articles on the topic of health hints for the international traveler.

Acquired Immunodeficiency Syndrome (AIDS) is the severest manifestation of infection by the human immunodeficiency virus (HIV). Other less severe illnesses, sometimes grouped under the term AIDS-related complex (ARC), as well as asymptomatic infections may also result from infection with HIV, but all infected persons remain at risk for developing AIDS indefinitely. The incubation period for AIDS may be long, ranging from a few months to many years. Some individuals infected with HIV remain asymptomatic for 8 years or more. Currently, there is no vaccine to protect against infection with HIV, and there is no cure for AIDS.

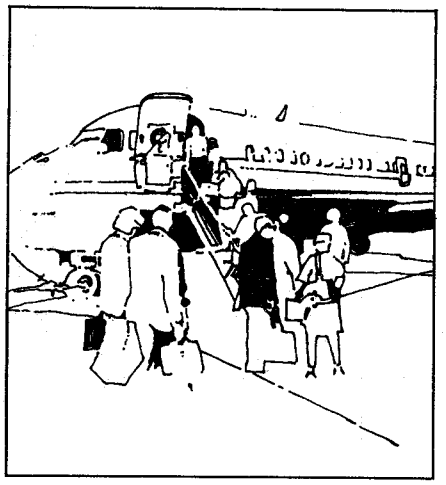
AIDS has been reported from more than 125 countries on every continent of the world. Adequate surveillance systems are lacking in many countries, so that the true number of cases is likely to be far greater than the number reported. In all countries, the number of persons infected with HIV will be far greater than the number of AIDS cases. Because HIV infection and AIDS are globally distributed, the risk to international travelers is determined less by their geographic destination than by their individual behavior.

The global epidemic of AIDS has raised several issues regarding HIV infection and international travel. The first is the increasing need of information for international travelers on how HIV is transmitted and how HIV infection can be prevented. Second is the use of a public conveyance by a person with AIDS or HIV infection. And finally, the recent policy by several countries for serologic testing for HIV and exclusion of those persons with AIDS or positive tests for HIV.

HIV infection is preventable. There is no documented evidence of HIV transmission through casual contacts; air, food, or water routes; contact with inanimate objects; or through mosquitoes or other arthropod vectors. The use of any public conveyance (e.g. airplane, boat, bus, train) by persons with AIDS or HIV infection does not pose a risk of HIV infection for other passengers. HIV is transmitted through sexual intercourse, blood or blood components, and perinatally from an infected pregnant woman.

Travelers are at risk if they:

- have sexual intercourse (homosexual or heterosexual) with an infected person, or a person whose infection status is unknown.
- use or allow the use of contaminated, unsterilized syringes or needles for any injections, e.g. illicit drugs, acupuncture, medical/dental procedures, or tattooing; or
- use infected blood, blood components, or clotting factor concentrate. This would be an extremely rare occurrence in those countries or cities where donated blood/plasma is screened for HIV antibody.



Travelers should avoid sexual encounters with a person who is thought to be infected with HIV or whose HIV infection status is unknown. This will mean avoiding sexual activity with intravenous drug users and persons with multiple sexual partners, including male or female prostitutes. Condoms may decrease, but not entirely eliminate, the risk of transmission of HIV. Persons who engage in vaginal, anal, or oral-genital intercourse with anyone who is infected with HIV or whose infection status is unknown should use condoms in combination with a spermicide.

In many countries, needlesharing by IV drug users is a major source of HIV transmission. Do not use drugs intravenously or share needles.

In the United States, Australia, Canada, Japan, and western European countries, the risk of infection of transfusion-associated HIV infection is greatly reduced through mandatory testing of all donated blood for the presence of antibodies to HIV.

If produced in the United States by procedures approved by the Food and Drug Administration, immune globulin preparations (such as those used for the prevention of hepatitis A and B) and hepatitis B virus vaccine are free of HIV and therefore safe to receive.

In other countries, especially less-developed nations, there may or may not be a formal testing program for testing blood or biological products for antibody to HIV. In these countries, use of locally-produced blood clotting factor concentrates should be avoided. If transfusion is necessary, the blood should be tested, if at all possible, for HIV antibodies by appropriately-trained laboratory technicians using a reliable test. Needles used to draw blood or administer injections should be sterile, preferably disposable, and prepackaged in a sealed, single unit container. Diabetics or other persons who require routine or frequent injections should carry a supply of syringes and needles sufficient to last their entire stay abroad.

International travelers should also be aware that some countries have recently established a policy to serologically screen incoming travelers (primarily those with extended visits) and to exclude persons with AIDS and those whose serum tests positive for HIV antibody. Persons intending to visit a country for a prolonged period should be informed of the policies of the particular country.

Reprinted from: Centers for Disease Control. Health Information for International Travel 1988. HHS Publicat. No. (CDC) 88-8280

Cases of selected notifiable diseases, Virginia, for the period January 1 through January 31, 1989.

Disease	State					Regions				
			Total to Date		Mean 5 Year To Date	This Month				
	This Month	Last Month	1988	1989		N.W.	N.	S.W.	C.	E.
Measles	0	19	0	0	0	0	0	0	0	0
Mumps	16	3	3	16	2	0	12	2	0	2
Pertussis	1	5	1	1	4	1	0	0	0	0
Rubella	0	0	0	0	0	0	0	0	0	0
Meningitis—Aseptic	16	16	7	16	13	0	4	6	3	3
*Bacterial	14	22	5	14	18	0	1	6	1	6
Hepatitis A (Infectious)	6	21	10	6	13	0	2	0	3	1
B (Serum)	23	37	15	23	33	0	2	8	3	10
Non-A, Non-B	1	4	2	1	6	0	0	0	0	1
Salmonellosis	81	88	72	81	71	12	17	10	21	21
Shigellosis	47	64	35	47	20	2	3	2	18	22
Campylobacter Infections	51	66	28	51	27	11	13	7	12	8
Tuberculosis	29	34	23	29	13	8	7	5	4	5
Syphilis (Primary & Secondary)	46	50	26	46	33	1	11	5	20	9
Gonorrhea	1261	1507	1230	1261	1476	—	—	—	—	—
Rocky Mountain Spotted Fever	0	0	0	0	0	0	0	0	0	0
Rabies in Animals	17	28	13	17	11	6	1	1	7	2
Meningococcal Infections	4	5	4	4	5	0	3	1	0	0
Influenza	31	23	95	31	195	10	1	0	1	19
Toxic Shock Syndrome	0	1	0	0	0	0	0	0	0	0
Reye Syndrome	0	0	0	0	0	0	0	0	0	0
Legionellosis	1	0	0	1	1	0	0	1	0	0
Kawasaki's Disease	0	1	0	0	2	0	0	0	0	0
Acquired Immunodeficiency Syndrome	30	31	18	30	—	1	12	3	10	4

Counties Reporting Animal Rabies: Albemarle 3 raccoons; Amelia 1 raccoon; Charles City 1 raccoon, 1 skunk; Chesterfield 1 skunk; Henrico 1 raccoon; Highland 1 cow; James City 1 raccoon; Nottoway 1 raccoon; Prince William 1 cat; Richmond City 1 raccoon; Russell 1 skunk; Shenandoah 1 cow, 1 skunk; York 1 raccoon.

Occupational Illnesses: Asbestosis 28; Asthma, Occupational; 1; Carpal Tunnel Syndrome 20; Dermatitis 1; Loss of Hearing 26; Mesothelioma 1; Pneumoconioses 43.

*other than meningococcal

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