Recommendations For Preventing Transmission Of HTLV-III/LAV 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.

*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 Associations; 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. (Continued to page 2)
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, scalpels, blades, and other sharp items must be placed in puncture-resistant containers for disposal. To prevent needlestick injuries, needles should not be recapped; purposefully bent or broken; removed from disposable syringes; or otherwise manipulated by hand. No data are currently available from controlled studies examining the effect, if any, of the use of needle-cutting devices on the incidence of needlestick injuries.

5. If an incident occurs during an invasive procedure that results in exposure of a patient to the blood of an HCW, the patient should be informed of the incident, and previous recommendations for management of such exposures (1) should be followed.

6. No HCW who has exudative lesions or weeping dermatitis should perform or assist in invasive procedures or other direct patient-care activities or handle equipment used for patient care.

7. All HCWs with evidence of any illness that may compromise their ability to adequately and safely perform invasive procedures should be evaluated medically to determine whether they are physically and mentally competent to perform invasive procedures.

8. Routine serologic testing for evidence of HTLV-III/LAV infection is not necessary for HCWs who perform or assist in invasive procedures or for patients undergoing invasive procedures, since the risk of transmission in this setting is so low. Results of such routine testing would not practically supplement the precautions recommended above in further reducing the negligible risk of transmission during operative, obstetric, or dental invasive procedures.

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

References


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Recommendations of the Immunization Practices Advisory Committee (ACIP) of the U.S. Public Health Service

Update: Prevention of *Haemophilus influenzae* Type b Disease

*Haemophilus influenzae* type b (Hib) is the most common cause of bacterial meningitis in the United States. It also causes other serious invasive illnesses, including epiglottitis, sepsis, cellulitis, septic arthritis, osteomyelitis, pericarditis, and pneumonia. By 5 years of age, one of every 200 children in the United States will have had a systemic infection due to Hib. A polysaccharide vaccine against systemic Hib disease was licensed in the United States in April 1985. Information on the vaccine and Immunization Practices Advisory Committee (ACIP) guidelines for its use should be consulted (1). The purpose of this statement is to update these recommendations and to provide guidelines for the prevention of secondary cases of Hib disease.

**Chemoprophylaxis**

*Risk of Secondary Disease.* Secondary disease, defined as illness within 1-60 days following contact with a child who has Hib disease, occurs for less than 5% of all invasive Hib disease. However, six studies of household contacts of Hib patients found a secondary attack rate of 0.3% in the month following disease onset in the index patient, which is about 600-fold higher than the age-adjusted risk in the general population (2-7). Among these studies, the attack rate among household contacts varied markedly with age: 4% for children under 2 years of age; 2% for children 2-3 years of age; 0.1% for children 4-5 years of age; and 0% for those over 6 years of age (2-7). Among these household contacts, 64% of secondary cases occurred within the first week, excluding the first 24 hours of disease onset in the index patient; 20%, during the second week; and 16%, during the third and fourth weeks.

The risk of secondary disease among children who were exposed to a primary case in day-care and who did not receive rifampin prophylaxis has been examined in four studies. A national collaborative study that calculated secondary attack rates for household and day-care classroom contacts found that one (1%) of 91 children under 4 years of age in day-care acquired disease in the month following the index patient, compared with three (2%) of 125 household contacts under 4 years of age (2). A multicenter study in Seattle-King County, Washington; Oklahoma; and Atlanta, Georgia, found that the risk of secondary Hib disease among day-care classroom contacts was age-dependent; 10 (3%) cases occurred among the 376 contacts 0-23 months old, whereas none of the 379 classroom contacts older than 23 months of age acquired secondary disease (8). No cases occurred among children who attended day-care for fewer than 25 hours per week. In this study, classroom contacts were defined as children who spent more than half their day-care time in the same classroom as a child with primary Hib disease in the week before disease onset of the primary case. The overall risk for classroom contacts was 0.7% (10/1,388), 20 times higher than the risk for other children in the center (0.04% [2/5,639]). Thirty-three percent of the secondary cases occurred within 3 weeks of onset of the index case; 13%, between days 21 and 40; and 53%, between days 41 and 60. Meningitis and other systemic Hib infections were equally likely to result in secondary cases.

Two prospective studies have examined the risk of subsequent Hib disease in day-care facilities. In Dallas County, Texas, follow-up for 60 days of classroom contacts revealed no cases of secondary disease in 361 children under 2 years old, and a secondary attack rate of 0.5% (1/213) in those 2-3 years of age (9). Other cases of Hib disease occurred but could not be classified as secondary cases because these children enrolled in the day-care facility after the index patient became ill. Since it is known that rates of asymptomatic transmission are elevated in day-care classrooms with children with Hib disease, some of these cases may have been associated with the index case.

A similar surveillance study was conducted in Minnesota. No cases of secondary Hib disease were found among 370 day-care contacts under 2 years of age; 263 (71%) were classroom contacts. These were defined as children who spent more than 8 hours in the same classroom as the primary case in the week before the patient with primary disease became ill. Similarly, secondary cases were not seen in 716 children 2-3 years of age, of whom 421 (59%) were classroom contacts (10).

The disparities in the risk of day-care-associated secondary Hib disease in Minnesota; Dallas County, Texas; and the two multicenter studies remain unexplained. Possible reasons include differences among the several study areas in day-care characteristics, such as classroom size and age distribution of children, which might affect intensity and duration of contact. There may be further unrecognized differences in epidemiologic factors or invasiveness of prevalent Hib strains.

**Efficacy of Rifampin Prophylaxis.** Most children at risk of secondary disease are too young to respond to the Hib polysaccharide vaccine. Therefore, the main preventive measure presently available is rifampin administration. Currently available data from several studies indicate rifampin in a dosage of 20 mg/kg per dose once daily (maximum daily dose 600 mg) for 4 days eradicated Hib carriage in >95% or more of contacts of primary cases, including children in day-care facilities (11-13). In a randomized placebo-controlled trial, rifampin in the currently recommended dosage administered to all household and day-care classroom contacts, including adults, significantly decreased secondary Hib disease among household and day-care contacts (none of 303 rifampin-treated contacts under 4 years of age had secondary disease, compared with four of 216 placebo-treated contacts under 4 years of age [p = 0.031] (2); the number of cases was insufficient to evaluate efficacy in the household or day-care setting alone. However, the collaborative study of day-care centers cited above found that among classroom contacts of Hib patients, children aged 0-23 months who received rifampin prophylaxis were significantly less likely to develop secondary disease than children who did not take rifampin (none of 232, compared with 10 [3%] of 376 [p < 0.02]) (8). Secondary disease did not develop in day-care classes in which over 75% of the class received rifampin. However, rifampin (Continued to page 4)
prophylaxis is unlikely to be 100% effective, and a day-care center in which rifampin prophylaxis failed to prevent subsequent disease has been reported (14).

Implementation of Chemoprophylaxis. Rifampin is available in 150-mg and 300-mg capsules. For those unable to swallow capsules, rifampin may be mixed with several teaspoons of applesauce immediately before administration, resulting in acceptable serum and salivary levels (15). Although there has been more experience with the applesauce mixture, a suspension of rifampin may also be freshly prepared in United States Pharmacopeia syrup; the preparation should be vigorously shaken before use. Side effects of rifampin in the recommended dose include nausea, vomiting, diarrhea, headache, or dizziness, which occurred among 20% of those taking rifampin and 11% of placebo recipients. No serious reactions occurred (2). Those taking rifampin (including parents and day-care staff) should be informed that orange discoloration of urine, discoloration of soft contact lenses, and decreased effectiveness of oral contraceptives can occur.

In implementing chemoprophylaxis in day-care centers, it is important to ensure that all classroom contacts receive rifampin during the same period. Some local and state health departments have facilitated the timely implementation of chemoprophylaxis by coordinating rifampin administration following consultation with private physicians or by providing information to parents of day-care contacts.

Vaccine

Effect of Haemophilus b Polysaccharide Vaccine on Nasopharyngeal Carrierage. Limited data are available on the effect of the Haemophilus b polysaccharide vaccine on nasopharyngeal carriage of the organism. By analogy to carriage studies after serogroups A and C meningococcal polysaccharide vaccination, some reduction in acquisition of carriage may occur shortly after immunization, but no long-term effect has been noted (16-18).

Use of Haemophilus b Polysaccharide Vaccine in Children with Preceding Hib Disease. Studies have shown that the development of anticapsular antibodies following invasive Hib disease is largely age-dependent. A study of acute and convalescent sera from 125 patients with meningitis, septicemia, or epiglottitis due to Hib determined that, among those who acquired disease when they were younger than 18 months, 41 (85%) of 48 failed to develop an adequate antibody response, in contrast to 18 (23%) of 77 of those older than 18 months (19). Cases have been reported in which children who do not mount an antibody response after an invasive episode of Hib have developed a second systemic infection with the organism (20).

Recommendations

The primary strategy for preventing Hib disease is immunization. Children should be vaccinated at 24 months of age. Those at high risk for Hib disease, including children attending day-care, may be given the vaccine at 18 months of age. ACIP guidelines for use of the vaccine should be consulted (I). This update addresses chemoprophylaxis (recommendations 1-7) and additional vaccine issues (recommendations 8 and 9).

Chemoprophylaxis. Although unexplained disparities in available data prevent a precise estimate of the magnitude of risk among day-care contacts, it is likely that the increased risk of disease observed among young household contacts is also present among day-care classroom contacts under 2 years of age. Since rifampin prophylaxis is effective in preventing subsequent cases in this high-risk group, the ACIP recommends that:

1. Contacts of all ages who develop symptoms suggestive of invasive Hib disease, such as fever or headache, be evaluated promptly by a physician.

2. In any household in which a case of invasive Hib disease has occurred and in which another child under 4 years of age resides, all members of the household, including adults, should receive rifampin according to the following regimen: rifampin in a dosage of 20 mg/kg per dose once daily (maximal daily dose 600 mg) for 4 days; the dose of neonates (under 1 month of age) is 10 mg/kg once daily for 4 days.

3. In day-care classrooms in which a case of Hib disease has occurred and in which another child under 2 years of age has been exposed, all parents should be notified (preferably in writing) regarding the occurrence of the case and the possibility of increased risk to their children. They should be informed about the symptoms and the need for prompt medical evaluation if symptoms occur. They should also be notified of the availability of rifampin prophylaxis. Although the data on which to base recommendations are not optimal, and some authorities disagree, the consensus of the ACIP is as follows: In a day-care classroom in which a case of systemic Hib disease has occurred, and in which one or more children under 2 years old have been exposed, strong consideration should be given to administering rifampin prophylaxis to all children and staff in the classroom, regardless of age.

4. Rifampin should not be used in...
pregnant women, as its effect on the fetus has not been established, and it is teratogenic in laboratory animals.

5. Chemoprophylaxis should be instituted as rapidly as possible. If more than 14 days have passed since the last contact with the index patient, the benefit of chemoprophylaxis is likely to be decreased.

6. All children convalescing from systemic Hib disease who are anticipated to resume close contact with other young children, at home or in day-care, should receive rifampin immediately after completing treatment for their illness. Therapy for systemic disease does not reliably eradicate respiratory carriage of Hib, and some physicians may wish to give rifampin to all index patients.

7. In day-care classrooms in which children are to receive chemoprophylaxis, children who have received the Haemophilus b polysaccharide vaccine should also receive rifampin. Although these children are felt to be at decreased risk for disease, the vaccine probably does not affect carriage of the organism, which they may pass on to susceptible classmates.

8. Children who have had invasive Hib disease when they were under 24 months of age should still receive the vaccine according to previous recommendations, since most children under 24 months of age fail to mount an immune response to the clinical disease.

9. Satisfactory response to the vaccine is not consistent among children 18-23 months of age, and most authorities believe that these children should be revaccinated. Although data on the precise timing of this second dose are not currently available, it would be reasonable to reimmunize 2-12 months after the initial dose but not before 24 months of age. Previous immunization does not change the immune response or adverse reaction to a subsequent dose of the vaccine (2).

References


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

**Background**

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

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

**Epidemiologic Studies**

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

Since August 1983, CDC has enrolled 938 individuals who have had parenteral or mucous-membrane exposures to blood or body fluids of AIDS patients in a prospective surveillance study. To date, 451 entrants have been followed and tested for HTLV-III/LAV antibody. Of these, 183 persons received IG and/or HBIG as prophylaxis against hepatitis B infection; 100 (55%) received only IG; 65 (36%) received only HBIG; and 18 (10%) received both. One of the 183 HBIG recipients is now positive for (Continued to page 7)
HTLV-III/LAV antibody, but no pre-exposure serum was available for this individual, and seropositivity may have predated the needlestick exposure and IG prophylaxis. Further, heterosexual transmission of HTLV-III/LAV infection in this individual cannot be ruled out. No documented seroconversions have occurred in any of the 183 health-care workers who received IG or HBIG.

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

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

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

Information regarding post therapy with immune globulins is available from 10,227 of 17,115 AIDS patients reported to CDC. Three hundred fifty-eight (4%) reported receipt of an IG preparation. All but seven of these patients also were members of groups known to be at high risk for developing AIDS. The percentage of patients with no recognized risk factors for AIDS was not significantly different among those who received immune globulins (7/358 [2%]) than among those who did not (358/9,869 [4%]).

**Laboratory Studies**

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

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

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

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

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

**References**


**New Commissioner to Arrive in July**

Dr. James B. Kenley left his post as Commissioner of Health on May 9th to take up a new position at the Medical College of Virginia (MCV), where he will serve as interim Chairman of the Department of Preventive Medicine. Dr. Kenley’s affiliation with the Department began 30 years ago when he served as District Health Director for the Fluvanna-Goochland-Louisa area. From 1963 to 1965 he directed the Bureau of Epidemiology in the central office in Richmond; for the last 10 years he has served as Virginia’s Commissioner of Health. We will miss Dr. Kenley’s leadership and his loyalty to Virginia and the people who worked for him. We wish him every success in his new position.

Replacing Dr. Kenley on July 1 will be Dr. C.M.G. (Kim) Buttery. Dr. Buttery currently serves as Director of Public Health for the Corpus Christi-Nueces County, Texas Department of Public Health. He formerly served as Director of Public Health for the City of Portsmouth, Virginia, and as Assistant Public Health Director for Fairfax County. He engaged in the private practice of family medicine in Rocky Mount, Virginia, from 1957-1966. We welcome Dr. Buttery back to Virginia, and look forward to working with him to promote and protect the health of all Virginians.
Cases of selected notifiable diseases, Virginia, for the period May 1 through May 31, 1986

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Counties Reporting Animal Rabies: Augusta 1 Grey fox; Culpeper 1 raccoon; Fauquier 1 raccoon; Shenandoah 1 skunk; Spotsylvania 1 raccoon; Fairfax 4 raccoons; Loudoun 2 raccoons; Russell 1 skunk, Scott 1 fox; Hanover 1 raccoon.

Occupational Illnesses: Pneumoconiosis 35; Asbestosis 11; Carpal tunnel syndrome 10; Silicosis 4; Dermatitis 2; Hearing loss 1.

*other than meningococcal

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