DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

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Dear Colleague:

This letter will cover a number of topics in the areas of smokeless tobacco, infection control, fluoridation, plus other areas of interest.

With regard to smokeless tobacco, we have provided a summary of both Federal and State legislation through December 1985; and discuss delegation of authority for smokeless tobacco to CDC and the CDC behavioral risk survey on smokeless tobacco.

A number of topics are covered in the areas of infection control, including reprints of two MMWR articles concerning prevention for hepatitis B and HIV transmission; oral findings in patients with AIDS; a revision of CDC's cased definition for AIDS; the odontogenic origin of toxic shock syndrome; and symptoms of irritation associated with exposure to glutaraldehyde.

In the area of fluoridation, we have included the American Medical Association's reaffirmation of its endorsement of fluoridation; a further refutation of the aluminum/fluoride association; Consumer Reports' comments on leaching of aluminum from aluminum cookware; correction of an erroneous statement by a news service concerning EPA's statement on indoor air pollution; EPA's denial of petition to include fluoride as a toxic chemical; and the significance of EPA's proposal to redefine non-community water systems.

Under additional noteworthy items is some general information about mercury, sweeteners, a hydrofluoric acid spill, and a call for abstracts from AAPHD.

We welcome any contributions and/or comments you may have with regard to this letter. With your assistance, we can continue to provide the most current information concerning the prevention of oral diseases and the promotion of oral health.

Sincerely yours,

Lawrence J. Furman

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SMOKELESS TOBACCO/TOBACCO

SUMMARY OF SMOKELESS TOBACCO LEGISLATION THROUGH 1985

The following information represents a comprehensive summary of smokeless tobacco legislation, both Federal and State, passed through 1985. We are aware that additional legislation was passed during 1986 and 1987. We are in the process of screening this information and plan to provide an equally comprehensive summary through the "Dear Colleague" letter in the near future.

As of December 1985, over 60 congressional bills discussing smoking or tobacco related issues had been introduced in the 98th and 99th sessions of Congress. In addition to the Federal legislation, a comprehensive search of State statute books and legislative tracking services indicate that nearly 400 State laws pertaining to smoking and the sale or use of tobacco products are currently in effect. The following is a summation of proposed or enacted legislation related to smokeless tobacco.

Federal Legislation

Taxation

Through December 1985, a total of 33 bills that applied to the taxation of cigarettes and smokeless tobacco were introduced in the House and Senate during the 99th session of Congress.

Two House bills and one Senate bill pertain solely to smokeless tobacco. One House bill (H.R. 3064) imposes an excise tax on smokeless tobacco products, with tax revenues allocated to the Medicaid program. The second House bill (H.R. 3078), which is broader in scope, establishes a Federal program to assist States in implementing programs on the dangers of smokeless tobacco, and imposes an excise tax of 32¢ on all smokeless tobacco products.

Proceeds from this tax would be used to establish a trust fund for cancer research and educational programs on smokeless tobacco and would disallow a deduction for expenses incurred in advertising smokeless tobacco. Senate bill 1782 would impose a $1.25 excise tax per pound on snuff and 40¢ per pound on chewing tobacco.

Regulation of Advertising Tobacco Products

With regard to smokeless tobacco, two bills were introduced in the 99th session of Congress and incorporated into S. 1574 which became Public Law 99-252 in February 1986. One bill (H.R. 2950), cited as the Comprehensive Smokeless Tobacco Education Act, would require labeling on all smokeless tobacco products and advertisements. The other bill (H.R. 3510), cited as the Comprehensive Smokeless Tobacco Health Risk Education Act, would establish a Federal initiative acknowledging the dangers of smokeless tobacco by providing assistance to States for developing programs and requiring the labeling of all smokeless tobacco products and advertisements. Public Law 99-52 is cited as the Comprehensive Smokeless Tobacco education Act of 1986.

In the 99th session, three bills specifically addressed the labeling of smokeless tobacco: H.R. 2950, cited as the Smokeless Tobacco Act, requires specific warnings on all smokeless tobacco products and advertisements. H.R. 3150, cited as the Comprehensive Smokeless Tobacco Health Risk Education Act, proposed to establish a Federal initiative to require warning labels on smokeless tobacco products and advertisements, and S. 1574 (now Public Law 99-252) makes it unlawful to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product bears one of three health warning labels.

H.R. 760, introduced in the 99th session of Congress, was to amend the Federal Cigarette Labeling and Advertising Act to prohibit the advertising of any tobacco product on any medium of electronic communication. Cited as the Health in Advertising Act, the bill amends Section 6 of the Act to make it unlawful to advertise cigarettes, little cigars, and any other tobacco product on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission.

State Legislation - All 50 States and the District of Columbia have enacted legislation pertaining to the sale or use of tobacco products.

Commerce, Including Taxation

All States tax cigarettes, and all States with the exception of West Virginia require that persons obtain licensing before engaging in the business of distributing, retailing, wholesaling, or manufacturing cigarettes, and other tobacco products or both.

Schools and School Health Education

Concern for the health and welfare of their residents has prompted 18 States to require elementary and secondary schools to include instruction on the dangers associated with tobacco use as part of their health education programs.

Alabama, Connecticut, and Oklahoma have directed their departments of education to establish and implement in-service training programs to educate teachers, school administrators, and other school personnel about the effects of nicotine and tobacco use.

All educational institutions in Minnesota that provide teacher training must offer programs in the personal use and misuse of and dependency on tobacco. Students must take and pass the program. Connecticut law dictates that universities that train teachers must provide instruction on the effects of nicotine and tobacco use on health, character, citizenship, and personality development and the best methods for instructing students on these topics. Connecticut will not grant a certificate to teach or supervise in any public school to any person who has not passed an examination on the effects of nicotine and tobacco use.

California and Florida have no specific statutory provisions for mandatory instruction on the effects of tobacco use in elementary and secondary schools. Both States, however, require that upon adoption of instructional materials for use in the schools, school boards shall include only instructional materials that portray accurately the physical effects of tobacco use.

In Iowa the school board may suspend or expel any student who violates the rule prohibiting the use of tobacco. In Louisiana, school principals are authorized to suspend any student who uses tobacco in school buildings, on school grounds, or in school buses.

Regulations of Sale to and Use of Tobacco Products by Minors

The sale or distribution of cigarettes or tobacco products to minors is regulated by 39 jurisdictions. Missouri and South Dakota impose no restrictions at the State level, but permit cities, towns, and municipalities to enact ordinances prohibiting the sale to or use of cigarettes by minors or both. The only States that do not regulate the sale or distribution of tobacco products to minors are Colorado, Georgia, Kentucky, Louisiana, Montana, New Hampshire, New Mexico, Virginia, Wisconsin, and Wyoming.

Indiana, Kansas, New York, and Oregon prohibit only the sale of cigarettes to minors. The other State statutes have much broader prohibitive language and randomly outlaw the sale or furnishing (or both) of cigars, cigarettes, snuff, chewing tobacco, smoking materials, and tobacco in any form to minors (see Table).

The majority of States prohibiting the sale of cigarettes or other tobacco products to minors define a minor as anyone under the age of 18 years. Ten jurisdictions define a minor as anyone under the age of 16 years, and four define a minor as 17 years of age or younger. At the two extremes are Hawaii, which prohibits the sale of tobacco products to anyone under the age of 15 years, and Alabama and Utah, which prohibit such sales to anyone under the age of 19 years.

The penalties for violation of the laws relating to selling or furnishing tobacco products to minors vary from State to State. In 12 States, such offenses are punishable only by a fine. In the remaining jurisdictions, such offenses are punishable by fine, imprisonment, or both.

In addition to prohibiting the sale or furnishing of cigarettes or other tobacco products to minors, 12 States prohibit the use or possession (or both) of such products by minors. Minors found guilty of using or possessing tobacco are punishable by fine in Idaho, Illinois, Rhode Island, and West Virginia, and by fine or imprisonment (or both) in Kansas, Michigan, and Tennessee. Louisiana does not specifically prohibit the use of tobacco by minors, but does authorize public school principals to suspend any student who uses tobacco in school buildings, on school property, or in school buses.

In the remaining five States, the offense is classified as either a misdemeanor or petty offense with no specific penalty described in the statute. Nine States require dealers, distributors, or vendors of cigarettes or other tobacco products to post notice at the point of sale that the sale to or purchase of such products by minors is prohibited by law.

Reference:

Smoking and Health: A National Status Report, A Report to Congress, U.S. DHHS, PHS, CDC,Center for Health Promotion and Education, Office on Smoking and Health, Rockville, MD, HHS/PHS/CDC - 87-8396

DELEGATION OF AUTHORITY FOR SMOKELESS TOBACCO PRODUCTS GIVEN TO CDC

Robert E. Windom, Assistant Secretary for Health, PHS, DHHS, has issued the following statement, which became effective on August 31, 1987:

> Notice is hereby given that in furtherance of the delegation of authority of August 10, 1987 (52 FR 31068) by the Secretary of Health and Human Services to the Assistant Secretary for Health, the Assistant Secretary for Health has delegated to the Director, Centers for Disease Control, with authority to redelegate, all the authorities delegated to the Assistant Secretary for Health under sections 2, 4, and 8(a) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (P.L. 99-252), as amended hereafter, concerning Public Education, Ingredient Reporting, and Reports, excluding the authorities to issue regulations and to submit reports to the Congress.

Reference:

Federal Register, September 9, 1987

BEHAVIORAL RISK TELEPHONE SURVEY - SMOKELESS TOBACCO

On June 18, 1987, data for individual States were collected by the Centers for Disease Control through a Behavioral Risk Telephone Survey on smokeless tobacco. By the time you receive this "Dear Colleague" letter, you should have received the data for your individual State.

TABLE

RESTRICTIONS ON SALE OR DISTRIBUTION OF CIGARETTES OR OTHER TOBACCO PRODUCTS TO MINORS

	CIGARETTES	CIGARS	SMOKING TOBACCO	CHEWING TOBACCO	ANY TOBACCO	SNUFF	SMOKING HERBS
Alabama	X			X			
Alaska	X	X			X		
Arizona	X	X					
Arkansas			X	X	X		
California	X				X		
Connecticut					X		
Delaware					X		
District of Columbia	X	X			X		
Florida					X		
Hawaii					X		
Idaho	X	X			X		
Illinois	X	X			X		X
Indiana					X		
Iowa	X				X		
Kansas	X						
Maine	X				X		
Maryland	X		X	X			
Massachusetts	X			X	X	X	
Michigan	X	X	X	X	X		
Minnesota					X		
Mississippi	X	X	X			X	
Nebraska	X				X		
Nevada	X				X		
New Jersey	X				X		
New York	X	X		X	X	X	
North Carolina	X				X		
North Dakota	X	X			X		X
Ohio	X				X		
Oklahoma	X						
Oregon		X			X		
Pennsylvania	X					X	
Rhode Island	X						
South Carolina	X				X		
Tennessee	X	X					X
Texas	X				X		
Utah	X	X			X		
Vermont		X			X	X	
Washington	X	X			X		
West Virginia	X	X			X		
TOTAL	30	15	4	6	29	5	3

INFECTION CONTROL

The following articles are reprinted from two issues of the CDC Morbidity and Mortality Report (MMWR):

"Update on Hepatitis B Prevention." June 19, 1987, Vol. 36, No. 23. This article provides an update on Hepatitis B (HB) vaccine usage and its impact on disease incidence in the 5 years following its licensure. It also provides both recommendations for using a new HB vaccine produced in yeast by recombinant DNA technology and an assessment of the need for HB vaccine booster doses for persons who have received the initial three-dose regimen.

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PUBLIC HEALTH SERVICE
From the *MMWR*, June 19, 1987, Vol. 36, No. 23,
pp. 353-360, 366

Recommendations of the Immunization Practices Advisory Committee

Update on Hepatitis B Prevention

INTRODUCTION

Hepatitis B virus (HBV) infection is a major cause of acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma in the United States and worldwide. Since 1982, a safe and effective hepatitis B (HB) vaccine manufactured from human plasma has been available in the United States. This vaccine has been recommended as preexposure prophylaxis for persons at high or moderate risk of HBV infection (*1*). In addition, the combination of HB vaccine and hepatitis B immunoglobulin (HBIG) has been recommended for postexposure prophylaxis in susceptible persons who have perinatal or needle-stick exposure to known HBV-positive persons or their blood.

This statement provides an update on HB vaccine usage and on its impact on disease incidence in the 5 years following its licensure. In addition, it provides both recommendations for using a new HB vaccine produced in yeast by recombinant DNA technology and an assessment of the need for HB vaccine booster doses for persons who have received the initial three-dose regimen. Basic recommendations on preexposure and postexposure usage of HB vaccine and on prevaccination serologic testing for susceptibility to hepatitis B are unchanged. Previous recommendations should be consulted for a complete discussion of the usage of HB vaccine (*1*).

PLASMA-DERIVED HB VACCINE

Patterns of Usage to Date

Since the plasma-derived HB vaccine became available in June 1982, 4,400,000 doses have been distributed in the United States, and an estimated 1,400,000 persons have completed the three-dose series (Merck Sharp & Dohme, unpublished data). During this 5-year period, vaccination programs and overall vaccine usage have focused primarily on three risk groups—persons who work in health-care professions and have exposure to blood, staff and clients of institutions for the developmentally disabled, and staff and patients in hemodialysis units. Although no precise figures are available, it is estimated that more than 85% of distributed vaccine has been used for these groups.

Development of vaccination programs for health-care workers has progressed steadily since vaccine licensure. Several surveys of hospitals in 1985 showed that

between 49% and 68% of hospitals had established HB vaccination programs and that the number has increased steadily each year (CDC, unpublished data). Large hospitals (>500 beds) were most likely to establish programs (90%). However, by June 1985, 60% of hospitals with fewer than 100 beds also had begun vaccination programs. In 75% of the programs, vaccination was recommended for high-risk health-care workers (as defined by the hospital), and, in 77%, the hospital paid for these vaccinations. In addition, 70% of states had established programs for vaccinating health-care workers under state jurisdiction (CDC, unpublished data).

In spite of these programs, the actual use of vaccine in high-risk health-care professions has been modest. One statewide survey showed that, in hospitals with HB vaccine programs, only 36% of persons at high risk had actually received vaccine (CDC, unpublished data). In one survey in three large cities, only 24% of physicians had received vaccine (CDC, unpublished data). National surveys have shown higher rates of vaccination among dentists (44% in early 1986) and hemodialysis staff (an estimated 44% in 1985); however, even these rates fall well short of optimal coverage (CDC, unpublished data).

Development of vaccination programs has also progressed for several other groups at high risk of HBV infection. By mid-1985, 94% of states had established vaccination programs for the developmentally disabled in institutions under state jurisdiction, and 75% had programs for staff of such facilities (CDC, unpublished data). By 1986, an estimated 27% of the developmentally disabled had received HB vaccine (Merck Sharp & Dohme, unpublished data). In addition, wide-scale programs directed at vaccinating all susceptible persons were established in 1981 for Alaskan Natives and in 1985 for the population of American Samoa.

Nevertheless, there has been little progress in developing vaccination programs for other major risk groups, including parenteral drug abusers, homosexual men, and heterosexually active persons with multiple sexual partners. Few states have established programs for offering vaccine to any of these groups, and private usage of vaccine among these groups is believed to be limited.

Impact on Disease Incidence

The incidence of reported hepatitis B has increased steadily over the last decade. Hepatitis B is now the most commonly reported type of hepatitis in the United States. In 1978, 15,000 cases of clinical hepatitis B were reported to CDC, for an incidence rate of 6.9/100,000 population. At that time, CDC estimated that there were actually 200,000 persons with HBV infection and that 50,000 of these had clinically confirmed cases with jaundice. The incidence rate of reported disease increased 33%, to 9.2/100,000, in 1981, the year prior to vaccine availability. It continued to increase during the initial 4 years of vaccine availability, reaching a rate of 11.5/100,000 in 1985 (*2*). Based on a comparison with the overall infection rate estimated in 1978, the incidence of HBV infection in the United States is now estimated at over 300,000 cases per year.

The apparent lack of impact of HB vaccine on the incidence of hepatitis B is attributable to several factors. First, the majority of acute hepatitis B cases now occur in three groups: homosexual men, parenteral drug abusers, and persons acquiring disease through heterosexual exposure (*3*). None of these groups is being reached effectively by current HB vaccine programs. In contrast, fewer than 10% of cases occur in health-care workers, the institutionalized developmentally disabled, and other groups currently accounting for the bulk of vaccine usage. Finally, up to 30% of patients deny any of the recognized risk factors, even after careful questioning. No effective strategy has been devised to prevent disease among this group, although some are probably undisclosed members of the three major risk groups.

A reduction in the incidence of hepatitis B can be expected only if significant proportions of persons at high risk receive vaccine. Increased efforts are needed to develop programs to vaccinate persons in all high-risk groups and to increase compliance among those who are susceptible in areas where programs are established. To have any effect on the incidence of hepatitis B, use of HB vaccine in the United States must extend beyond the current groups of recipients.

NEW RECOMBINANT DNA HB VACCINE

Formulation

In July 1986, a new, genetically engineered HB vaccine (Recombivax HB®; Merck Sharp & Dohme) was licensed by the U.S. Food and Drug Administration. This vaccine, as formulated, has an immunogenicity comparable to that of the currently

available plasma-derived vaccine (Heptavax B®; Merck Sharp & Dohme). The two vaccines are also comparably effective when given with HBIG to prevent perinatal HBV transmission. The new vaccine provides an alternative to the plasma-derived HB vaccine for almost all groups at risk of HBV infection.

The recombinant vaccine is produced by *Saccharomyces cerevisiae* (common baker's yeast) into which a plasmid containing the gene for the Hepatitis B surface antigen (HBsAg) subtype adw has been inserted (*4*). HBsAg is harvested by lysing the yeast cells and is separated from yeast components by hydrophobic interaction and size-exclusion chromatography. The purified HBsAg protein undergoes sterile filtration and treatment with formalin prior to packaging. The vaccine is packaged to contain 10μg HBsAg protein per ml, adsorbed with 0.5 mg/ml aluminum hydroxide; a 1:20,000 concentration of thimerosal is added as a preservative.

The recombinant HBsAg takes the form of 17-25 nm spherical particles, similar in appearance to human plasma-derived HBsAg. The recombinant particles differ in that the HBsAg is not glycosylated, whereas up to 25% of plasma-derived HBsAg is glycosylated. The vaccine contains more than 95% HBsAg protein. Yeast-derived protein can constitute up to 4% of the final product, but no yeast DNA is detectable in the vaccine.

Immunogenicity and Efficacy

The immunogenicity of the recombinant HB vaccine is comparable to that of the plasma-derived product (*5*). When given in a three-dose series (10μg per dose), recombinant HB vaccine induces protective antibodies (anti-HBs*) in over 95% of healthy adults 20-39 years of age. Studies comparing antibody responses of healthy adults show equal rates of seroconversion following the three doses of either the recombinant vaccine (10μg per dose) or the plasma-derived vaccine (20μg per dose). However, the geometric mean titers (GMT) of antibodies developed by recipients of the recombinant vaccine have ranged from equal to to 30% as high as those developed by recipients of the plasma-derived vaccine. The recombinant vaccine, like the plasma-derived vaccine, produces a somewhat lower antibody response in older adults than in younger adults (*5*).

In studies using three 5-μg doses of recombinant vaccine for children<12 years of age, over 99% of the recipients have developed protective levels of antibodies. Hemodialysis patients develop a poorer response to the recombinant vaccine than do healthy adults. For example, in one study using three 40-μg doses of recombinant HB vaccine, only 64% of vaccine recipients developed protective levels of antibodies.

The recombinant HB vaccine has been shown to prevent HBV infection of vaccinated chimpanzees challenged intravenously with HBV of either adw or ayr subtypes. In studies of infants born to HBsAg- and HBeAg-positive mothers, the combination of HBIG (0.5 cc at birth) and recombinant HB vaccine (5μg in each of three doses) protected 94% of infants from developing the chronic carrier state, an efficacy equalling that of HBIG plus plasma-derived HB vaccine (*6*). The simultaneous administration of HBIG did not interfere with induction of anti-HBs antibody response by the recombinant HB vaccine.

There have been no large-scale efficacy trials of recombinant vaccine in adults. Nevertheless, the immunogenicity studies, the challenge studies using chimpanzees, and the efficacy trials of the HB vaccine and HBIG in infants born to mothers who are carriers of HBV strongly suggest that the efficacy of recombinant HB vaccine in adults is comparable to that of the plasma-derived product.

Safety

Because only the portion of the HBV viral genome that codes for the surface coat of the virus (HBsAg) is present in the recombinant yeast cells, no potentially infectious viral DNA or complete viral particles can be produced. No human or animal plasma or other blood derivative is used in the preparation of recombinant HB vaccine.

During prelicensure trials, approximately 4,500 persons received at least one dose, and 2,700 persons completed the vaccine series (*5*). Reported side effects were similar in extent and variety to those following administration of the plasma-derived vaccine. Seventeen percent of those vaccinated experienced soreness at the injection site, and 15% experienced mild systemic symptoms (fever, headache, fatigue, and nausea). To date, no severe side effects have been observed, nor have significant

*Greater than 10 milli-International Units (mIU)/ml of anti-HBs, approximately equal to 10 sample ratio units by radioimmunoassay or positive by enzyme immunoassay.

allergic reactions been reported. Although yeast-derived proteins may constitute up to 4% of the protein in the vaccine, no adverse reactions that could be related to changes in titers of antibodies to yeast-derived antigens occurred during clinical trials.

Early concerns about safety of plasma-derived HB vaccine, especially the concern that infectious agents such as human immunodeficiency virus (HIV) present in donor plasma pools might contaminate the final product, have proven to be unfounded (*7*). There are no data to indicate that the recombinant vaccine is potentially or actually safer than the currently licensed plasma-derived product.

Dosage and Schedule

The recombinant HB vaccine is given in a series of three doses over a 6-month period. The second dose is administered 1 month after the first, and the third dose, 5 months after the second. For normal adults and children>10 years of age, the recommended dose is 10μg (1 ml) intramuscularly in each of the three inoculations. Children<11 years of age should receive a 5-μg dose (0.5 ml) by the same schedule. Newborns of mothers who are carriers of HBsAg should receive the three-dose series (5μg per dose) by the same schedule; however, the first dose, which is given at birth, should be combined with a single dose of HBIG (0.5 ml) given intramuscularly at another site.

The recommended dose of recombinant HB vaccine for hemodialysis patients or other immunosuppressed persons is 40μg, which is identical to the dose of plasma-derived vaccine recommended for these groups. A specially formulated preparation (40μg HBsAg protein/ml adsorbed with 0.5 mg aluminum hydroxide) is being developed for these patients. At present, it is not advisable to administer the standard formulation of recombinant HB vaccine to these patients because this would require a large volume (4.0 cc), which is inconvenient for injection in the deltoid muscle, and would contain more aluminum hydroxide (2.0 mg) than currently recommended as an adjuvant in vaccines (1.25 mg per dose). Only plasma-derived vaccine should be used for these patients.

As with plasma-derived vaccine, recombinant HB vaccine should only be given to older children and adults in the deltoid muscle and to neonates or infants in the anterolateral thigh muscle. The vaccine should be stored at 2 C to 6 C (36 F to 43 F) and *should not be frozen*; freezing destroys the potency of this vaccine.

The response to vaccination by the standard schedule using one or two doses of plasma-derived vaccine followed by the remaining doses of recombinant vaccine has not been studied. However, because the immunogenicities of the two vaccines are similar, it is likely that the response will be comparable to that induced by three doses of either vaccine alone. The response to revaccination with the recombinant vaccine following nonresponse to an initial series of plasma vaccine has not been evaluated.

Indications for Use

The indications for use of the recombinant HB vaccine are identical to those for the plasma-derived product, except that the present formulation of the recombinant HB vaccine should not be used for hemodialysis patients or other immunosuppressed persons (Table 1) (*1*). For other groups, including persons with Down's syndrome,

TABLE 1. Persons for whom hepatitis B vaccine is recommended or should be considered*

Preexposure

Persons for whom vaccine is recommended:

- Health-care workers having blood or needle-stick exposures
- Clients and staff of institutions for the developmentally disabled
- Hemodialysis patients
- Homosexually active men
- Users of illicit injectable drugs
- Recipients of certain blood products
- Household members and sexual contacts of HBV carriers
- Special high-risk populations

Persons for whom vaccine should be considered:

- Inmates of long-term correctional facilities
- Heterosexually active persons with multiple sexual partners
- International travelers to HBV endemic areas

Postexposure

- Infants born to HBV positive mothers
- Health-care workers having needle-stick exposures to human blood

*Detailed information on recommendations for HB vaccination is available (*1*).

there are no data indicating that the recombinant HB vaccine is either superior or inferior to the plasma-derived HB vaccine for any preexposure or postexposure indication.

Precautions

The recombinant HB vaccine contains only noninfectious HBsAg particles; therefore, vaccination of a pregnant woman should entail no risk to either the woman or the fetus. Furthermore, HBV infection in a pregnant woman can result in severe disease for the mother and chronic infection of the newborn. Pregnancy should not be considered a contraindication for women in high-risk groups who are eligible to receive this vaccine.

NEED FOR VACCINE BOOSTER DOSES

Long-Term Protection by Plasma-Derived HB Vaccine

In short-term efficacy studies, the plasma-derived HB vaccine provided protection against HBV infection for 85%-95% of vaccine recipients, including virtually all those who developed adequate levels of antibodies (see footnote on pg. 355) (*8,9*). A recent evaluation of the long-term protection afforded by this vaccine (>5 years) provides a basis for recommendations concerning the need for booster doses in previously vaccinated persons (*10*).

Currently available data indicate that vaccine-induced antibody levels decline significantly (*10*). Antibody may decrease to low levels for 30%-40% of vaccinated adults who initially develop adequate levels of antibody during the 5 years after vaccination, and it may become undetectable in 10%-15% of them. The duration of antibody persistence is directly related to the peak level achieved after the third dose of vaccine (*11*). The longer persistence of detectable levels of antibody observed in children and young adults (<20 years of age) is consistent with the higher peak response in these age groups.

Studies of the licensed plasma-derived HB vaccine in adults have demonstrated that, in spite of declining levels of antibody, protection against clinical (or viremic) HBV infection persists for >5 years (*10*). Although the risks of HBV infection appear to increase as antibody levels become low or undetectable, the resultant infections are almost always innocuous and do not cause detectable viremia, liver inflammation, or clinical illness. These infections are detected by serologic evidence of an increase of anti-HBs levels associated with the appearance of antibody to the hepatitis B core antigen (anti-HBc). To date, only one transient viremic infection has been recognized in a vaccine responder within 72 months after vaccination. This infection produced mild alanine aminotransferase elevation, but no clinical illness (*10*). Thus, among adults who have responded to the vaccine, protection against clinically significant HBV infection appears to outlast the presence of detectable anti-HBs and can persist for ≥2 years among vaccine recipients whose antibodies have declined to low or undetectable levels.

For infants born to mothers who are carriers of HBV, there are insufficient data to assess duration of antibody persistence and protection against clinically significant HBV infection with the U.S. plasma-derived vaccine. One study, in a developing country (Senegal) and using a different plasma-derived HB vaccine, has demonstrated that protection against viremic HBV infection can decline within 6 years in infants vaccinated between 6 months and 2 years of age (*12*). Firm data on the duration of protection among infants receiving the vaccines licensed in the United States will be necessary before recommendations on booster doses can be made for this group.

Postvaccination Testing of Response to Vaccine

When properly administered, HB vaccine produces anti-HBs in more than 90% of healthy persons. Testing for immunity following vaccination has been recommended only for persons in whom suboptimal response to vaccine is anticipated, including persons who received vaccine in the buttock or persons, such as hemodialysis patients, whose subsequent management depends on knowing their immune status (*1*). Revaccination, which has produced adequate antibody in only 30%-50% of persons who have not responded to primary vaccination in the deltoid, is not routinely recommended (*1,10*).

Vaccine program coordinators in hospitals may decide to test vaccine recipients serologically to assess their antibody responses, even though such postvaccination testing is not routinely recommended. Persons electing to do postvaccination testing should be aware of potential difficulties in interpreting the results. Serologic testing

within 6 months of completing the primary series will differentiate persons who respond to vaccine from those who fail to respond. However, the results of testing undertaken more than 6 months after completion of the primary series are more difficult to interpret. A vaccine recipient who is negative for anti-HBs between 1 and 5 years after vaccination can be 1) a primary nonresponder who remains susceptible to hepatitis B or 2) a vaccine responder whose antibody levels have decreased below detectability but who is still protected against clinical HBV disease (*10*).

There is no need for routine anti-HBs testing 1 to 5 years after vaccination unless there has been a decision to provide booster doses for persons who are anti-HBs negative. This strategy is medically acceptable, but costly, and will prevent few additional cases of disease because of the excellent long-term protection already provided by the primary series of vaccine.

Recommendations for Booster Doses

Adults and children with normal immune status. For adults and children with normal immune status, the antibody response to properly administered vaccine is excellent, and protection lasts for at least 5 years. *Booster doses of vaccine are not routinely recommended, nor is routine serologic testing to assess antibody levels in vaccine recipients necessary during this period.* The possible need for booster doses after longer intervals will be assessed as additional information becomes available.

Hemodialysis patients. For hemodialysis patients, in whom vaccine-induced protection is less complete and may persist only as long as antibody levels remain above 10 mIU/ml, the need for booster doses should be assessed by semiannual antibody testing (*13*). Booster doses should be given when antibody levels decline below 10 mIU/ml.

Postexposure Prophylaxis of Persons Exposed to HBsAg Positive Needle Sticks

In vaccinated persons who experience percutaneous or needle exposure to HBsAg-positive blood, serologic testing to assess immune status is recommended unless testing within the previous 12 months has indicated adequate levels of antibody. If the exposed person is tested and found to have an inadequate antibody level, treatment with HBIG and/or a booster dose of vaccine is indicated, depending on whether vaccination has been completed and whether the person is known to have previously responded to HB vaccine. Detailed recommendations on prophylaxis in this situation are provided in the previous recommendations for HB vaccine (*1*).

Dosage

When indicated, HB vaccine recipients can be given booster doses of either plasma-derived or recombinant HB vaccine. Booster doses of either vaccine induce prompt anamnestic responses in over 90% of persons who initially respond to vaccine but subsequently lose detectable antibody (*14,15*). The booster dose for normal adults is 20μg of plasma-derived vaccine or 10μg of recombinant vaccine. For newborns and children<10 years of age, the dose is half that recommended for adults. For hemodialysis patients, a dose of 40μg of plasma-derived vaccine is recommended; a formulation of recombinant HB vaccine is not yet available for this group. Vaccine should be given in the deltoid muscle. Buttock injection does not induce adequate levels of antibody.

Precautions

Reported adverse effects following booster doses have been limited to soreness at the injection site. Data are not available on the safety of the vaccine for the developing fetus, but there should be no risk because both plasma-derived and recombinant HB vaccines are inactivated and do not contain live virus particles. Booster doses need not be withheld from pregnant women who are at ongoing risk of HBV infection.

References

1. ACIP. Recommendations for protection against viral hepatitis. MMWR 1985;34:313-24, 329-35.
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"Recommendations for Prevention of HIV Transmission in Health-Care Settings." Supplement. August 21, 1987, Vol. 36, No. 2S. These recommendations consolidate and update CDC recommendations published earlier for preventing Human Immunodeficiency Virus (HIV) transmission in health-care settings: precautions for clinical and laboratory staffs and precautions for health-care workers and allied professionals; recommendations for preventing HIV transmission in the workplace and during invasive procedures; recommendations for preventing possible transmission of HIV from tears; and recommendations for providing dialysis treatment for HIV-infected patients. These recommendations also reemphasize some of the recommendations contained in "Infection Control Practices for Dentistry." The recommendations contained in this supplement have been developed for use in health-care settings and emphasize the need to treat blood and other body fluids from all patients as potentially infective. These same prudent precautions should also be taken in other settings in which persons may be exposed to blood or other body fluids.

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Recommendations for Prevention of HIV Transmission in Health-Care Settings

Introduction

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

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

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

Definition of Health-Care Workers

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

Health-Care Workers with AIDS

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

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

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

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

Two other prospective studies to assess the risk of nosocomial acquisition of HIV infection for health-care workers are ongoing in the United States. As of April 30, 1987, 332 health-care workers with a total of 453 needlestick or mucous-membrane exposures to the blood or other body fluids of HIV-infected patients were tested for HIV antibody at the National Institutes of Health (*10*). These exposed workers

included 103 with needlestick injuries and 229 with mucous-membrane exposures; none had seroconverted. A similar study at the University of California of 129 health-care workers with documented needlestick injuries or mucous-membrane exposures to blood or other body fluids from patients with HIV infection has not identified any seroconversions (*11*). Results of a prospective study in the United Kingdom identified no evidence of transmission among 150 health-care workers with parenteral or mucous-membrane exposures to blood or other body fluids, secretions, or excretions from patients with HIV infection (*12*).

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

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

Precautions To Prevent Transmission of HIV

Universal Precautions

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

1. All health-care workers should routinely use appropriate barrier precautions to prevent skin and mucous-membrane exposure when contact with blood or other body fluids of any patient is anticipated. Gloves should be worn for touching blood and body fluids, mucous membranes, or non-intact skin of all patients, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Masks and protective eyewear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of the mouth, nose, and eyes. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids.
2. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids. Hands should be washed immediately after gloves are removed.
3. All health-care workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures. To prevent needlestick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are

used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal; the puncture-resistant containers should be located as close as practical to the use area. Large-bore reusable needles should be placed in a puncture-resistant container for transport to the reprocessing area.

4. Although saliva has not been implicated in HIV transmission, to minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices should be available for use in areas in which the need for resuscitation is predictable.
5. Health-care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.
6. Pregnant health-care workers are not known to be at greater risk of contracting HIV infection than health-care workers who are not pregnant; however, if a health-care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health-care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission.

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

Precautions for Invasive Procedures

In this document, an invasive procedure is defined as surgical entry into tissues, cavities, or organs or repair of major traumatic injuries 1) in an operating or delivery room, emergency department, or outpatient setting, including both physicians' and dentists' offices; 2) cardiac catheterization and angiographic procedures; 3) a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or 4) the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists. The universal blood and body-fluid precautions listed above, combined with the precautions listed below, should be the minimum precautions for **all** such invasive procedures.

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

Precautions for Dentistry*

Blood, saliva, and gingival fluid from **all** dental patients should be considered infective. Special emphasis should be placed on the following precautions for

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

preventing transmission of blood-borne pathogens in dental practice in both institutional and non-institutional settings.

1. In addition to wearing gloves for contact with oral mucous membranes of all patients, all dental workers should wear surgical masks and protective eyewear or chin-length plastic face shields during dental procedures in which splashing or spattering of blood, saliva, or gingival fluids is likely. Rubber dams, high-speed evacuation, and proper patient positioning, when appropriate, should be utilized to minimize generation of droplets and spatter.
2. Handpieces should be sterilized after use with each patient, since blood, saliva, or gingival fluid of patients may be aspirated into the handpiece or waterline. Handpieces that cannot be sterilized should at least be flushed, the outside surface cleaned and wiped with a suitable chemical germicide, and then rinsed. Handpieces should be flushed at the beginning of the day and after use with each patient. Manufacturers' recommendations should be followed for use and maintenance of waterlines and check valves and for flushing of handpieces. The same precautions should be used for ultrasonic scalers and air/water syringes.
3. Blood and saliva should be thoroughly and carefully cleaned from material that has been used in the mouth (e.g., impression materials, bite registration), especially before polishing and grinding intra-oral devices. Contaminated materials, impressions, and intra-oral devices should also be cleaned and disinfected before being handled in the dental laboratory and before they are placed in the patient's mouth. Because of the increasing variety of dental materials used intra-orally, dental workers should consult with manufacturers as to the stability of specific materials when using disinfection procedures.
4. Dental equipment and surfaces that are difficult to disinfect (e.g., light handles or X-ray-unit heads) and that may become contaminated should be wrapped with impervious-backed paper, aluminum foil, or clear plastic wrap. The coverings should be removed and discarded, and clean coverings should be put in place after use with each patient.

Precautions for Autopsies or Morticians' Services

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

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

Precautions for Dialysis

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

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

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

Precautions for Laboratories[†]

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

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

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

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

Environmental Considerations for HIV Transmission

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

Sterilization and Disinfection

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

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

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

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

of Pesticides, Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

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

Survival of HIV in the Environment

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

When considered in the context of environmental conditions in health-care facilities, these results do not require any changes in currently recommended sterilization, disinfection, or housekeeping strategies. When medical devices are contaminated with blood or other body fluids, existing recommendations include the cleaning of these instruments, followed by disinfection or sterilization, depending on the type of medical device. These protocols assume "worst-case" conditions of extreme virologic and microbiologic contamination, and whether viruses have been inactivated after drying plays no role in formulating these strategies. Consequently, no changes in published procedures for cleaning, disinfecting, or sterilizing need to be made.

Housekeeping

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

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

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

Cleaning and Decontaminating Spills of Blood or Other Body Fluids

Chemical germicides that are approved for use as "hospital disinfectants" and are tuberculocidal when used at recommended dilutions can be used to decontaminate spills of blood and other body fluids. Strategies for decontaminating spills of blood and other body fluids in a patient-care setting are different than for spills of cultures

or other materials in clinical, public health, or research laboratories. In patient-care areas, visible material should first be removed and then the area should be decontaminated. With large spills of cultured or concentrated infectious agents in the laboratory, the contaminated area should be flooded with a liquid germicide before cleaning, then decontaminated with fresh germicidal chemical. In both settings, gloves should be worn during the cleaning and decontaminating procedures.

Laundry

Although soiled linen has been identified as a source of large numbers of certain pathogenic microorganisms, the risk of actual disease transmission is negligible. Rather than rigid procedures and specifications, hygienic and common-sense storage and processing of clean and soiled linen are recommended (*26*). Soiled linen should be handled as little as possible and with minimum agitation to prevent gross microbial contamination of the air and of persons handling the linen. All soiled linen should be bagged at the location where it was used; it should not be sorted or rinsed in patient-care areas. Linen soiled with blood or body fluids should be placed and transported in bags that prevent leakage. If hot water is used, linen should be washed with detergent in water at least 71 C (160 F) for 25 minutes. If low-temperature($\leq$70 C [158 F]) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration should be used.

Infective Waste

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

Implementation of Recommended Precautions

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

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

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

Serologic Testing for HIV Infection

Background

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

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

The specificity of the currently licensed EIA tests is approximately 99% when repeatedly reactive tests are considered. Repeat testing of initially reactive specimens by EIA is required to reduce the likelihood of laboratory error. To increase further the specificity of serologic tests, laboratories must use a supplemental test, most often the Western blot, to validate repeatedly reactive EIA results. Under optimal laboratory conditions, the sensitivity of the Western blot test is comparable to or greater than that of a repeatedly reactive EIA, and the Western blot is highly specific when strict criteria are used to interpret the test results. The testing sequence of a repeatedly reactive EIA and a positive Western blot test is highly predictive of HIV infection, even in a population with a low prevalence of infection (Table 2). If the Western blot test result is indeterminant, the testing sequence is considered equivocal for HIV infection. When this occurs, the Western blot test should be repeated on the same serum sample, and, if still indeterminant, the testing sequence should be repeated on a sample collected 3-6 months later. Use of other supplemental tests may aid in interpreting of results on samples that are persistently indeterminant by Western blot.

Testing of Patients

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

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

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

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

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

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

In addition to the universal precautions recommended for all patients, certain additional precautions for the care of HIV-infected patients undergoing major surgical operations have been proposed by personnel in some hospitals. For example, surgical procedures on an HIV-infected patient might be altered so that hand-to-hand passing of sharp instruments would be eliminated; stapling instruments rather than hand-suturing equipment might be used to perform tissue approximation; electrocautery devices rather than scalpels might be used as cutting instruments; and, even though uncomfortable, gowns that totally prevent seepage of blood onto the skin of members of the operative team might be worn. While such modifications might further minimize the risk of HIV infection for members of the operative team, some of these techniques could result in prolongation of operative time and could potentially have an adverse effect on the patient.

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

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

Testing of Health-Care Workers

Although transmission of HIV from infected health-care workers to patients has not been reported, transmission during invasive procedures remains a possibility. Transmission of hepatitis B virus (HBV)—a blood-borne agent with a considerably greater

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

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

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

potential for nosocomial spread—from health-care workers to patients has been documented. Such transmission has occurred in situations (e.g., oral and gynecologic surgery) in which health-care workers, when tested, had very high concentrations of HBV in their blood (at least 100 million infectious virus particles per milliliter, a concentration much higher than occurs with HIV infection), and the health-care workers sustained a puncture wound while performing invasive procedures or had exudative or weeping lesions or microlacerations that allowed virus to contaminate instruments or open wounds of patients (*33,34*).

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

Management of Infected Health-Care Workers

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

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

Management of Exposures

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

If the source patient has AIDS, is positive for HIV antibody, or refuses the test, the health-care worker should be counseled regarding the risk of infection and evaluated clinically and serologically for evidence of HIV infection as soon as possible after the exposure. The health-care worker should be advised to report and seek medical evaluation for any acute febrile illness that occurs within 12 weeks after the exposure. Such an illness—particularly one characterized by fever, rash, or lymphadenopathy—may be indicative of recent HIV infection. Seronegative health-care workers should be

retested 6 weeks post-exposure and on a periodic basis thereafter (e.g., 12 weeks and 6 months after exposure) to determine whether transmission has occurred. During this follow-up period—especially the first 6-12 weeks after exposure, when most infected persons are expected to seroconvert—exposed health-care workers should follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV (*36,37*).

No further follow-up of a health-care worker exposed to infection as described above is necessary if the source patient is seronegative unless the source patient is at high risk of HIV infection. In the latter case, a subsequent specimen (e.g., 12 weeks following exposure) may be obtained from the health-care worker for antibody testing. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized. Serologic testing should be available to all health-care workers who are concerned that they may have been infected with HIV.

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

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ORAL FINDINGS IN PATIENTS WITH AIDS

The following is taken from the article, "Oral Findings in Patients with Acquired Immunodeficiency Syndrome:"

> "Oral examinations of 103 consecutive patients with acquired immunodeficiency syndrome (AIDS) were performed. Of these patients, 74 (72%) were heterosexuals and 29 (28%) were homosexual or bisexual men. Lesions that were identified on subsequent examination were recorded separately. Oral candidiasis was the most common finding, occurring in 94 patients. Other findings were herpes simplex ulceration (ten patients), exfoliative chelitis (nine patients), xerostomia (ten patients), "hairy" leukoplakia (seven patients), and Kaposi's sarcoma (four patients). A patchy, depapillated tongue was

seen in six patients, and ulcers with uncertain cause were seen in three patients. Gingival bleeding, perioral molluscum contagiosum, and brown hairy tongue each occurred in one patient. In this study, "hairy" leukoplakia and Kaposi's sarcoma occurred exclusively in homosexual and bisexual men with AIDS, and occurred significantly more frequently in this group than in heterosexual patients with AIDS. There was no significant difference between these groups in the frequency of occurrence of other findings."

Reference:

Joan A. Phelan, D.D.S., Brian R. Saltzman, M.D., Gerald H. Friedland, M.D., and Robert S. Klein, M.D., Montefiore Medical Center, North Central Bronx Hospital, and Albert Einstein College of Medicine. "Oral Findings in Patients with Acquired Immunodeficiency Syndrome," Oral Surg. Oral Med. Oral Pathol. 1987;64:50-6.

REVISION OF CDC SURVEILLANCE CASE DEFINITION FOR AIDS

A revised case definition for surveillance of acquired immunodeficiency syndrome (AIDS) has been developed by CDC in collaboration with public health and clinical specialists. The Council of State and Territorial Epidemiologists (CSTE) has officially recommended adoption of the revised definition for national reporting of AIDS. The objectives of the revision are (1) To track more effectively the severe disabling morbidity associated with infection with human immunodeficiency virus (HIV) (including HIV-1 and HIV-2); (2) to simplify reporting of AIDS cases; (3) to increase the sensitivity and specificity of the definition through greater diagnostic application of laboratory evidence for HIV infection; and (4) to be consistent with current diagnostic practice. which in some cases includes presumptive, i.e., without confirmatory laboratory evidence, diagnosis of AIDS-indicative diseases (e.g., Pneumocystis carinii pneumonia, Kaposi's sarcoma).

The new definition is effective immediately. State and local health departments are requested to apply the new definition henceforth to patients reported to them. The following is taken from the new definition and covers those areas which would be applicable to dentistry:

> (For national reporting, a case of AIDS is defined as an illness characterized by one or more of the following "indicator" diseases, depending on the status of laboratory evidence of HIV infection.)
>
> Indicator diseases diagnosed definitively - candidiasis of the esophagus, trachea, bronchi, or lungs; cytomegalovirus disease of an organ other than liver, spleen, or lymph nodes in a patient more than 1 month of age; herpes simplex virus infection causing a mucocutaneous ulcer that persists longer than 1 month; Kaposi's sarcoma affecting a patient less than 60 years of age.

Definitive diagnostic methods for diseases indicative of AIDS:

- Candidiasis - gross inspection by endoscopy or autopsy or by microscopy (histology or cytology) on a specimen obtained directly from the tissues affected (including scrapings from the mucosal surface), not from a culture.

- Herpes simplex virus - microscopy (histology or cytology), culture, or detection of antigen in a specimen in a specimen obtained directly from the tissues affected affected or a fluid from those tissues.

Suggested guidelines for presumptive diagnosis of diseases indicative of AIDS:

- Candidiasis of esophagus - (1) Recent onset of retrosternal pain on swallowing; AND (2) oral candidiasis diagnosed by the gross appearance of white patches or plaques on an erythematous base or by the microscopic appearance of fungal mycelial filaments in an uncultured specimen scraped from the oral mucosa.

- Kaposi's sarcoma - A characteristic gross appearance of an erythematous or violaceous plaque-like lesion on skin or mucous membrane. (NOTE: Presumptive diagnosis of Kaposi's sarcoma should not be made by clinicians who have seen few cases of it.)

Reference:

Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome. CDC MMWR Supplement, August 14, 1987. Vol. 36, No. 1S.

ODONTOGENIC ORIGIN OF TOXIC SHOCK SYNDROME

Some question has arisen concerning the possibility of an odontogenic origin of toxic shock syndrome (TSS). Benjamin Schwartz, M.D., EIS Officer, Meningitis and Special Pathogens Branch, Division of Bacterial Diseases, Center for Infectious Diseases, Centers for Disease Control, has reviewed toxic shock case report forms for 2 years. The following are his observations:

> (NOTE: Many of the case forms do not specify a site of origin of the infection.) "Of all definite TSS cases reported through passive surveillance, a total of 7.1%, or 194 cases, were associated with a surgical or nonsurgical wound. The sites of these infections are varied, and may include any site infected with toxin producing Staphylococcus aureus. Given the frequency with which this organism is found in the oral cavity, it is likely that other cases either have occurred or will occur in this setting. I am not familiar with the dental literature and other case reports may have published previously.

"Nosocomial transmission of TSS has been mentioned in two recent reports. Three cases of TSS occurred in the practice of a single surgeon who later had a nasopharyngeal S. Aureus isolate which was identical to that isolated from his patients, and two women developed TSS following Cesarean delivery in the same operating room. The potential for nosocomial transmission of TSS during dental procedures is certainly obvious; dentists and oral surgeons should be aware of this possibility."

SYMPTOMS OF IRRITATION ASSOCIATED WITH EXPOSURE TO GLUTARALDEHYDE

Within the past 10 years, the use of chemical germicides containing glutaraldehyde has increased. Originally developed as a quick-acting sporicidal agent that lacked the undesirable health effects associated with formaldehyde, glutaraldehyde-based germicides are now used primarily to disinfect and/or sterilize a variety of medical and dental equipment. The following is taken from the article, "Symptoms of Irritation Associated with Exposure to Glutaraldehyde - Colorado:"

During an evaluation by the National Institute for Occupational Safety and Health (NIOSH) of exposures to formaldehyde at a biomedical research hospital in Denver, Colorado, several employees complained of irritation from using another substance, glutaraldehyde. At the hospital, glutaraldehyde was present in solutions used for tissue fixation, histologic examinations, and disinfection and/or cold-sterilization of respiratory therapy equipment. NIOSH investigated these complaints in 1983.

To measure airborne levels of glutaraldehyde, the investigator collected eight samples from personal breathing zones of employees and 13 samples from area air during procedures scheduled especially for the evaluation. The employees' symptoms were recorded during informal interviews and on medical questionnaires.

Glutaraldehyde concentrations in personal breathing zones ranged from non-detectable (ND) to 1.5 mg/m^3; six of the eight samples exceeded the ceiling threshold limit value (TLV) of 0.7 mg/m^3 set by the American Conference of Governmental Industrial Hygienists. Concentrations in area air ranged from ND to 1.5 mg/m^3, six of the 13 samples exceeded the TLV. The Occupational Safety and Health Administration has no standard and NIOSH has no recommended exposure limit for occupational exposure to glutaraldehyde.

Nine of the 11 nurses who were using solutions containing glutaraldehyde as a disinfectant had symptoms of some type of irritation. Eight reported skin symptoms, ranging in severity from itching or irritation to cracking and bleeding; seven reported eye irritation; six, throat discomfort; five, nasal discomfort; five, chest tightness or other pulmonary discomfort; four, cough; and two, headache.

Another NIOSH study currently in process indicates that the Denver experience is not unique. Preliminary data from this study conducted in Morristown, Pennsylvania, reveal glutaraldehyde exposure concentrations and reported irritation symptoms that closely resemble those from the Denver evaluation.

Because of the widespread and increasing use of glutaraldehyde in many areas, public health professionals should be aware of its potential for producing adverse health effects.

Reference:

Symptoms of Irritation Associated with Exposure to Glutaraldehyde - Colorado. CDC MMWR, April 3, 1987, Vol. 36, No. 12.

FLUORIDATION

AMERICAN MEDICAL ASSOCIATION REAFFIRMS ENDORSEMENT OF FLUORIDATION

The following actions were taken by the American Medical Association (AMA) at its Interim Meeting held in Las Vegas, Nevada, December 7-10, 1986:

1. Resolution 9 - Statewide Fluoridation. Resolution 9 asked that AMA urge State health departments to consider the value of requiring statewide fluoridation in communities of 5,000 or more where local water supplies are fluoride-deficient, and to initiate such action as deemed appropriate. The House of Delegates adopted the following Substitute Resolution 9:

   "Resolved, That the American Medical Association urge State health departments to consider the value of requiring statewide fluoridation, preferably a comprehensive program of fluoridation of all public water supplies, where these are fluoride-deficient, and to initiate such action as deemed appropriate; and be it further

   Resolved, That the AMA communicate its endorsement of statewide water fluoridation to State medical associations, the American Dental Association, the American Academy of Pediatrics, the American Public Health Association, and the Association of State and Territorial Health Officers, and urge favorable consideration."

The American Medical Association (AMA) has been a long-time advocate of municipally fluoridated water supplies. Their support for fluoridation dates back to 1957; this support was reaffirmed in 1972 and again in 1974. Dr. James H. Sammons, Executive Vice President, AMA, confirmed that what was stated in 1974 is "no less true today than it was then" in a letter sent to commissioners of public health on May 13, 1987. The following is the reaffirmation of AMA's endorsement of fluoridation plus other comments made by Dr. Sammons in that letter:

"Few health measures have been accorded greater clinical and laboratory research, epidemiological study, massive clinical trial(s) of community populations and public attention--both favorable and adverse... . Research has been established that people consuming water (throughout life) containing the (recommended) optimum level of fluoride (0.7-1.2 ppm) experience no adverse effects on their kidneys, thyroid glands, reproductive functions, growth, development blood, urine or hearing. No cases of allergic reactions have been linked with consumption of water fluoridated at the recommended levels.

"Research has also provided evidence that suitable amounts of fluoride may (help or alleviate) bone diseases such as osteoporosis, especially in our aging population.

"No other alternatives or techniques for the provision of fluoride can at present replace the fluoridation of drinking water as an

effective and practicable public health measure. When (community) water fluoridation is not feasible, other means of supplying the proper amount of fluoride should be employed.

"Many public health officials and elected representatives have tried in the past to implement community fluoridation, only to be defeated in the courts, the legislature and the public media by a vociferous, poorly informed minority of private opinion. The scientific proof is on our side, but it cannot speak for itself; it must be presented forcefully and credibly by members of the health profession in order to overcome the false claims of detractors.

"I urge you to renew your efforts to enlarge the scope of community fluoridation programs within your state, so that those efforts might bring the benefits of efficacious and inexpensive dental prophylaxis to everyone in this country. We pledge to you our support with the recognition that the care of the nations' health is one of our mutual concerns."

FURTHER REFUTATION OF THE ALUMINUM/FLUORIDE ASSOCIATION

In May 1987, the Dental Disease Prevention Activity (DDPA) issued a periodic memorandum refuting allegations concerning a reported laboratory experiment in Sri Lanka which stated that aluminum can be released from aluminum utensils during cooking. (Refer to FL-132 - "No Association Between Aluminum, Fluoride, and Alzheimer's Disease.) The results of the Sri Lankan experiment appeared in Nature, January 15, 1987.

In an attempt to further reinforce this refutation, DDPA contacted the Criteria and Standards Division, Office of Drinking Water, Environmental Protection Agency (EPA), who, in turn, requested that their Technical Support Division attempt to verify the experimental results reported in Nature. The following result was stated, in part, by Lowell A. Ven Den Berg, Director, Director, Technical Support Division, Office of Drinking Water, EPA:

"Samples were prepared in two off-the-shelf cooking utensils and the pH adjusted to 3.0 as stated in the reference. This limited study, under the stated conditions, indicates relatively low aluminum concentrations at the fluoride levels required by our regulations. These results are much lower than those reported in the referenced article."

CONSUMER REPORTS - LEACHING OF ALUMINUM FROM ALUMINUM COOKWARE

The following is taken from the article, "Pots and Pans," Consumer Reports, August 1987:

"Questions about whether or not aluminum pots leach unsafe amounts of the metal into food have come up repeatedly since aluminum cookware

was introduced some 90 years ago. A recent research report suggested that cooking acidic foods like tomatoes with fluoridated water in aluminum pots can dramatically increase the amount of aluminum that leaches into food.

"We cooked tomato puree made with fluoridated or distilled water in a variety of aluminum pans. Our sauces picked up only a trace of aluminum from the pans. The fluoride made no detectable difference.

"A typical daily diet contains an estimated 20-60 mg of aluminum. Most of our samples of tomato sauce contained 1-3 mg in a 6-oz. serving. By contrast, a typical daily dose of several popular antacids contains more than 1,000 mg of aluminum."

CORRECTION OF NEWS SERVICE ERROR - EPA STATEMENT ON INDOOR AIR POLLUTION

On September 16, 1987, the Scripps Howard News Service sent out a story on an Environmental Protection Agency (EPA) report on the hazards of indoor air pollution. The story was picked up by several newspapers around the country.

Contained in the story was the statement, "Hot showers can release chloroform, a toxic chemical that results from the breakdown of fluoride in water." The word "chlorine" should have appeared, not "fluoride." The author of the story, Mr. Robert Engelmen, upon being contacted by the Dental Disease Prevention Activity (DDPA), sent a letter to DDPA on October 6. The following is taken from that letter:

"In this story, I inadvertently confused fluoride with chlorine in describing how chloroform can be a component of water used for showers and other purposes. Chloroform, of course, is a byproduct of the breakdown of chlorine in water (chlorine being used to kill microorganisms) and not a byproduct of the breakdown of fluoride, which has the purpose of preventing caries development in teeth.

...I apologize for the confusion this error may have created in the minds of some readers, and I would appreciate it you could relay my regret ... to any readers who contact you with misperceptions about fluoride in water based on my article."

EPA DENIES PETITION TO INCLUDE FLUORIDE AS A TOXIC CHEMICAL

The U.S. Environmental Protection Agency (EPA) in May 1987 denied a petition to add inorganic fluorides to the list of toxic chemicals subject to reporting under the Superfund emergency planning and community right-to-know programs. Based on the contention that inorganic fluorides cause adverse human health effects, the Safe Water Foundation of Texas had petitioned EPA to list inorganic fluorides, commonly added to drinking water supplies for dental benefits, among those to be reported.

EPA's toxicity evaluation (Federal Register, May 29) found inorganic fluorides to be lethal to humans in dose ranges from 50 to 225 mg/kg of body weight (3 to 18 grams for an average human male), but concluded that exposures of such magnitude are not likely to occur. The agency further determined that the contribution to human exposure to fluorides from industrial sources is insignificant.

In analyzing health problems associated with ingestion of fluorides in drinking water, EPA essentially reiterated its rationale for recently doubling the allowable level of fluoride in drinking water to 4 mg/L. This controversial action had been contested in the U.S. Court of Appeals, which upheld EPA's action.

That rationale defined dental fluorosis, a mottling of the teeth caused by consuming high levels of fluoride, as an undesirable but not adverse health effect. EPA defined crippling skeletal fluorosis as an adverse health effect. EPA estimates that a daily consumption rate of 20 mg or more of fluoride from all sources for 20 or more years would be necessary to bring about the problem.

In denying the petition, EPA said it had found no cases where the total fluoride exposure from industrial sources and drinking water would result in crippling skeletal fluorosis.

Reference:

American Water Works Association, Mainstream, Vol. 31, No. 7, July 1987.

SIGNIFICANCE OF EPA PROPOSAL TO REDEFINE NON-COMMUNITY WATER SYSTEMS

In a November 1985 notice, the U.S. Environmental Protection Agency (EPA) proposed to redefine the term "community water system" to include certain non-community water systems such as rural school water systems. The resulting adverse comments caused EPA to reconsider its position. However, EPA still believes that it is appropriate to protect drinking water consumers from long-term exposure to contaminated drinking water.

In the July 8, 1987, issue of the Federal Register, EPA has promulgated regulations which have further defined non-community water systems into transient and non-transient water systems, and added monitoring requirements for these systems. A non-transient, non-community water system means a public water system that is not a community water system, and that regularly serves at least 25 of the same persons over 6 months per year. This includes rural school water systems.

Under these new EPA regulations, school water systems must now monitor and report on eight volatile synthetic organic chemicals (VOCs). Also, EPA has stated very clearly that, as they evaluate and revise the existing regulations, they intend to apply future National Primary Drinking Water Regulations to non-transient, non-community water systems At the present time, the inorganic chemical maximum contaminant levels (MCL's),including fluoride at 4 mg/l, do not apply to school water systems--they apply only to community water systems.

Reference:

Federal Register, July 8, 1987

CLARIFICATION OF SALE OF VIDEOTAPE BY ADA

In the previous issue of the "Dear Colleague" letter, it was inadvertently stated that the videotape, "Fluoridation: The Facts and the Challenge," was available from the American Dental Association (ADA) for $12.50. The videotape is available through ADA's Order Department for sale at $70.00:

American Dental Association
Order Department
211 E. Chicago Avenue
Chicago, Illinois 60611

The videotape may also be rented from:

ADA Audiovisual Library
5000 Park Street North
St. Petersburg, Florida 33709
(813) 541-4710 (no collect calls)

ADDITIONAL NOTEWORTHY ITEMS

CONSUMER REPORTS REPRINTS AVAILABLE - "THE MERCURY SCARE"

Reprints of the Consumer Reports article, "The Mercury Scare," are available from the Dental Disease Prevention Activity. In summary, the article states, "In CU's view, dentists who purport to treat health problems by ripping out fillings are putting their own economic interests ahead of their patients' welfare. Amalgams have been used for more than 150 years. Except for a few people with a genuine allergy to mercury, CU knows of no one who's been harmed by them. There's little danger of the U.S. becoming a nation of Mad Hatters."

Copies of reprints may be obtained from:

Dental Disease Prevention Activity
Freeway Park, Room 424
Centers for Disease Control
Atlanta, Georgia 30333
Telephone: (404) 329-1830
FTS: 236-1830

ADVERSE EFFECTS FROM SWEETENERS

Sorbitol intolerance: A study of 124 healthy adults of different ethnic backgrounds (41 in the United States, 83 in India) showed that about one-third were clinically intolerant to 10 g sorbitol. Biochemical intolerance was detected in 30% of whites, 36% of blacks, and 32% of Asian Indians, and clinical intolerance in 36%, 36%, and 30% respectively. All 40 clinically-intolerant volunteers were also biochemically intolerant.

This survey indicates that about one-third of the population regardless of ethnic origin, may be intolerant to small amounts of sorbitol: the dose of 10 grams used in this study can easily be ingested in the course of normal intake of sorbitol-sweetened dietetic food. This information is important since symptoms of sorbitol intolerance can easily be mistaken to be of organic origin and can lead to an unnecessary diagnostic workup.

Reference:

N.K. Jain, et al. Sorbitol Intolerance in Adults. Nutrition Research Newsletter, July 1987.

HYDROFLUORIC ACID LEAK IN TEXAS CITY, TEXAS

On October 31, a hydrofluoric acid leak occurred at a petroleum refinery in Texas City, Texas. The leak occurred when a crane dropped a heavy piece of equipment, shearing off a pipe leading into a tank containing hydrofluoric acid. Before emptying the leaking tank, workers cooled it with water and neutralized the acid with soda ash and lime.

Hydrofluoric acid is poisonous if inhaled, drops the amount of oxygen in the blood, and causes skin, eye, and throat irritation. A local hospital treated 203 people. Sixty-six of those patients were admitted in serious condition, including one person in critical condition with severe lung problems. One-hundred and thirty-seven others were treated for minor injuries and released.

CALL FOR ABSTRACTS FOR 1988 AAPHD ANNUAL SESSION

The American Association of Public Health Dentistry (AAPHD) is inviting papers on a broad range of dental public health subjects for presentation at AAPHD's 51st Annual Meeting in Washington, D.C. The meeting will be held from October 5 through October 7, 1988, in conjunction with the Fifth Annual International Conference of Chief Dental Officers.

Since this year's theme is one of international partnership, a special call for international papers is being made. Key topics include trends in oral disease, innovative preventive and educational measures, national dental programs, dental care delivery systems, infection control, and health promotion. Papers dealing with U.S. national, State, and local public health are also welcome.

Abstracts will be selected by a review process and will be rated on the following criteria: originality, significance, and quality of supporting data. Abstracts should be 200 words or less, fit on one-half of an 8 1/2" x 11" sheet of paper, single spaced, should first give the title (10 word limit), and then list authors, capitalizing initials and last names. Place an asterisk after the name of the presenter. Institutions should follow the last author's name. The paper should be submitted with the understanding that the same paper will not be presented at another meeting. Acceptance of the abstract requires that you present the paper at the Annual Meeting. Authors who fail to present the paper after acceptance may forfeit their privilege to present at future meetings. Please provide the name, address, and phone number of the presenter of contact author. Both oral and poster presentations are likely. Indicate your preference and if you are willing to present in either mode. Three copies of the abstract and a self-addressed, stamped envelope must be received by April 1, 1988. Authors will be notified by July 1, 1988, of acceptance. Abstracts should be submitted to:

R. Gary Rozier, D.D.S., M.P.H.
Department of Health Policy & Administration
CB #8140, Kron Building
University of North Carolina
Chapel Hill, North Carolina 27599-8140

FOR YOUR INFORMATION

The Dental Disease Prevention Activity (DDPA) "Dear Colleague" letter is developed by DDPA, Center for Prevention Services, Centers for Disease

Control, Atlanta, GA 30333. Articles and/or written comments should be sent to:

Ms. Betty Ballinger
Dental Disease Prevention Activity
Freeway Park, Room 424
Centers for Disease Control
Atlanta, Georgia 30333
Telephone: (404) 329-1830
FTS: 236-1830

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