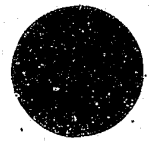

Ohio State Highway Patrol
Planning and Analysis
December 1991

Staff Study
HIV-HBV Transmission

Research and Development

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Problem

Should Additional Measures be Taken to Protect
Officers of the Highway Patrol from
Contracting of HIV-HBV?

Relevant Facts

1. The safety and well-being of officers of the Patrol is of primary concern.

2. HIV (Human Immunodeficiency Virus) is the virus that creates the symptoms known as AIDS (Acquired Immune Deficiency Syndrome).

    a. AIDS, at this time, is a terminal illness that kills by disabling the human body's ability to fight off disease.

    b. There is no vaccine available to prevent or cure AIDS.

3. HBV (Hepatitis B Virus) is a virus that attacks the liver cells of the infected person.

    a. HBV attacks the liver which may cause mild illness, chronic infection, liver damage (such as cirrhosis), liver cancer or even death (due to liver failure).

    b. There is a vaccine available to prevent (with near 90% effectiveness) and treat (with near 75% effectiveness) HBV.

4. The Ohio Department of Health recommends that any person exposed to blood from another person a minimum of once a month should be immunized against HBV.

Assumptions

1. Officers of the Patrol would desire protection from potentially deadly diseases like HBV.

2. Patrol officers are exposed one or more times a month to blood from another person.

3. Emergency situations may involve prolonged contact with potential HBV carriers.

Discussion

Human Immunodeficiency Virus

HIV

Currently, there are two Division policies that directly address Human Immunodeficiency Virus (HIV) and the symptom that results, Acquired Immune Deficiency Syndrome (AIDS). There have not been any significant break throughs since policy 9-507.03 was issued. Discussed are precautionary measures and legal aspects revolving around the HIV issue. Policy 9-907.07, under development, will also address methods of dealing with victims that reduce the opportunity for HIV to be spread.

Hepatitis B Virus

HBV

Although AIDS continues to elude a cure or vaccine, HBV can be prevented or treated in the vast majority of cases. Vaccination is preferable to post infection treatment because there is no cure, only treatment. Those individuals properly vaccinated are protected in over 90% of all cases for 7 years[I]. However, those

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I Only 7 years of historical records are available. The specific life of the vaccination is yet to be identified. After the vaccination expires, a single dose booster is expected to reestablish protection.

infected for 1 week that receive a similar serum as treatment have a 76%, on average, chance of success[II].

HBV is transmitted by all the same mechanisms associated with the spread of HIV. The mechanisms salient to Patrol officers for occupational exposure include, infected blood to an open wound, infected fluid to the mucus membrane (eyes, nose, or mouth) and similar exchange routes. The crucial difference between HIV and HBV is required exposure. HBV is much easier to transmit than HIV[III]. Officers involved in altercations resulting in cuts or abrasions could easily be contaminated by an infected persons blood. To emphasize the ease of transmission, the sharing of personal care items such as toothbrushes, razors and nail clippers are listed as transfer mechanisms. It is not uncommon for a carrier of HBV to infect other household members.

As with HIV, HBV cannot be transmitted by casual contact. Officers would not be exposed to HBV during a routine traffic stop, where the individual remains in their car. Performing normal DUI tests would not place the officer at risk, assuming contact to direct the individuals activities. The most effective

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II Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers, Morbidity and Mortality Weekly Report, Centers for Disease Control, vol 38, no. S-6, pg. 6.

III Joseph Bronwoski, Ohio Department of Health - Communicable Diseases, telephone interview, December 1991.

way to transmit HBV is to exchange blood during an altercation or during emergency life saving activities.

HBV has an incubation period of 6 weeks to 6 months. For some, the symptoms that develop afterwards include tiredness, loss of appetite/weight, mild fever, aching muscles or joints, stomach pain, nausea, and diarrhea. In fewer cases, victims may develop jaundice, dark colored urine or light colored bowel movements. It is common for infected individuals to think they have the flu. Others may never develop any symptoms at all. Once symptoms develop most people will recover in about 6 months. Carriers can infect others before symptoms develop and for an unknown time after they disappear.

There are disturbing statistics associated with HBV. An estimated 1,000,000 people in the United States are carriers. 300,000 people are infected annually according to estimates. Of these 300,000 infected each year, 10,000 will be hospitalized and 250 will die. 25% of those infected will develop chronic active hepatitis, which often progresses to cirrhosis and increases the victims chance of developing liver cancer from 12-300 times. Each year, it is estimated that 4,000 die from cirrhosis and 800 die from liver cancer related to HBV[IV].

IV Protection Against Viral Hepatitis Recommendations of the Immunization Practices Advisory Committee (ACIP), February 9, 1991, pg H6.

Having an active HBV infection opens the door for another form of hepatitis. Hepatitis D (HDV), or delta hepatitis, can only develop in the presence of an active HBV infection. There are tests available to identify this strain. Information on this strain is limited and exposure is not believed to be very wide spread. Commonly, when HDV interacts with HBV the individual develops clinical acute hepatitis and possible chronic active hepatitis.

There are several types of vaccines available for HBV. The one used for standard preventative purposes is genetically engineered by using common yeast cells. Vaccine doses vary by type and age group. Also, timing can be coordinated into 3 or 4 injections, dependent on the specific vaccine used and group involved. FAILURE TO COMPLETE THE SERIES WILL LEAVE THE INDIVIDUAL UNPROTECTED. A second form of the vaccine that is distilled from the blood of previously exposed individuals is used as a post infection treatment. The injections are intramuscular (IM) given only in the deltoid muscle of the arm for adults.

For Patrol personnel, immunization of three injections on a 0-30-180 day time line is recommended by the Department of Health. Due to the physiological response generated from each injection, the time between doses cannot be decreased. However, theoretically, there could be a delay in receiving the next injection

without interfering with the procedure[V]. For instance, if the second dose was delayed to the 40th day, ten days late, then the third dose would be at 190 days. The specific doses and timing of the vaccination series have been developed and tested over many years.

Since it is possible to have HBV and not be aware of it, officers may choose to be tested to determine if they have already been exposed. The cost at Doctors Hospital North in Columbus, Ohio for an HBV test is $120. The administration of the vaccination series will not have any ill effects if given to an individual who has previously been exposed. The vaccination will cause the already existing relevant (anti-HB) antibody blood level to increase for a period of time.

There are side effects to the vaccination that occur in a small percentage of the vaccinated population. 10% to 20% of the population may experience tenderness and redness at the injection site plus a low grade fever. Other more severe symptoms that occur in a very small percentage of the population include rash, nausea, joint pain, and mild fatigue. There have been several cases where individuals developed neurological disorders after

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V The fact that once a series is begun delays, do not necessitate starting over is the foundation for this theory by the Department of Health.

having received the vaccine, however, there is no proof to connect neurological illness with the vaccine. The diseases that vaccinated individuals have developed after treatment have been attributed to the normal "back ground" illness that would be expected from any group. There is a rare possibility that allergic and serious reactions or even death could occur, as with any drug or vaccine. No deaths have been reported resulting from vaccination. There may be other side effects that appear as the vaccine is used more extensively.

Vaccination

The regulations regarding vaccination are not nearly as difficult as coordinating the logistical process throughout the state could be. If the Division wished to, a system could be developed allowing individual officers to seek the vaccination from the health care professional of their choice. Any system of inoculation that provides patient autonomy will likely cost from $210 to $380 per officer to complete the series. This type of system would require the least amount of Division coordination, however, it is not cost effective.

For public employee vaccinations the Department of Health has access to an agent (Merck, Sharp & Dohme) with federal authorization to purchase the serum under a grant reducing the cost per series to nearly $90. The Division would purchase the serum

directly from the agent and it would be shipped to the Ohio Department of Health from which we would take one full delivery. The exact cost of administration would depend on the agency contracted to administer the shots. The serum has a minimum refrigerated life of 18 months and can be refused if the expiration stamp does not indicate so. The serum is inert and can be kept at room temperature for 24 to 48 hours during the delivery process without danger of destroying it. However, as with any federally funded program, the Division must follow several specific procedures to be eligible for the discount.

The federal requirements are straight forward and simple. The vaccine must be ordered through the local health department, in our case the state health department. Every person who elects to receive the vaccine must sign a consent form listing the associated benefits and dangers before each injection. The authorization forms MUST be kept on file for a minimum of **10 years** after the date given, by the administrator or their agency. No individual receiving the vaccine may be charged for the purchase thereof. An administrative fee may be assessed, HOWEVER, **no one** may be denied the vaccine for failure to pay the administration fee. Additionally, individuals choosing against inoculation must have the opportunity to reverse their decision in the future.

To utilize the grant, the Division would be responsible for contracting with local individuals or agencies to perform the injections and provide supplies. The vaccine can be purchased in

1 or 3 dose vials (1ml or 1cc each) and the cost is the same per dose. One dose vials reduce the chance of error. To complete the process the administrator would have to keep the documents for 10 years, store and refrigerate 3 vials of vaccine and use 3 intramuscular syringes for each recipient. For example, if the Patrol were to contract with the county health department within a post area that would require negotiating 57 contracts. Surprisingly, not every county health department will administer vaccinations.

A third logistical option is to let each post determine the most cost effective plan for their area. For example, the Fairfield county health department is willing to inoculate troopers in their county for $45.88. The health department will donate nurse time and supplies, the cost to the Division is strictly for the vaccine. In Franklin county, however, the county health department will not immunize anyone even if all supplies are provided. For troopers assigned to the Lancaster post, the local health department would provide vaccinations for less than a health care provider or the federal grant program. In appendix F is a table comparing the costs associated with the different logistical methods. These figures are provided for general comparison purposes only, they will not accurately project final costs.

The greatest hurdle is getting recipients to show up for ALL THREE injections. The Iowa State Patrol is explicit in depicting it's difficulties in getting officers in the right place at the

right time. Since the officer is not protected until all 3 injections are administered at the proper intervals, short sighted individuals may find themselves infected rather than protected.

Regardless of the distribution method chosen, the primary issue is officer interest. The Ohio Department of Health recommends that every officer activity on patrol or otherwise exposed to a high risk group, like prison inmates, should be immunized. In reality there are officers who will not be interested for a number of reasons. Since there is the possibility of negative consequences associated with the vaccine, officers would need to choose voluntarily to be vaccinated.

Once the target audience has been identified, it is crucial that they have every opportunity to gain any and all information regarding the benefits and hazards of the procedure. Government literature and copies of the consent form would provide information sufficient to generate careful thought. It is important to allow the individual to make his or her decision without the Division providing any persuasion.

Officers could also be encouraged to perform their own research to determine if the vaccine is right for them. There are numerous other factors that may influence an officer's decision that are not directly related to their occupation. Sample groups that should give careful consideration to receiving HBV vaccina-

tion include persons with blood product dependence, such as clotting agents, pregnancy, and sexual activity or orientation. These issues are discussed in various publications regarding HBV.

In the view of the Ohio Department of Health, the potential hazards of HBV should outweigh the dangers of the vaccine. Perhaps this is best summed by recalling the facts that 250 people die each year directly from HBV and no deaths have been directly attributed to the vaccine.

Conclusions

1. The Ohio Department of Health and the Occupational Safety and Health Administration recommend that police officers exposed to bodily fluids of another on a regular basis be immunized against HBV.

2. Since there is no cure for HBV the best course of action is to be immunized.

3. Each post has the potential to find an option for immunization that is less expensive than any centralized program. Local exploration for cost effective options could save the Division thousands of dollars.

Recommendations

The Division should offer to vaccinate any officer that is occupationally exposed to the bodily fluids of another at least once a month for the HBV virus. This would disqualify the majority of officers currently assigned to extended non-enforcement positions. Although the vaccination can be given as a post infection treatment it is not as effective. The Division should provide basic information regarding HBV to all interested individuals to be used as the basis for determining initial interest. Once the officers have had sufficient opportunity to research the issue to their satisfaction, a specific count should be taken to determine the best method of administering the inoculations.

Officers must have an opportunity to enroll in the program at a future time should their particular occupational exposure change. To achieve the most cost effective vaccination of all those interested, each facility will need to search within their local area and identify their best option.

CENTERS FOR DISEASE CONTROL

June 23, 1989 / Vol. 38 / No. S-6

MMWR

Recommendations and Reports

MORBIDITY AND MORTALITY WEEKLY REPORT

Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health
Atlanta, Georgia 30333

I. Introduction

A. Background

This document is a response to recently enacted legislation. Public Law 100-607, The Health Omnibus Programs Extension Act of 1988, Title II, Programs with Respect to Acquired Immune Deficiency Syndrome ("AIDS Amendments of 1988"). Subtitle I, General Provisions, Section 253(a) of Title II specifies that "the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall develop, issue, and disseminate guidelines to all health workers, public safety workers (including emergency response employees) in the United States concerning –

(1) methods to reduce the risk in the workplace of becoming infected with the etiologic agent for acquired immune deficiency syndrome; and

(2) circumstances under which exposure to such etiologic agent may occur."

It is further noted that "The Secretary [of Health and Human Services] shall transmit the guidelines issued under subsection (a) to the Secretary of Labor for use by the Secretary of Labor in the development of standards to be issued under the Occupational Safety and Health Act of 1970," and that "the Secretary, acting through the Director of the Centers for Disease Control, shall develop a model curriculum for emergency response employees with respect to the prevention of exposure to the etiologic agent for acquired immune deficiency syndrome during the process of responding to emergencies."

Following development of these guidelines and curriculum, "[t]he Secretary shall –

(A) transmit to State public health officers copies of the guidelines and the model curriculum developed under paragraph (1) with the request that such officers disseminate such copies as appropriate throughout the State; and

(B) make such copies available to the public."

B. Purpose and Organization of Document

The purpose of this document is to provide an overview of the modes of transmission of human immunodeficiency virus (HIV) in the workplace, an assessment of the risk of transmission under various assumptions, principles underlying the control of risk, and specific risk-control recommendations for employers and workers. This document also includes information on medical management of persons who have sustained an exposure at the workplace to these viruses (e.g., an emergency medical technicians who incurs needle-stick injury while performing professional duties). These de

for use by a technically informed audience. As noted above, a separate model curriculum based on the principles and practices discussed in this document is being developed for use in training workers and will contain less technical wording.

Information concerning the protection of workers against acquisition of the human immunodeficiency virus (HIV) while performing job duties, the virus that causes AIDS, is presented here. Information on hepatitis B virus (HBV) is also presented in this document on the basis of the following assumptions:

- the modes of transmission for hepatitis B virus (HBV) are similar to those of HIV,
- the potential for HBV transmission in the occupational setting is greater than for HIV,
- there is a larger body of experience relating to controlling transmission of HBV in the workplace, and
- general practices to prevent the transmission of HBV will also minimize the risk of transmission of HIV.

Blood-borne transmission of other pathogens not specifically addressed here will be interrupted by adherence to the precautions noted below. It is important to note that the implementation of control measures for HIV and HBV does not obviate the need for continued adherence to general infection-control principles and general hygiene measures (e.g., hand washing) for preventing transmission of other infectious diseases to both worker and client. General guidelines for control of these diseases have been published (*1,2,3*).

This document was developed primarily to provide guidelines for fire-service personnel, emergency medical technicians, paramedics (see section IV, page 19), and law-enforcement and correctional-facility personnel (see section V, page 22). Throughout the report, paramedics and emergency medical technicians are called "emergency medical workers" and fire-service, law-enforcement, and correctional-facility personnel, "public-safety workers." Previously issued guidelines address the needs of hospital-, laboratory-, and clinic-based health-care workers (*4,5*). A condensation of general guidelines for protection of workers from transmission of blood-borne pathogens, derived from the Joint Advisory Notice of the Departments of Labor and Health and Human Services (*6*), is provided in section III (see page 11).

C. Modes and Risk of Virus Transmission in the Workplace

Although the potential for HBV transmission in the workplace setting is greater than for HIV, the modes of transmission for these two viruses are similar. Both have been transmitted in occupational settings only by percutaneous inoculation or contact with an open

wound, nonintact (e.g., chapped, abraded, weeping, or dermatitic) skin, or mucous membranes to blood, blood-contaminated body fluids, or concentrated virus. **Blood is the single most important source of HIV and HBV in the workplace setting.** Protection measures against HIV and HBV for workers should focus primarily on preventing these types of exposures to blood as well as on delivery of HBV vaccination.

The risk of hepatitis B infection following a parenteral (i.e., needle stick or cut) exposure to blood is directly proportional to the probability that the blood contains hepatitis B surface antigen (HBsAg), the immunity status of the recipient, and on the efficiency of transmission (*7*). The probability of the source of the blood being HBsAg positive varies from 1 to 3 per thousand in the general population to 5%–15% in groups at high risk for HBV infection, such as immigrants from areas of high endemicity (China and Southeast Asia, sub-Saharan Africa, most Pacific islands, and the Amazon Basin); clients in institutions for the mentally retarded; intravenous drug users; homosexually active males; and household (sexual and non-sexual) contacts of HBV carriers. Of persons who have not had prior hepatitis B vaccination or postexposure prophylaxis, 6%–30% of persons who receive a needle-stick exposure from an HBsAg-positive individual will become infected (*7*).

The risk of infection with HIV following one needle-stick exposure to blood from a patient known to be infected with HIV is approximately 0.5% (*4,5*). This rate of transmission is considerably lower than that for HBV, probably as a result of the significantly lower concentrations of virus in the blood of HIV-infected persons. Table 1 (see page 31) presents theoretical data concerning the likelihood of infection given repeated needle-stick injuries involving patients whose HIV serostatus is unknown. Though inadequately quantified, the risk from exposure of nonintact skin or mucous membranes is likely to be far less than that from percutaneous inoculation.

D. Transmission of Hepatitis B Virus to Workers

1. Health-care workers

In 1987, the CDC estimated the total number of HBV infections in the United States to be 300,000 per year, with approximately 75,000 (25%) of infected persons developing acute hepatitis. Of these infected individuals, 18,000–30,000 (6%–10%) will become HBV carriers, at risk of developing chronic liver disease (chronic active hepatitis, cirrhosis, and primary liver cancer), and infectious to others.

CDC has estimated that 12,000 health-care workers whose jobs entail exposure to blood become infected with HBV each year, that 500–600 of them are hospitalized as a result of that infection, and that 700–1,200 of those infected become HBV carriers. Of the infected workers, approximately 250 will die (12–15 from fulminant hepatitis, 170–200 from cirrhosis, and 40–50 from liver cancer). Studies indicate that

10%–30% of health-care or dental workers show serologic evidence of past or present HBV infection.

2. Emergency medical and public-safety workers

Emergency medical workers have an increased risk for hepatitis B infection (*8,9,10*). The degree of risk correlates with the frequency and extent of blood exposure during the conduct of work activities. A few studies are available concerning risk of HBV infection for other groups of public-safety workers (law-enforcement personnel and correctional-facility workers), but reports that have been published do not document any increased risk for HBV infection (*11,12,13*). Nevertheless, in occupational settings in which workers may be routinely exposed to blood or other body fluids as described below, an increased risk for occupational acquisition of HBV infection must be assumed to be present.

3. Vaccination for hepatitis B virus

A safe and effective vaccine to prevent hepatitis B has been available since 1982. Vaccination has been recommended for health-care workers regularly exposed to blood and other body fluids potentially contaminated with HBV (*7,14,15*). In 1987, the Department of Health and Human Services and the Department of Labor stated that hepatitis B vaccine should be provided to all such workers at no charge to the worker (*6*).

Available vaccines stimulate active immunity against HBV infection and provide over 90% protection against hepatitis B for 7 or more years following vaccination (*7*). Hepatitis B vaccines also are 70–88% effective when given within 1 week after HBV exposure. Hepatitis B immune globulin (HBIG), a preparation of immunoglobulin with high levels of antibody to HBV (anti-HBs), provides temporary passive protection following exposure to HBV. Combination treatment with hepatitis B vaccine and HBIG is over 90% effective in preventing hepatitis B following a documented exposure (*7*).

E. Transmission of Human Immunodeficiency Virus to Workers

1. Health-care workers with AIDS

As of September 19, 1988, a total of 3,182 (5.1%) of 61,929 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 setting. Of the health-care workers with AIDS, 95% reported high-risk behavior; for the remaining 5% (169 workers), the means of HIV acquisition was undetermined.

Of these 169 health-care workers with AIDS with undetermined risk, information is

incomplete for 28 (17%) because of death or refusal to be interviewed; 97 (57%) are still being investigated. The remaining 44 (26%) health-care workers were interviewed directly or had other follow-up information available. The occupations of these 44 were nine nursing assistants (20%); eight physicians (18%), four of whom were surgeons; eight housekeeping or maintenance workers (18%); six nurses (14%); four clinical laboratory technicians (9%); two respiratory therapists (5%); one dentist (2%); one paramedic (2%); one embalmer (2%); and four others who did not have contact with patients (9%). Eighteen of these 44 health-care workers reported parenteral and/or other non-needle-stick exposure to blood or other 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, and HIV seroconversion of the health-care worker was not documented following a specific exposure.

2. Human immunodeficiency virus transmission in the workplace

As of July 31, 1988, 1,201 health-care workers had been enrolled and tested for HIV antibody in ongoing CDC surveillance of health-care workers exposed via needlestick or splashes to skin or mucous membranes to blood from patients known to be HIV-infected (*16*). Of 860 workers who had received needle-stick injuries or cuts with sharp objects (i.e., parenteral exposures) and whose serum had been tested for HIV antibody at least 180 days after exposure, 4 were positive, yielding a seroprevalence rate of 0.47%. Three of these individuals experienced an acute retroviral syndrome associated with documented seroconversion. Investigation revealed no nonoccupational risk factors for these three workers. Serum collected within 30 days of exposure was not available from the fourth person. This worker had an HIV-seropositive sexual partner, and heterosexual acquisition of infection cannot be excluded. None of the 103 workers who had contamination of mucous membranes or nonintact skin and whose serum had been tested at least 180 days after exposure developed serologic evidence of HIV infection.

Two other ongoing prospective studies assess the risk of nosocomial acquisition of HIV infection among health-care workers in the United States. As of April 1988, the National Institutes of Health had tested 983 health-care workers, 137 with documented needle-stick injuries and 345 health-care workers who had sustained mucous-membrane exposures to blood or other body fluids of HIV-infected patients; none had seroconverted (*17*) (one health-care worker who subsequently experienced an occupational HIV seroconversion has since been reported from NIH [*18*]). As of March 15, 1988, a similar study at the University of California of 212 health-care workers with 625 documented accidental parenteral exposures involving HIV-infected patients had identified one seroconversion following a needle stick (*19*). Prospective studies in the United Kingdom and Canada show no evidence of HIV

transmission among 220 health-care workers with parenteral, mucous-membrane, or cutaneous exposures (*20,21*).

In addition to the health-care workers enrolled in these longitudinal surveillance studies, case histories have been published in the scientific literature for 19 HIV-infected health-care workers (13 with documented seroconversion and 6 without documented seroconversion). None of these workers reported nonoccupational risk factors (see Table 2, pages 32, 33).

3. Emergency medical service and public-safety workers

In addition to the one paramedic with undetermined risk discussed above, three public-safety workers (law-enforcement officers) are classified in the undetermined risk group. Follow-up investigations of these workers could not determine conclusively if HIV infection was acquired during the performance of job duties.

II. Principles of Infection Control and Their Application to Emergency and Public-Safety Workers

A. General Infection Control

Within the health-care setting, general infection control procedures have been developed to minimize the risk of patient acquisition of infection from contact with contaminated devices, objects, or surfaces or of transmission of an infectious agent from health-care workers to patients (*1,2,3*). Such procedures also protect workers from the risk of becoming infected. General infection-control procedures are designed to prevent transmission of a wide range of microbiological agents and to provide a wide margin of safety in the varied situations encountered in the health-care environment.

General infection-control principles are applicable to other work environments where workers contact other individuals and where transmission of infectious agents may occur. The modes of transmission noted in the hospital and medical office environment are observed in the work situations of emergency and public-safety workers, as well. Therefore, the principles of infection control developed for hospital and other health-care settings are also applicable to these work situations. Use of general infection control measures, as adapted to the work environments of emergency and public-safety workers, is important to protect both workers and individuals with whom they work from a variety of infectious agents, not just HIV and HBV.

Because emergency and public-safety workers work in environments that provide inherently unpredictable risks of exposures, general infection-control procedures should be adapted to these work situations. Exposures are unpredictable, and protective measures may often be used in situations that do not appear to present risk. Emergency and public-safety workers perform their duties in the community under extremely variable conditions; thus, control measures that are simple and uniform across all situations have the greatest likelihood of worker compliance. Administrative procedures to ensure compliance also can be more readily developed than when procedures are complex and highly variable.

B. Universal Blood and Body Fluid Precautions to Prevent Occupational HIV and HBV Transmission

In 1985, CDC developed the strategy of "universal blood and body fluid precautions" to address concerns regarding transmission of HIV in the health-care setting (*4*). The concept, now referred to simply as "universal precautions" stresses that **all patients should be assumed to be infectious for HIV and other blood-borne pathogens**. In the hospital and other health-care setting, "universal precautions" should be followed when workers are exposed to blood, certain other body fluids (amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, and vaginal

transmission has not been documented from exposure to other body fluids (feces, nasal secretions, sputum, sweat, tears, urine, and vomitus), "universal precautions" do not apply to these fluids. Universal precautions also do not apply to saliva, except in the dental setting, where saliva is likely to be contaminated with blood (7).

For the purpose of this document, human "exposure" is defined as contact with blood or other body fluids to which universal precautions apply through percutaneous inoculation or contact with an open wound, nonintact skin, or mucous membrane during the performance of normal job duties. An "exposed worker" is defined, for the purposes of this document, as an individual exposed, as described above, while performing normal job duties.

The unpredictable and emergent nature of exposures encountered by emergency and public-safety workers may make differentiation between hazardous body fluids and those which are not hazardous very difficult and often impossible. For example, poor lighting may limit the worker's ability to detect visible blood in vomitus or feces. Therefore, **when emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous.**

The application of the principles of universal precautions to the situations encountered by these workers results in the development of guidelines (listed below) for work practices, use of personal protective equipment, and other protective measures. To minimize the risks of acquiring HIV and HBV during performance of job duties, emergency and public-safety workers should be protected from exposure to blood and other body fluids as circumstances dictate. Protection can be achieved through adherence to work practices designed to minimize or eliminate exposure and through use of personal protective equipment (i.e., gloves, masks, and protective clothing), which provide a barrier between the worker and the exposure source. In some situations, redesign of selected aspects of the job through equipment modifications or environmental control can further reduce risk. These approaches to primary prevention should be used together to achieve maximal reduction of the risk of exposure.

If exposure of an individual worker occurs, medical management, consisting of collection of pertinent medical and occupational history, provision of treatment, and counseling regarding future work and personal behaviors, may reduce risk of developing disease as a result of the exposure episode (22). Following episodic (or continuous) exposure, decontamination and disinfection of the work environment, devices, equipment, and clothing or other forms of personal protective equipment can reduce subsequent risk of exposures. Proper disposal of contaminated waste has similar benefits.

III. Employer Responsibilities

A. General

Detailed recommendations for employer responsibilities in protecting workers from acquisition of blood-borne diseases in the workplace have been published in the Department of Labor and Department of Health and Human Services Joint Advisory Notice and are summarized here (*6*). In developing programs to protect workers, employers should follow a series of steps: 1) classification of work activity, 2) development of standard operating procedures, 3) provision of training and education, 4) development of procedures to ensure and monitor compliance, and 5) workplace redesign. As a first step, every employer should classify work activities into one of three categories of potential exposure (see Table 3, page 34). Employers should make protective equipment available to all workers when they are engaged in Category I or II activities. Employers should ensure that the appropriate protective equipment is used by workers when they perform Category I activities.

As a second step, employers should establish a detailed work practices program that includes standard operating procedures (SOPs) for all activities having the potential for exposure. Once these SOPs are developed, an initial and periodic worker education program to assure familiarity with work practices should be provided to potentially exposed workers. No worker should engage in such tasks or activities before receiving training pertaining to the SOPs, work practices, and protective equipment required for that task. Examples of personal protective equipment for the prehospital setting (defined as a setting where delivery of emergency health care takes place away from a hospital or other health-care setting) are provided in Table 4 (page 35). (A curriculum for such training programs is being developed in conjunction with these guidelines and should be consulted for further information concerning such training programs.)

To facilitate and monitor compliance with SOPs, administrative procedures should be developed and records kept as described in the Joint Advisory Notice (*6*). Employers should monitor the workplace to ensure that required work practices are observed and that protective clothing and equipment are provided and properly used. The employer should maintain records documenting the administrative procedures used to classify job activities and copies of all SOPs for tasks or activities involving predictable or unpredictable exposure to blood or other body fluids to which universal precautions apply. In addition, training records, indicating the dates of training sessions, the content of those training sessions along with the names of all persons conducting the training, and the names of all those receiving training should also be maintained.

Whenever possible, the employer should identify devices and other approaches to modifying the work environment which will reduce exposure risk. Such approaches are desirable, since they don't require individual worker action or management activity. For example, jails and correctional facilities should have classification procedures that require

the segregation of offenders who indicate through their actions or words that they intend to attack correctional-facility staff with the intent of transmitting HIV or HBV.

B. Medical

In addition to the general responsibilities noted above, the employer has the specific responsibility to make available to the worker a program of medical management. This program is designed to provide for the reduction of risk of infection by HBV and for counseling workers concerning issues regarding HIV and HBV. These services should be provided by a licensed health professional. All phases of medical management and counseling should ensure that the confidentiality of the worker's and client's medical data is protected.

1. Hepatitis B vaccination

All workers whose jobs involve participation in tasks or activities with exposure to blood or other body fluids to which universal precautions apply (as defined above on page 9) should be vaccinated with hepatitis B vaccine.

2. Management of percutaneous exposure to blood and other infectious body fluids

Once an exposure has occurred (as defined above on page 10), a blood sample should be drawn after consent is obtained from the individual from whom exposure occurred and tested for hepatitis B surface antigen (HBsAg) and antibody to human immunodeficiency virus (HIV antibody). Local laws regarding consent for testing source individuals should be followed. Policies should be available for testing source individuals in situations where consent cannot be obtained (e.g., an unconscious patient). Testing of the source individual should be done at a location where appropriate pretest counseling is available; posttest counseling and referral for treatment should be provided. It is extremely important that all individuals who seek consultation for any HIV-related concerns receive counseling as outlined in the "Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS" (22).

a. Hepatitis B virus postexposure management

For an exposure to a source individual found to be positive for HBsAg, the worker who has not previously been given hepatitis B vaccine should receive the vaccine series. A single dose of hepatitis B immune globulin (HBIG) is also recommended, if this can be given within 7 days of exposure. For exposures from an HBsAg-positive source to workers who have previously received vaccine, the exposed worker should be tested for antibody to hepatitis B surface antigen (anti-HBs), and given one dose of vaccine and one dose

of HBIG if the antibody level in the worker's blood sample is inadequate (i.e., < 10 SRU by RIA, negative by EIA) (*7*).

If the source individual is negative for HBsAg and the worker has not been vaccinated, this opportunity should be taken to provide hepatitis B vaccination.

If the source individual refuses testing or he/she cannot be identified, the unvaccinated worker should receive the hepatitis B vaccine series. HBIG administration should be considered on an individual basis when the source individual is known or suspected to be at high risk of HBV infection. Management and treatment, if any, of previously vaccinated workers who receive an exposure from a source who refuses testing or is not identifiable should be individualized (*7*).

b. Human immunodeficiency virus postexposure management

For any exposure to a source individual who has AIDS, who is found to be positive for HIV infection (*4*), or who refuses testing, the 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. In view of the evolving nature of HIV postexposure management, the health-care provider should be well informed of current PHS guidelines on this subject. The 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. Following the initial test at the time of exposure, seronegative workers should be retested 6 weeks, 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 workers should follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV (*22*). These include refraining from blood donation and using appropriate protection during sexual intercourse (*23*). During all phases of follow-up, it is vital that worker confidentiality be protected.

If the source individual was tested and found to be seronegative, baseline testing of the exposed worker with follow-up testing 12 weeks later may be performed if desired by the worker or recommended by the health-care provider.

If the source individual cannot be identified, decisions regarding appropriate follow-up should be individualized. Serologic testing should be made available by the employer to all workers who may be concerned they have been infected with HIV through an occupational exposure as defined above (see page 10).

3. Management of human bites

On occasion, police and correctional-facility officers are intentionally bitten by suspects or prisoners. When such bites occur, routine medical and surgical therapy (including an assessment of tetanus vaccination status) should be implemented as soon as possible, since such bites frequently result in infection with organisms other than HIV and HBV. Victims of bites should be evaluated as described above (see page 12) for exposure to blood or other infectious body fluids.

Saliva of some persons infected with HBV has been shown to contain HBV-DNA at concentrations 1/1,000 to 1/10,000 of that found in the infected person's serum (*5,24*). HbsAg-positive saliva has been shown to be infectious when injected into experimental animals and in human bite exposures (*25–27*). However, HBsAg-positive saliva has not been shown to be infectious when applied to oral mucous membranes in experimental primate studies (*27*) or through contamination of musical instruments or cardiopulmonary resuscitation dummies used by HBV carriers (*28,29*). Epidemiologic studies of nonsexual household contacts of HIV-infected patients, including several small series in which HIV transmission failed to occur after bites or after percutaneous inoculation or contamination of cuts and open wounds with saliva from HIV-infected patients, suggest that the potential for salivary transmission of HIV is remote (*5,30–33*). One case report from Germany has suggested the possibility of transmission of HIV in a household setting from an infected child to a sibling through a human bite (*34*). The bite did not break the skin or result in bleeding. Since the date of seroconversion to HIV was not known for either child in this case, evidence for the role of saliva in the transmission of virus is unclear (*34*).)

4. Documentation of exposure and reporting

As part of the confidential medical record, the circumstances of exposure should be recorded. Relevant information includes the activity in which the worker was engaged at the time of exposure, the extent to which appropriate work practices and protective equipment were used, and a description of the source of exposure.

Employers have a responsibility under various federal and state laws and regulations to report occupational illnesses and injuries. Existing programs in the National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services; the Bureau of Labor Statistics, Department of Labor (DOL); and the Occupational Safety and Health Administration (DOL) receive such information

for the purposes of surveillance and other objectives. Cases of infectious disease, including AIDS and HBV infection, are reported to the Centers for Disease Control through State health departments.

5. Management of HBV- or HIV-infected workers

Transmission of HBV from health-care workers to patients has been documented. Such transmission has occurred during certain types of invasive procedures (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 (*35,36*). A worker who is HBsAg positive and who has transmitted hepatitis B virus to another individual during the performance of his or her job duties should be excluded from the performance of those job duties which place other individuals at risk for acquisition of hepatitis B infection.

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 other persons with infectious diseases that are easily transmitted if appropriate precautions are not taken (e.g., measles, varicella). Any worker with an impaired immune system should be counseled about the potential risk associated with providing health care to persons with any transmissible infection and should continue to follow existing recommendations for infection control to minimize risk of exposure to other infectious agents (*2,3*). Recommendations of the Immunization Practices Advisory Committee (ACIP) and institutional policies concerning requirements for vaccinating workers with live-virus vaccines (e.g., measles, rubella) should also be considered.

The question of whether workers infected with HIV 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 worker's personal physician(s) in conjunction with the employer's medical advisors.

C. Disinfection, Decontamination, and Disposal

As described in Section I.C. (see page 4), the only documented occupational risks of HIV and HBV infection are associated with parenteral (including open wound) and mucous membrane exposure to blood and other potentially infectious body fluids. Nevertheless, the precautions described below should be routinely followed.

1. Needle and sharps disposal

All workers should take precautions to prevent injuries caused by needles, scalpel blades, 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 needle-stick 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 (e.g., in the ambulance or, if sharps are carried to the scene of victim assistance from the ambulance, a small puncture-resistant container should be carried to the scene, as well). Reusable needles should be left on the syringe body and should be placed in a puncture-resistant container for transport to the reprocessing area.

2. Hand washing

Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood, other body fluids to which universal precautions apply, or potentially contaminated articles. Hands should always be washed after gloves are removed, even if the gloves appear to be intact. Hand washing should be completed using the appropriate facilities, such as utility or restroom sinks. Waterless antiseptic hand cleanser should be provided on responding units to use when hand-washing facilities are not available. When hand-washing facilities are available, wash hands with warm water and soap. When hand-washing facilities are not available, use a waterless antiseptic hand cleanser. The manufacturer's recommendations for the product should be followed.

3. Cleaning, disinfecting, and sterilizing

Table 5 (see pages 36, 37) presents the methods and applications for cleaning, disinfecting, and sterilizing equipment and surfaces in the prehospital setting. These methods also apply to housekeeping and other cleaning tasks. Previously issued guidelines for health-care workers contain more detailed descriptions (*4*).

4. Cleaning and decontaminating spills of blood

All spills of blood and blood-contaminated fluids should be promptly cleaned up using an EPA-approved germicide or a 1:100 solution of household bleach in the following manner **while wearing gloves.** Visible material should first be removed with disposable towels or other appropriate means that will ensure against direct contact with blood. If splashing is anticipated, protective eyewear should be worn along with an impervious gown or apron which provides an effective barrier to splashes. The

area should then be decontaminated with an appropriate germicide. Hands should be washed following removal of gloves. Soiled cleaning equipment should be cleaned and decontaminated or placed in an appropriate container and disposed of according to agency policy. Plastic bags should be available for removal of contaminated items from the site of the spill.

Shoes and boots can become contaminated with blood in certain instances. Where there is massive blood contamination on floors, the use of disposable impervious shoe coverings should be considered. Protective gloves should be worn to remove contaminated shoe coverings. The coverings and gloves should be disposed of in plastic bags. A plastic bag should be included in the crime scene kit or the car which is to be used for the disposal of contaminated items. Extra plastic bags should be stored in the police cruiser or emergency vehicle.

5. Laundry

Although soiled linen may be contaminated with pathogenic microorganisms, the risk of actual disease transmission is negligible. Rather than rigid procedures and specifications, hygienic storage and processing of clean and soiled linen are recommended. Laundry facilities and/or services should be made routinely available by the employer. 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. Linen soiled with blood should be placed and transported in bags that prevent leakage. Normal laundry cycles should be used according to the washer and detergent manufacturers' recommendations.

6. Decontamination and laundering of protective clothing

Protective work clothing contaminated with blood or other body fluids to which universal precautions apply should be placed and transported in bags or containers that prevent leakage. Personnel involved in the bagging, transport, and laundering of contaminated clothing should wear gloves. Protective clothing and station and work uniforms should be washed and dried according to the manufacturer's instructions. Boots and leather goods may be brush-scrubbed with soap and hot water to remove contamination.

7. Infective waste

The selection of procedures for disposal of infective waste is determined by the relative risk of disease transmission and application of local regulations, which vary widely. **In all cases, local regulations should be consulted prior to disposal procedures and followed.** Infective waste, in general, should either be incinerated or should be decontaminated 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, where permitted. Sanitary sewers may also be used to dispose of other infectious wastes capable of being ground and flushed into the sewer, where permitted. Sharp items should be placed in puncture-proof containers and other blood-contaminated items should be placed in leak-proof plastic bags for transport to an appropriate disposal location.

Prior to the removal of protective equipment, personnel remaining on the scene after the patient has been cared for should carefully search for and remove contaminated materials. Debris should be disposed of as noted above.

IV. Fire and Emergency Medical Services

The guidelines that appear in this section apply to fire and emergency medical services. This includes structural fire fighters, paramedics, emergency medical technicians, and advanced life support personnel. Fire fighters often provide emergency medical services and therefore encounter the exposures common to paramedics and emergency medical technicians. Job duties are often performed in uncontrolled environments, which, due to a lack of time and other factors, do not allow for application of a complex decision-making process to the emergency at hand.

The general principles presented here have been developed from existing principles of occupational safety and health in conjunction with data from studies of health-care workers in hospital settings. The basic premise is that workers must be protected from exposure to blood and other potentially infectious body fluids in the course of their work activities. There is a paucity of data concerning the risks these worker groups face, however, which complicates development of control principles. Thus, the guidelines presented below are based on principles of prudent public health practice.

Fire and emergency medical service personnel are engaged in delivery of medical care in the prehospital setting. The following guidelines are intended to assist these personnel in making decisions concerning use of personal protective equipment and resuscitation equipment, as well as for decontamination, disinfection, and disposal procedures.

A. Personal Protective Equipment

Appropriate personal protective equipment should be made available routinely by the employer to reduce the risk of exposure as defined above. For many situations, the chance that the rescuer will be exposed to blood and other body fluids to which universal precautions apply can be determined in advance. Therefore, if the chances of being exposed to blood is high (e.g., CPR, IV insertion, trauma, delivering babies), the worker should put on protective attire before beginning patient care. Table 4 (see page 35) sets forth examples of recommendations for personal protective equipment in the prehospital setting; the list is not intended to be all-inclusive.

1. Gloves

Disposable gloves should be a standard component of emergency response equipment, and should be donned by all personnel prior to initiating any emergency patient care tasks involving exposure to blood or other body fluids to which universal precautions apply. Extra pairs should always be available. Considerations in the choice of disposable gloves should include dexterity, durability, fit, and the task being performed. Thus, there is no single type or thickness of glove appropriate for protection in all situations. For situations where large amounts of blood are likely to be encountered, it is important that gloves fit tightly at the wrist to prevent blood contamination

of hands around the cuff. For multiple trauma victims, gloves should be changed between patient contacts, if the emergency situation allows.

Greater personal protective equipment measures are indicated for situations where broken glass and sharp edges are likely to be encountered, such as extricating a person from an automobile wreck. Structural fire-fighting gloves that meet the Federal OSHA requirements for fire-fighters gloves (as contained in 29 CFR 1910.156 or National Fire Protection Association Standard 1973, Gloves for Structural Fire Fighters) should be worn in any situation where sharp or rough surfaces are likely to be encountered (*37*).

While wearing gloves, avoid handling personal items, such as combs and pens, that could become soiled or contaminated. Gloves that have become contaminated with blood or other body fluids to which universal precautions apply should be removed as soon as possible, taking care to avoid skin contact with the exterior surface. Contaminated gloves should be placed and transported in bags that prevent leakage and should be disposed of or, in the case of reusable gloves, cleaned and disinfected properly.

2. Masks, eyewear, and gowns

Masks, eyewear, and gowns should be present on all emergency vehicles that respond or potentially respond to medical emergencies or victim rescues. These protective barriers should be used in accordance with the level of exposure encountered. Minor lacerations or small amounts of blood do not merit the same extent of barrier use as required for exsanguinating victims or massive arterial bleeding. Management of the patient who is not bleeding, and who has no bloody body fluids present, should not routinely require use of barrier precautions. Masks and eyewear (e.g., safety glasses) should be worn together, or a faceshield should be used by all personnel prior to any situation where splashes of blood or other body fluids to which universal precautions apply are likely to occur. Gowns or aprons should be worn to protect clothing from splashes with blood. If large splashes or quantities of blood are present or anticipated, impervious gowns or aprons should be worn. An extra change of work clothing should be available at all times.

3. Resuscitation equipment

No transmission of HBV or HIV infection during mouth-to-mouth resuscitation has been documented. However, because of the risk of salivary transmission of other infectious diseases (e.g., herpes simplex and *Neisseria meningitidis*) and the theoretical risk of HIV and HBV transmission during artificial ventilation of trauma victims, disposable airway equipment or resuscitation bags should be used. Disposable resuscitation equipment and devices should be used once and disposed of or, if reusable,

thoroughly cleaned and disinfected after each use according to the manufacturer's recommendations.

Mechanical respiratory assist devices (e.g., bag-valve masks, oxygen demand valve resuscitators) should be available on all emergency vehicles and to all emergency response personnel that respond or potentially respond to medical emergencies or victim rescues.

Pocket mouth-to-mouth resuscitation masks designed to isolate emergency response personnel (i.e., double lumen systems) from contact with victims' blood and blood-contaminated saliva, respiratory secretions, and vomitus should be provided to all personnel who provide or potentially provide emergency treatment.

V. Law-Enforcement and Correctional-Facility Officers

Law-enforcement and correctional-facility officers may face the risk of exposure to blood during the conduct of their duties. For example, at the crime scene or during processing of suspects, law-enforcement officers may encounter blood-contaminated hypodermic needles or weapons, or be called upon to assist with body removal. Correctional-facility officers may similarly be required to search prisoners or their cells for hypodermic needles or weapons, or subdue violent and combative inmates.

The following section presents information for reducing the risk of acquiring HIV and HBV infection by law-enforcement and correctional-facility officers as a consequence of carrying out their duties. However, there is an extremely diverse range of potential situations which may occur in the control of persons with unpredictable, violent, or psychotic behavior. Therefore, informed judgment of the individual officer is paramount when unusual circumstances or events arise. These recommendations should serve as an adjunct to rational decision making in those situations where specific guidelines do not exist, particularly where immediate action is required to preserve life or prevent significant injury.

The following guidelines are arranged into three sections: a section addressing concerns shared by both law-enforcement and correctional-facility officers, and two sections dealing separately with law-enforcement officers and correctional-facility officers, respectively. Table 4 (see page 35) contains selected examples of personal protective equipment that may be employed by law-enforcement and correctional-facility officers.

A. Law-Enforcement and Correctional-Facilities Considerations

1. Fights and assaults

Law-enforcement and correctional-facility officers are exposed to a range of assaultive and disruptive behavior through which they may potentially become exposed to blood or other body fluids containing blood. Behaviors of particular concern are biting, attacks resulting in blood exposure, and attacks with sharp objects. Such behaviors may occur in a range of law-enforcement situations including arrests, routine interrogations, domestic disputes, and lockup operations, as well as in correctional-facility activities. Hand-to-hand combat may result in bleeding and may thus incur a greater chance for blood-to-blood exposure, which increases the chances for blood-borne disease transmission.

Whenever the possibility for exposure to blood or blood-contaminated body fluids exists, the appropriate protection should be worn, if feasible under the circumstances. In all cases, extreme caution must be used in dealing with the suspect or prisoner if there is any indication of assaultive or combative behavior. When blood is present and a suspect or an inmate is combative or threatening to staff, gloves should always

be put on as soon as conditions permit. In case of blood contamination of clothing, an extra change of clothing should be available at all times.

2. Cardiopulmonary resuscitation

Law-enforcement and correctional personnel are also concerned about infection with HIV and HBV through administration of cardiopulmonary resuscitation (CPR). Although there have been no documented cases of HIV transmission through this mechanism, the possibility of transmission of other infectious diseases exists. Therefore, agencies should make protective masks or airways available to officers and provide training in their proper use. Devices with one-way valves to prevent the patients' saliva or vomitus from entering the caregiver's mouth are preferable.

B. Law-Enforcement Considerations

1. Searches and evidence handling

Criminal justice personnel have potential risks of acquiring HBV or HIV infection through exposures which occur during searches and evidence handling. Penetrating injuries are known to occur, and puncture wounds or needle sticks in particular pose a hazard during searches of persons, vehicles, or cells, and during evidence handling. The following precautionary measures will help to reduce the risk of infection:

- An officer should use great caution in searching the clothing of suspects. Individual discretion, based on the circumstances at hand, should determine if a suspect or prisoner should empty his own pockets or if the officer should use his own skills in determining the contents of a suspect's clothing.
- A safe distance should always be maintained between the officer and the suspect.
- Wear protective gloves if exposure to blood is likely to be encountered.
- Wear protective gloves for all body cavity searches.
- If cotton gloves are to be worn when working with evidence of potential latent fingerprint value at the crime scene, they can be worn over protective disposable gloves when exposure to blood may occur.
- Always carry a flashlight, even during daylight shifts, to search hidden areas. Whenever possible, use long-handled mirrors and flashlights to search such areas (e.g., under car seats).

- If searching a purse, carefully empty contents directly from purse, by turning it upside down over a table.

- Use puncture-proof containers to store sharp instruments and clearly marked plastic bags to store other possibly contaminated items.

- To avoid tearing gloves, use evidence tape instead of metal staples to seal evidence.

- Local procedures for evidence handling should be followed. In general, items should be air dried before sealing in plastic.

Not all types of gloves are suitable for conducting searches. Vinyl or latex rubber gloves provide little protection against sharp instruments, and they are not puncture-proof. There is a direct trade-off between level of protection and manipulability. In other words, the thicker the gloves, the more protection they provide, but the less effective they are in locating objects. Thus, there is no single type or thickness of glove appropriate for protection in all situations. Officers should select the type and thickness of glove which provides the best balance of protection and search efficiency.

Officers and crime scene technicians may confront unusual hazards, especially when the crime scene involves violent behavior, such as a homicide where large amounts of blood are present. Protective gloves should be available and worn in this setting. In addition, for very large spills, consideration should be given to other protective clothing, such as overalls, aprons, boots, or protective shoe covers. They should be changed if torn or soiled, and always removed prior to leaving the scene. While wearing gloves, avoid handling personal items, such as combs and pens, that could become soiled or contaminated.

Face masks and eye protection or a face shield are required for laboratory and evidence technicians whose jobs which entail potential exposures to blood via a splash to the face, mouth, nose, or eyes.

Airborne particles of dried blood may be generated when a stain is scraped. It is recommended that protective masks and eyewear or face shields be worn by laboratory or evidence technicians when removing the blood stain for laboratory analyses.

While processing the crime scene, personnel should be alert for the presence of sharp objects such as hypodermic needles, knives, razors, broken glass, nails, or other sharp objects.

2. Handling deceased persons and body removal

For detectives, investigators, evidence technicians, and others who may have to touch or remove a body, the response should be the same as for situations requiring CPR or first aid: wear gloves and cover all cuts and abrasions to create a barrier and carefully wash all exposed areas after any contact with blood. The precautions to be used with blood and deceased persons should also be used when handling amputated limbs, hands, or other body parts. Such procedures should be followed after contact with the blood of **anyone**, regardless of whether they are known or suspected to be infected with HIV or HBV.

3. Autopsies

Protective masks and eyewear (or face shields), laboratory coats, gloves, and waterproof aprons should be worn when performing or attending all autopsies. All autopsy material should be considered infectious for both HIV and HBV. Onlookers with an opportunity for exposure to blood splashes should be similarly protected. Instruments and surfaces contaminated during postmortem procedures should be decontaminated with an appropriate chemical germicide (*4*). Many laboratories have more detailed standard operating procedures for conducting autopsies; where available, these should be followed. More detailed recommendations for health-care workers in this setting have been published (*4*).

4. Forensic laboratories

Blood from all individuals should be considered infective. To supplement other worksite precautions, the following precautions are recommended for workers in forensic laboratories.

a. All specimens of blood should be put in a well-constructed, appropriately labelled 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.

b. All persons processing blood specimens should wear gloves. Masks and protective eyewear or face shields should be worn if mucous-membrane contact with blood is anticipated (e.g., removing tops from vacuum tubes). Hands should be washed after completion of specimen processing.

c. For routine procedures, such as histologic and pathologic studies or microbiological 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.

d. Mechanical pipetting devices should be used for manipulating all liquids in the laboratory. Mouth pipetting must not be done.

e. 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.

f. Laboratory work surfaces should be cleaned of visible materials and then decontaminated with an appropriate chemical germicide after a spill of blood, semen, or blood-contaminated body fluid and when work activities are completed.

g. Contaminated materials used in laboratory tests should be decontaminated before reprocessing or be placed in bags and disposed of in accordance with institutional and local regulatory policies for disposal of infective waste.

h. Scientific equipment that has been contaminated with blood should be cleaned and then decontaminated before being repaired in the laboratory or transported to the manufacturer.

i. All persons should wash their hands after completing laboratory activities and should remove protective clothing before leaving the laboratory.

j. Area posting of warning signs should be considered to remind employees of continuing hazard of infectious disease transmission in the laboratory setting.

C. Correctional-Facility Considerations

1. Searches

Penetrating injuries are known to occur in the correctional-facility setting, and puncture wounds or needle sticks in particular pose a hazard during searches of prisoners or their cells. The following precautionary measures will help to reduce the risk of infection:

- A correctional-facility officer should use great caution in searching the clothing of prisoners. Individual discretion, based on the circumstances at hand, should determine if a prisoner should empty his own pockets or if the officer should use his own skills in determining the contents of a prisoner's clothing.

- A safe distance should always be maintained between the officer and the prisoner.

- Always carry a flashlight, even during daylight shifts, to search hidden areas. Whenever possible, use long-handled mirrors and flashlights to search such areas (e.g., under commodes, bunks, and in vents in jail cells).

- Wear protective gloves if exposure to blood is likely to be encountered.

- Wear protective gloves for all body cavity searches.

Not all types of gloves are suitable for conducting searches. Vinyl or latex rubber gloves can provide little, if any, protection against sharp instruments, and they are not puncture-proof. There is a direct trade-off between level of protection and manipulability. In other words, the thicker the gloves, the more protection they provide, but the less effective they are in locating objects. Thus, there is no single type or thickness of glove appropriate for protection in all situations. Officers should select the type and thickness of glove which provides the best balance of protection and search efficiency.

2. Decontamination and disposal

Prisoners may spit at officers and throw feces; sometimes these substances have been purposefully contaminated with blood. Although there are no documented cases of HIV or HBV transmission in this manner and transmission by this route would not be expected to occur, other diseases could be transmitted. These materials should be removed with a paper towel after donning gloves, and the area then decontaminated with an appropriate germicide. Following clean-up, soiled towels and gloves should be disposed of properly.

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Table 1. The Risk of HIV Infection
Following Needlestick Injury: Hypothetical Model

Prevalence of HIV Infection (A)	Probability of Infection Given Needlestick Injury with Blood Containing HIV (B)	Probability of Infection Given Random Needlestick (Unknown Serostatus) A * B = (C)	Probability of Infection Given 10 Random Needlesticks $1-(1-C)^{10}$	Probability of Infection Given 100 Random Needlesticks $1-(1-C)^{100}$
0.0001	0.001	0.0000001	0.000001	0.00001
0.0001	0.005	0.0000005	0.000005	0.00005
0.001	0.001	0.000001	0.00001	0.0001
0.001	0.005	0.000005	0.00005	0.0005
0.01	0.001	0.00001	0.0001	0.001
0.01*	0.005	0.00005	0.0005	0.005
0.05	0.001	0.00005	0.0005	0.005
0.05	0.005	0.00025	0.0025	0.025

* For example, if the prevalence of infection in the population is 0.01 (i.e., 1 per 100) and the risk of a seroconversion following a needlestick with blood known to contain HIV is 0.005 (i.e., 1 in 200), then the probability of HIV infection given a random needlestick is 0.00005 (i.e., 5 in 100,000). If an individual sustains 10 needlestick injuries, the probability of acquiring HIV infection is 0.0005 (i.e., 1 in 2,000); if the individual sustains 100 needlestick injuries, the probability of acquiring HIV infection is 0.005 (i.e., 1 in 200).

Table 2.
HIV-infected health-care workers with no reported nonoccupational risk factors and for whom case histories have been published in the scientific literature

Cases with Documented Seroconversion

Case	Occupation	Country	Type of Exposure	Source
1*	NS†	United States	Needlestick	AIDS patient
2	NS	United States	Needlestick	AIDS patient
3	NS	United States	Needlestick	AIDS patient
4	NS	United States	2 Needlesticks	AIDS patient, HIV-infected patient
5	NS	United States	Needlestick	AIDS patient
6	Nurse	England	Needlestick	AIDS patient
7	Nurse	France	Needlestick	HIV-infected patient
8	Nurse	Martinique	Needlestick	AIDS patient
9	Research lab worker	United States	Cut with sharp object	Concentrated virus
10	Home health-care worker	United States	Cutaneous#	AIDS patient
11	NS	United States	Nonintact skin	AIDS patient
12	Phlebotomist	United States	Mucous-membrane	HIV-infected patient
13	Technologist	United States	Nonintact skin	HIV-infected patient
14	NS	United States	Needlestick	AIDS patient
15	Nurse	Italy	Mucous membrane	HIV-infected patient
16	Nurse	France	Needlestick	AIDS patient
17	Navy medic	United States	Needlestick	AIDS patient
18	Clinical lab worker	United States	Cut with sharp object	AIDS patient

* AIDS case
† Not specified
# Mother who provided nursing care for her child with HIV infection; extensive contact with the child's blood and body secretions and excretions occurred; the mother did not wear gloves and often did not wash her hands immediately after exposure.

Table 2, continued.
HIV-infected health-care workers with no reported nonoccupational risk factors and for whom case histories have been published in the scientific literature

Cases without Documented Seroconversion

Case	Occupation	Country	Type of Exposure	Source
19	NS	United States	Puncture wound	AIDS patient
20	NS	United States	2 Needlesticks	2 AIDS patients
21	Research lab worker	United States	Nonintact skin	Concentrated virus
22	Home health-care provider	England	Nonintact skin	AIDS patient
23	Dentist	United States	Multiple needle-sticks	Unknown
24*	Technician	Mexico	Multiple needle-sticks and mucous-membrane	Unknown
25	Lab worker	United States	Needlestick, puncture wound	Unknown

* AIDS case

Table 3. Summary of Task Categorization and Implications for Personal Protective Equipment

Joint Advisory Notice Category[1]	Nature of Task/Activity	Personal protective equipment should be: Available?	Worn?
I.	Direct contact with blood or other body fluids to which universal precautions apply	Yes	Yes
II.	Activity performed without blood exposure but exposure may occur in emergency	Yes	No
III.	Task/activity does not entail predictable or unpredictable exposure to blood	No	No

[1] U.S. Department of Labor, U.S. Department of Health and Human Services. Joint advisory notice: protection against occupational exposure to hepatitis B virus (HBV) and human immunodeficiency virus (HIV). Washington, DC: US Department of Labor, US Department of Health and Human Services, 1987.

Table 4. Examples of Recommended Personal Protective Equipment for Worker Protection Against HIV and HBV Transmission[1] in Prehospital[2] Settings

Task or Activity	Disposable Gloves	Gown	Mask[3]	Protective Eyewear
Bleeding control with with spurting blood	Yes	Yes	Yes	Yes
Bleeding control with minimal bleeding	Yes	No	No	No
Emergency childbirth	Yes	Yes	Yes, if splashing is likely	Yes, if splashing is likely
Blood drawing	At certain times[4]	No	No	No
Starting an intravenous (IV) line	Yes	No	No	No
Endotracheal intubation, esophageal obturator use	Yes	No	No, unless splashing is likely	No, unless splashing is likely
Oral/nasal suctioning, manually cleaning airway	Yes[5]	No	No, unless splashing is likely	No, unless splashing is likely
Handling and cleaning instruments with microbial contamination	Yes	No, unless soiling is likely	No	No
Measuring blood pressure	No	No	No	No
Measuring temperature	No	No	No	No
Giving an injection	No	No	No	No

[1]The examples provided in this table are based on application of universal precautions. Universal precautions are intended to supplement rather than replace recommendations for routine infection control, such as handwashing and using gloves to prevent gross microbial contamination of hands (e.g., contact with urine or feces).

[2]Defined as setting where delivery of emergency health care takes place away from a hospital or other health-care facility.

[3]Refers to protective masks to prevent exposure of mucous membranes to blood or other potentially contaminated body fluids. The use of resuscitation devices, some of which are also referred to as "masks," is discussed on page 23.

[4]For clarification see Appendix A, page 7, and Appendix B, page 7.

[5]While not clearly necessary to prevent HIV or HBV transmission unless blood is present, gloves are recommended to prevent transmission of other agents (e.g., *Herpes simplex*).

Table 5. Reprocessing Methods for Equipment Used in the Prehospital[1] Health-Care Setting

Sterilization:	Destroys:	All forms of microbial life including high numbers of bacterial spores.
	Methods:	Steam under pressure (autoclave), gas (ethylene oxide), dry heat, or immersion in EPA-approved chemical "sterilant" for prolonged period of time, e.g., 6–10 hours or according to manufacturers' instructions. Note: liquid chemical "sterilants" should be used only on those instruments that are impossible to sterilize or disinfect with heat.
	Use:	For those instruments or devices that penetrate skin or contact normally sterile areas of the body, e.g., scalpels, needles, etc. Disposable invasive equipment eliminates the need to reprocess these types of items. When indicated, however, arrangements should be made with a health-care facility for reprocessing of reusable invasive instruments.
High-Level Disinfection:	Destroys:	All forms of microbial life except high numbers of bacterial spores.
	Methods:	Hot water pasteurization (80–100 C, 30 minutes) or exposure to an EPA-registered "sterilant" chemical as above, except for a short exposure time (10–45 minutes or as directed by the manufacturer).
	Use:	For reusable instruments or devices that come into contact with mucous membranes (e.g., laryngoscope blades, endotracheal tubes, etc.).
Intermediate-Level Disinfection:	Destroys:	*Mycobacterium tuberculosis*, vegetative bacteria, most viruses, and most fungi, but does not kill bacterial spores.
	Methods:	EPA-registered "hospital disinfectant" chemical germicides that have a label claim for tuberculocidal activity; commercially available hard-surface germicides or solutions containing at least 500 ppm free available chlorine (a 1:100 dilution of common household bleach – approximately ¼ cup bleach per gallon of tap water).
	Use:	For those surfaces that come into contact only with intact skin, e.g., stethoscopes, blood pressure cuffs, splints, etc., and have been visibly contaminated with blood or bloody body fluids. Surfaces must be precleaned of visible material before the germicidal chemical is applied for disinfection.

Table 5. Reprocessing Methods for Equipment Used in the Prehospital[1] Health-Care Setting – Continued

Low-Level Disinfection:	Destroys:	Most bacteria, some viruses, some fungi, but not *Mycobacterium tuberculosis* or bacterial spores.
	Methods:	EPA-registered "hospital disinfectants" (no label claim for tuberculocidal activity).
	Use:	These agents are excellent cleaners and can be used for routine housekeeping or removal of soiling in the absence of visible blood contamination.
Environmental Disinfection:		Environmental surfaces which have become soiled should be cleaned and disinfected using any cleaner or disinfectant agent which is intended for environmental use. Such surfaces include floors, woodwork, ambulance seats, countertops, etc.
IMPORTANT:		To assure the effectiveness of any sterilization or disinfection process, equipment and instruments must first be thoroughly cleaned of all visible soil.

[1]Defined as setting where delivery of emergency health-care takes place prior to arrival at hospital or other health-care facility.

Protection Against Viral Hepatitis

Recommendations of the Immunization Practices Advisory Committee (ACIP)

*The following statement updates all previous recommendations on protection against viral hepatitis, including use of hepatitis B vaccine and hepatitis B immune globulin for prophylaxis of hepatitis B (*MMWR *1985;34:313-24,329-35 and* MMWR *1987,36:353-66), universal screening of pregnant women to prevent perinatal hepatitis B transmission (*MMWR *1988;37:341-46,51), and use of immune globulin to prevent other types of viral hepatitis* (MMWR *1985;34:313-24,329-35).*

INTRODUCTION

The term "viral hepatitis" is commonly used for several clinically similar diseases that are etiologically and epidemiologically distinct (*1*). Two of these, hepatitis A (formerly called infectious hepatitis) and hepatitis B (formerly called serum hepatitis), have been recognized as separate entities since the early 1940s and can be diagnosed with specific serologic tests. A third category, currently known as non-A, non-B hepatitis, includes two epidemiologically distinct types of hepatitis: parenterally transmitted and enterically transmitted non-A, non-B hepatitis. Parenterally transmitted non-A, non-B hepatitis is associated with both posttransfusion and sporadic cases of acute hepatitis and may be caused by at least two different agents. Part of the genome for one of these agents has recently been cloned, and a candidate serologic assay for antibody to this virus (proposed as hepatitis C virus) has been developed (*2,3*). Enterically transmitted non-A, non-B hepatitis, which is spread by the fecal-oral route and is different from the types seen in the United States, has been reported in parts of Asia, Africa, and Mexico (*4*). Another distinct type of hepatitis, delta hepatitis, is an infection dependent on the hepatitis B virus. It may occur as a coinfection with acute hepatitis B infection or as superinfection of a hepatitis B carrier (*5*).

HEPATITIS SURVEILLANCE

Approximately 28,500 cases of hepatitis A, 23,200 cases of hepatitis B, 2,620 cases of non-A, non-B hepatitis, and 2,470 cases of hepatitis type unspecified were reported in 1988 in the United States. Most cases of each type occur among young adults. Since reporting from many localities is incomplete, the actual number of hepatitis cases occurring annually is thought to be several times the reported number.

IMMUNE GLOBULINS

Immune globulins are important tools for preventing infection and disease before or after exposure to hepatitis viruses. Immune globulins used in medical practice are sterile solutions of antibodies (immunoglobulins) from human plasma. They are prepared by cold ethanol fractionation of large plasma pools and contain 10%-18% protein. In the United States, plasma is primarily obtained from paid donors. Only plasma shown to be free of hepatitis B surface antigen (HBsAg) and antibody to human immunodeficiency virus (HIV) is used to prepare immune globulins.

Immune globulin (IG) (formerly called immune serum globulin, ISG, or gamma globulin) produced in the United States contains antibodies against the hepatitis A virus (anti-HAV) and the HBsAg (anti-HBs). Hepatitis B immune globulin (HBIG) is an IG prepared from plasma containing high titers of anti-HBs.

There is no evidence that hepatitis B virus (HBV), HIV (the causative agent of acquired immunodeficiency syndrome [AIDS]), or other viruses have ever been transmitted by IG or HBIG commercially available in the United States (*6*). Since late April 1985, all plasma units for preparation of IGs have been screened for antibody to HIV, and reactive units are discarded. No instances of HIV infection or clinical illness have occurred that can be attributed to receiving IG or HBIG, including lots prepared before April 1985. Laboratory studies have shown that the margin of safety based on the removal of HIV infectivity by the fractionation process is extremely high (*7*). Some HBIG lots prepared before April 1985 have detectable HIV antibody. Shortly after being given HBIG, recipients have occasionally been noted to have low levels of passively acquired HIV antibody, but this reactivity does not persist (*8*).

Serious adverse effects from IGs administered as recommended have been rare. IGs prepared for intramuscular administration should be used for hepatitis prophylaxis. IGs prepared for intravenous administration to immunodeficient and other selected patients are not intended for hepatitis prophylaxis. IG and HBIG are not contraindicated for pregnant or lactating women.

HEPATITIS A

Hepatitis A is caused by the hepatitis A virus (HAV), a 27-nm ribonucleic acid (RNA) agent that is classified as a picornavirus. Patients with illness caused by HAV characteristically have abrupt onsets of symptoms including fever, malaise, anorexia, nausea, abdominal discomfort, dark urine, and jaundice. Severity is related to age. Among children, most infections are asymptomatic, and illness is usually not accompanied by jaundice. Most infected adults become symptomatically ill with jaundice. The case-fatality rate among reported cases is about 0.6%.

Hepatitis A is primarily transmitted by person-to-person contact, generally through fecal contamination and oral ingestion. Transmission is facilitated by poor personal hygiene, poor sanitation, and intimate (intrahousehold or sexual) contact. In recent years, cases of hepatitis A among intravenous drug users, most likely due to person-to-person contact, have been reported with increasing frequency (*9*). Common-source epidemics from contaminated food and water also occur. Sharing utensils or cigarettes or kissing is not believed to transmit the hepatitis A virus.

The incubation period of hepatitis A is 15-50 days (average 28). High concentrations of HAV (10^8 particles/g) are found in stool specimens from infected persons. Virus in the feces reaches its highest concentration late in the incubation period and early in the prodromal phase of illness, and it diminishes rapidly once jaundice appears. Greatest infectivity is during the 2-week period immediately before the onset of jaundice. Viremia probably occurs during the period that the virus is shed in feces. Virus has not been found in urine. A chronic carrier state with HAV in blood or feces has not been demonstrated. Transmission of HAV by blood transfusion has been reported but is uncommon (*10*).

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

Although the incidence of hepatitis A in the United States in the 1980s was lower than that in the 1970s, a 26% increase in incidence was observed between 1983 and 1988. It is still a common infection among older children and young adults. In 1988, 50% of reported cases of hepatitis in this country were attributable to hepatitis A.

Recommendations for IG Prophylaxis for Hepatitis A

Numerous field studies conducted in the past 4 decades confirm that IG given before exposure or during the incubation period of hepatitis A is protective against clinical illness (*11-13*). Its prophylactic value is greatest (80%-90%) when given early in the incubation period and declines thereafter (*13*). Recent tests have shown slightly decreased titers of anti-HAV in current IG lots compared with lots tested 8 years previously; however, no differences in IG efficacy have been noted.

Preexposure Prophylaxis

The major group for whom preexposure prophylaxis is recommended is international travelers. The risk of hepatitis A for U.S. citizens traveling abroad varies with living conditions, length of stay, and the incidence of hepatitis A infection in areas visited (*14-16*). In general, travelers to developed areas of

North America, western Europe, Japan, Australia, and New Zealand are at no greater risk of infection than they would be in the United States. For travelers to developing countries, risk of infection increases with duration of travel and is highest for those who live in or visit rural areas, trek in back country, or frequently eat or drink in settings of poor sanitation. Nevertheless, recent studies have shown that many cases of travel-related hepatitis A occur in travelers with "standard" tourist itineraries, accommodations, and food and beverage consumption behaviors (*16* and CDC unpublished data). In developing countries, travelers should minimize their exposure to hepatitis A and other enteric diseases by avoiding potentially contaminated water or food. Travelers should avoid drinking water (or beverages with ice) of unknown purity and eating uncooked shellfish or uncooked fruits or vegetables that they did not prepare.

IG is recommended for all susceptible travelers to developing countries (*17*). IG is especially important for persons who will be living in or visiting rural areas, eating or drinking in settings of poor or uncertain sanitation, or who will have close contact with local persons (especially young children) in settings with poor sanitary conditions. Persons who plan to reside in developing areas for long periods should receive IG regularly.

For travelers, a single dose of IG of 0.02 ml/kg of body weight is recommended if travel is for <3 months. For prolonged travel or residence in developing countries, 0.06 ml/kg should be given every 5 months. For persons who require repeated IG prophylaxis, screening for total anti-HAV before travel is useful to define susceptibility and eliminate unnecessary doses of IG for those who are immune. IG produced in developing countries may not meet the standards for purity required in most developed countries. Persons needing repeat doses overseas should use products that meet U.S. license requirements.

Postexposure Prophylaxis

Hepatitis A cannot be reliably diagnosed on clinical presentation alone, and serologic confirmation of index patients is recommended before contacts are treated. Serologic screening of contacts for anti-HAV before they are given IG is not recommended because screening is more costly than IG and would delay its administration.

For postexposure IG prophylaxis, a single intramuscular dose of 0.02 ml/kg is recommended. IG should be given as soon as possible after last exposure; giving IG more than 2 weeks after exposure is not indicated.

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

1. Close personal contact. IG is recommended for all household and sexual contacts of persons with hepatitis A.
2. Day-care centers. Day-care facilities attended by children in diapers can be important settings for HAV transmission (*18-20*). IG should be administered to all staff and attendees of day-care centers or homes if a) one or more children or employees are diagnosed as having hepatitis A, or b) cases are recognized in two or more households of center attendees. When an outbreak (hepatitis cases in three or more families) occurs, IG should also be considered for members of households that have children (center attendees) in diapers. In centers not enrolling children in diapers, IG need only be given to classroom contacts of an index patient.
3. Schools. Contact at elementary and secondary schools is usually not an important means of transmitting hepatitis A. Routine administration of IG is not indicated for pupils and teachers in contact with a patient. However, when an epidemiologic investigation clearly shows the existence of a school- or classroom-centered outbreak, IG may be given to persons who have close contact with patients.
4. Institutions for custodial care. Living conditions in some institutions, such as prisons and facilities for the developmentally disabled, favor transmission of hepatitis A. When outbreaks occur, giving IG to residents and staff who have close contact with patients with hepatitis A may reduce the spread of disease. Depending on the epidemiologic circumstances, prophylaxis can be limited or can involve the entire institution.
5. Hospitals. Routine IG prophylaxis for hospital personnel is not indicated. Rather, sound hygienic practices should be emphasized. Staff education should point out the risk of exposure to hepatitis A and should emphasize precautions regarding direct contact with potentially infective materials (*21*).

Outbreaks of hepatitis A occur occasionally among hospital staff, usually in association with an unsuspected index patient who is fecally incontinent. Large outbreaks have occurred from contact with infected infants in neonatal intensive care units (*10*). In outbreaks, prophylaxis of persons exposed to feces of infected patients may be indicated.

6. Offices and factories. Routine IG administration is not indicated under the usual office or factory conditions for persons exposed to a fellow worker with hepatitis A. Experience shows that casual contact in the work setting does not result in virus transmission.
7. Common-source exposure. IG use might be effective in preventing foodborne or waterborne hepatitis A if exposure is recognized in time. However, IG is not recommended for persons exposed to a common-source of hepatitis infection after cases have begun to occur, since the 2-week period during which IG is effective will have been exceeded.

If a food handler is diagnosed as having hepatitis A, common-source transmission is possible but uncommon. IG should be administered to other food handlers but is usually not recommended for patrons (*22*). However, IG administration to patrons may be considered if all of the following conditions exist: a) the infected person is directly involved in handling, without gloves, foods that will not be cooked before they are eaten, and b) the hygienic practices of the food handler are deficient or the food handler has had diarrhea, and c) patrons can be identified and treated within 2 weeks of exposure. Situations in which repeated exposures may have occurred, such as in institutional cafeterias, may warrant stronger consideration of IG use.

TABLE 1. Hepatitis nomenclature

	Abbreviation	Term	Definition/Comments
A. Hepatitis A	HAV	Hepatitis A virus	Etiologic agent of "infectious" hepatitis; a picornavirus; single serotype.
	Anti-HAV	Antibody to HAV	Detectable at onset of symptoms; lifetime persistence.
	IgM anti-HAV	IgM class antibody to HAV	Indicates recent infection with hepatitis A; detectable for 4-6 months after infection.
B. Hepatitis B	HBV	Hepatitis B virus	Etiologic agent of "serum" hepatitis; also known as Dane particle.
	HBsAg	Hepatitis B surface antigen	Surface antigen(s) of HBV detectable in large quantity in serum; several subtypes identified.
	HBeAg	Hepatitis B e antigen	Soluble antigen; correlates with HBV replication, high titer HBV in serum, and infectivity of serum.
	HBcAg	Hepatitis B core antigen	No commercial test available.
	Anti-HBs	Antibody to HBsAg	Indicates past infection with and immunity to HBV, passive antibody from HBIG, or immune response from HB vaccine.
	Anti-HBe	Antibody to HBeAg	Presence in serum of HBsAg carrier indicates lower titer of HBV.
	Anti-HBc	Antibody to HBcAg	Indicates prior infection with HBV at some undefined time.
	IgM anti-HBc	IgM class antibody to HBcAg	Indicates recent infection with HBV; detectable for 4-6 months after infection.
C. Delta hepatitis	HDV	Hepatitis D virus	Etiologic agent of delta hepatitis; can cause infection only in presence of HBV.
	HDAg	Delta antigen	Detectable in early acute delta infection.
	Anti-HDV	Antibody to delta antigen	Indicates present or past infection with delta virus.
D. Non-A, non-B hepatitis	PT-NANB	Parenterally transmitted	Diagnosis by exclusion. At least two candidate viruses, one of which has been proposed as hepatitis C virus; shares epidemiologic features with hepatitis B.
	ET-NANB	Enterically transmitted	Diagnosis by exclusion. Causes large epidemics in Asia, Africa, and Mexico; fecal-oral or waterborne.
E. Immune globulins	IG	Immune globulin (previously ISG, immune serum globulin, or gamma globulin)	Contains antibodies to HAV, low-titer antibodies to HBV.
	HBIG	Hepatitis B immune globulin	Contains high-titer antibodies to HBV.

HEPATITIS B

Hepatitis B infection is caused by the hepatitis B virus (HBV), a 42-nm, double-shelled deoxyribonucleic acid (DNA) virus of the class hepadnaviridae. Several well-defined antigen-antibody systems are associated with HBV infection (Table 1). HBsAg is found on the surface of the virus and is also produced in excess amounts, circulating in blood as 22-nm spherical and tubular particles. HBsAg can be identified in serum 30-60 days after exposure to HBV and persists for variable periods. Anti-HBs develops after a resolved infection and is responsible for long-term immunity. Antibody to the core antigen (anti-HBc) develops in all HBV infections and persists indefinitely. IgM anti-HBc appears early in infection and persists for ≥6 months. It is a reliable marker of acute or recent HBV infection. A third antigen, hepatitis B e antigen (HBeAg), may be detected in samples from persons with acute or chronic HBV infection. The presence of HBeAg correlates with viral replication and high infectivity. Antibody to HBeAg (anti-HBe) develops in most HBV infections and correlates with the loss of replicating virus and with lower infectivity.

The incubation period of hepatitis B is long (45-160 days; average = 120), and the onset of acute disease is generally insidious. Clinical symptoms and signs include anorexia, malaise, nausea, vomiting, abdominal pain, and jaundice. Extrahepatic manifestations of disease—such as skin rashes, arthralgias, and arthritis—can also occur. The case-fatality rate for reported cases is approximately 1.4%.

A variable proportion of individuals infected with HBV will become chronically infected with the virus. The HBV carrier is central to the epidemiology of HBV transmission. A carrier is defined as a person who is either HBsAg-positive on at least two occasions (at least 6 months apart) or who is HBsAg-positive and IgM anti-HBc negative when a single serum specimen is tested. Although the degree of infectivity is best correlated with HBeAg-positivity, any person positive for HBsAg is potentially infectious. The likelihood of becoming chronically infected with HBV varies inversely with the age at which infection occurs. HBV transmitted from HBsAg-positive mothers to their newborns results in HBV carriage for up to 90% of infants. Between 25% and 50% of children infected before 5 years of age become carriers, whereas only 6%-10% of acutely infected adults become carriers.

Carriers and persons with acute infection have the highest concentrations of HBV in blood and serous fluids. A lower concentration is present in other body fluids, such as saliva and semen. Transmission occurs via percutaneous or permucosal routes, and infective blood or body fluids can be introduced at birth, through sexual contact, or by contaminated needles. Infection can also occur in settings of continuous close personal contact (such as in households or among children in institutions for the developmentally disabled), presumably via inapparent or unnoticed contact of infective secretions with skin lesions or mucosal surfaces. Transmission of infection by transfusion of blood or blood products is rare because of routine screening of blood for HBsAg and because of current donor selection procedures. Transmission of HBV from infected health-care workers to patients is uncommon but has been documented during types of invasive procedures (e.g., oral and gynecologic surgery) (*23,24*). HBsAg-positive health-care workers need not be restricted from patient contact unless they have been epidemiologically associated with HBV transmission. Rather, they should be educated about the potential mechanisms of HBV transmission. Adherence to aseptic techniques minimizes the risk of transmission. HBV is not transmitted via the fecal-oral route.

Worldwide, HBV infection is a major cause of acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma. The frequency of HBV infection and patterns of transmission vary markedly in different parts of the world. In the United States, Western Europe, and Australia, it is a disease of low endemicity, with infection occurring primarily during adulthood and with only 0.2%-0.9% of the population being chronically infected. In contrast, HBV infection is highly endemic in China and Southeast Asia, most of Africa, most Pacific Islands, parts of the Middle East, and in the Amazon Basin. In these areas, most persons acquire infection at birth or during childhood, and 8%-15% of the population are chronically infected with HBV. In other parts of the world, HBV infection is moderately endemic, with 2%-7% of the population being HBV carriers. Prevention strategies for populations in which HBV infection is highly endemic are directed at vaccinating infants with hepatitis B vaccine, usually beginning at birth, to prevent both perinatal and childhood transmission of infection (*25*). Recommendations for hepatitis B prophylaxis in other areas should be designed to maximize the interruption of HBV transmission in accordance with local patterns of transmission. The recommendations that follow are intended for use in the United States.

Hepatitis B Virus Infection in the United States

Each year, an estimated 300,000 persons, primarily young adults, are infected with HBV. One-quarter become ill with jaundice, more than 10,000 patients require hospitalization, and an average of 250 die of fulminant disease. The United States currently contains an estimated pool of 750,000-1,000,000 infectious carriers. Approximately 25% of carriers develop chronic active hepatitis, which often progresses to cirrhosis. Furthermore, HBV carriers have a risk of developing primary liver cancer that is 12-300 times higher than that of other persons. An estimated 4,000 persons die each year from hepatitis B-related cirrhosis, and more than 800 die from hepatitis B-related liver cancer.

Serologic surveys demonstrate that, although HBV infection is uncommon among adults in the general population, it is highly prevalent in certain groups. Those at risk, based on the prevalence of serologic markers of infection, are described in Table 2. Persons born in areas of high HBV endemicity and their descendents remain at high risk of infection, as do certain populations in which HBV is highly endemic (Alaskan Natives and Pacific Islanders). Certain lifestyles (e.g., homosexual activity, intravenous drug abuse) result in early acquisition of HBV infection and high rates of infection. Persons who have heterosexual activity with multiple partners are at significant risk of infection. Inmates of prisons have a high prevalence of HBV markers, usually because of parenteral drug abuse before or during imprisonment. Patients in custodial institutions for the developmentally disabled are also at increased risk of having HBV infection. Household contacts and sexual partners of HBV carriers are at increased risk, as are hemodialysis patients and recipients of certain plasma-derived products that have not been inactivated (e.g., anti-hemophilic factor).

Those at occupational risk of HBV infection include medical and dental workers, related laboratory and support personnel, and public service employees who have contact with blood, as well as staff in institutions or classrooms for the mentally retarded.

Hepatitis B Prevention Strategies in the United States

The incidence of reported acute hepatitis B cases increased steadily over the past decade and reached a peak in 1985 (11.50 cases/10^5/year), despite the introduction of hepatitis B vaccine 3 years previously. Incidence decreased modestly (18%) by 1988, but still remains higher than a decade ago. This minimal impact of hepatitis B vaccine on disease incidence is attributable to several factors. The sources of infection for most cases include intravenous drug abuse (28%), heterosexual contact with

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

Population group	Prevalence of serologic markers of HBV infection	
	HBsAg (%)	Any marker (%)
Immigrants/refugees from areas of high HBV endemicity	13	70-85
Alaskan Natives/Pacific Islanders	5-15	40-70
Clients in institutions for the developmentally disabled	10-20	35-80
Users of illicit parenteral drugs	7	60-80
Sexually active homosexual men	6	35-80
Household contacts of HBV carriers	3-6	30-60
Patients of hemodialysis units	3-10	20-80
Health-care workers — frequent blood contact	1-2	15-30
Prisoners (male)	1-8	10-80
Staff of institutions for the developmentally disabled	1	10-25
Heterosexuals with multiple partners	0.5	5-20
Health-care workers — no or infrequent blood contact	0.3	3-10
General population (NHANES II)*		
Blacks	0.9	14
Whites	0.2	3

*Second National Health and Nutrition Examination Survey (*25*).

infected persons or multiple partners (22%), and homosexual activity (9%). In addition, 30% of patients with Hepatitis B deny any of the recognized risk factors for infection.

The present strategy for hepatitis B prevention is to vaccinate those individuals at high risk of infection. Most persons receiving vaccine as a result of this strategy have been persons at risk of acquiring HBV infection through occupational exposure, a group that accounts for approximately 4% of cases. The major deterrents to vaccinating the other high-risk groups include their lack of knowledge about the risk of disease and its consequences, the lack of public-sector programs, the cost of vaccine, and the inability to access most of the high-risk populations.

For vaccine to have an impact on the incidence of hepatitis B, a comprehensive strategy must be developed that will provide hepatitis B vaccination to persons before they engage in behaviors or occupations that place them at risk of infection. Universal HBsAg screening of pregnant women was recently recommended to prevent perinatal HBV transmission. The previous recommendations for selective screening failed to identify most HBsAg-positive pregnant women (*27*). As an alternative to high-risk-group vaccination, universal vaccination of infants and adolescents needs to be examined as a possible strategy to control the transmission of disease.

Hepatitis B Prophylaxis

Two types of products are available for prophylaxis against hepatitis B. Hepatitis B vaccines, first licensed in 1981, provide active immunization against HBV infection, and their use is recommended for both preexposure and postexposure prophylaxis. HBIG provides temporary, passive protection and is indicated only in certain postexposure settings.

HBIG

HBIG is prepared from plasma preselected to contain a high titer of anti-HBs. In the United States, HBIG has an anti-HBs titer of >100,000 by radioimmunoassay (RIA). Human plasma from which HBIG is prepared is screened for antibodies to HIV; in addition, the Cohn fractionation process used to prepare this product inactivates and eliminates HIV from the final product.There is no evidence that the causative agent of AIDS (HIV) has been transmitted by HBIG (*6*).

Hepatitis B Vaccine

Two types of hepatitis B vaccines are currently licensed in the United States. Plasma-derived vaccine consists of a suspension of inactivated, alum-adsorbed, 22-nm, HBsAg particles that have been purified from human plasma by a combination of biophysical (ultracentrifugation) and biochemical procedures. Inactivation is a threefold process using 8M urea, pepsin at pH 2, and 1:4,000 formalin. These treatment steps have been shown to inactivate representatives of all classes of viruses found in human blood, including HIV (*28*). Plasma-derived vaccine is no longer being produced in the United States, and use is now limited to hemodialysis patients, other immunocompromised hosts, and persons with known allergy to yeast.

Currently licensed recombinant hepatitis B vaccines are produced by *Saccharomyces cerevisiae* (common baker's yeast), into which a plasmid containing the gene for the HBsAg has been inserted. Purified HBsAg is obtained by lysing the yeast cells and separating HBsAg from yeast components by biochemical and biophysical techniques. These vaccines contain more than 95% HBsAg protein. Yeast-derived protein constitutes no more than 5% of the final product.

Hepatitis B vaccines are packaged to contain 10-40 μg HBsAg protein/ml and are adsorbed with aluminum hydroxide (0.5 mg/ml). Thimerosal (1:20,000 concentration) is added as a preservative.

The recommended series of three intramuscular doses of hepatitis B vaccine induces an adequate antibody response* in >90% of healthy adults and in >95%of infants, children, and adolescents from birth through 19 years of age (*29-31*). The deltoid (arm) is the recommended site for hepatitis B vaccination of adults and children; immunogenicity of vaccine for adults is substantially lower when injections are given in the buttock (*32*). Larger vaccine doses (two to four times normal adult dose) or an increased number of doses (four doses) are required to induce protective antibody in a high proportion of hemodialysis patients and may also be necessary for other immunocompromised persons (such as those on immunosuppressive drugs or with HIV infection) (*33,34*).

Field trials of the vaccines licensed in the United States have shown 80%-95% efficacy in preventing infection or clinical hepatitis among susceptible persons (*31,35*). Protection against illness is virtually

*An adequate antibody response is ≥10 milliInternational Units (mIU)/ml, approximately equivalent to 10 sample ratio units (SRU) by RIA or positive by enzyme immunoassay (EIA), measured 1-6 months after completion of the vaccine series.

complete for persons who develop an adequate antibody response after vaccination. The duration of protection and need for booster doses are not yet fully defined. Between 30% and 50% of persons who develop adequate antibody after three doses of vaccine will lose detectable antibody within 7 years, but protection against viremic infection and clinical disease appears to persist (*36-38*). Immunogenicity and efficacy of the licensed vaccines for hemodialysis patients are much lower than in normal adults. Protection in this group may last only as long as adequate antibody levels persist (*33*).

Vaccine Usage

Primary vaccination comprises three intramuscular doses of vaccine, with the second and third doses given 1 and 6 months, respectively, after the first. Adults and older children should be given a full 1.0 ml/dose, while children <11 years of age should usually receive half (0.5 ml) this dose. See Table 3 for complete information on age-specific dosages of currently available vaccines. An alternative schedule of four doses of vaccine given at 0, 1, 2, and 12 months has been approved for one vaccine for postexposure prophylaxis or for more rapid induction of immunity. However, there is no clear evidence that this regimen provides greater protection than the standard three-dose series. Hepatitis B vaccine should be given only in the deltoid muscle for adults and children or in the anterolateral thigh muscle for infants and neonates.

For patients undergoing hemodialysis and for other immunosuppressed patients, higher vaccine doses or increased numbers of doses are required. A special formulation of one vaccine is now available for such persons (Table 3). Persons with HIV infection have an impaired response to hepatitis B vaccine. The immunogenicity of higher doses of vaccine is unknown for this group, and firm recommendations on dosage cannot be made at this time (*34*).

Vaccine doses administered at longer intervals provide equally satisfactory protection, but optimal protection is not conferred until after the third dose. If the vaccine series is interrupted after the first dose, the second and third doses should be given separated by an interval of 3-5 months. Persons who are late for the third dose should be given this dose when convenient. Postvaccination testing is not considered necessary in either situation.

In one study, the response to vaccination by the standard schedule using one or two doses of one vaccine, followed by the remaining doses of a different vaccine, was comparable to the response to vaccination with a single vaccine. Moreover, because the immunogenicities of the available vaccines are similar, it is likely that responses in such situations will be comparable to those induced by any of the vaccines alone.

The immunogenicity of a series of three low doses (0.1 standard dose) of plasma-derived hepatitis B vaccine administered by the intradermal route has been assessed in several studies. The largest studies of adults show lower rates of developing adequate antibody (80%-90%) and twofold to fourfold lower antibody titers than with intramuscular vaccination with recommended doses (*39* and CDC unpublished data). Data on immunogenicity of low doses of recombinant vaccines given intradermally are limited. At this time, intradermal vaccination of adults using low doses of vaccine should be done only under research protocol, with appropriate informed consent and with postvaccination testing to

TABLE 3. Recommended doses and schedules of currently licensed HB vaccines

Group	Vaccine					
	Heptavax-B*,†		Recombivax HB*		Engerix-B*§	
	Dose (µg)	(ml)	Dose (µg)	(ml)	Dose (µg)	(ml)
Infants of HBV-carrier mothers	10	(0.5)	5	(0.5)	10	(0.5)
Other infants and children <11 years	10	(0.5)	2.5	(0.25)	10	(0.5)
Children and adolescents 11-19 years	20	(1.0)	5	(0.5)	20	(1.0)
Adults >19 years	20	(1.0)	10	(1.0)	20	(1.0)
Dialysis patients and other immunocompromised persons	40	(2.0)¶	40	(1.0)**	40	(2.0)¶,††

*Usual schedule: three doses at 0, 1, 6 months.
†Available only for hemodialysis and other immunocompromised patients and for persons with known allergy to yeast.
§Alternative schedule: four doses at 0, 1, 2, 12 months.
¶Two 1.0-ml doses given at different sites.
**Special formulation for dialysis patients.
††Four-dose schedule recommended at 0, 1, 2, 6 months.

identify persons with inadequate response who would be eligible for revaccination. Intradermal vaccination is not recommended for infants or children.

All hepatitis B vaccines are inactivated (noninfective) products, and there is no evidence of interference with other simultaneously administered vaccines.

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

Vaccine storage and shipment

Vaccine should be shipped and stored at 2 C-8 C but not frozen. *Freezing destroys the potency of the vaccine.*

Side effects and adverse reactions

The most common side effect observed following vaccination with each of the available vaccines has been soreness at the injection site. Postvaccination surveillance for 3 years after licensure of the plasma-derived vaccine showed an association of borderline significance between Guillain-Barré syndrome and receipt of the first vaccine dose (*40*). The rate of this occurrence was very low (0.5/100,000 vaccinees) and was more than compensated by disease prevented by the vaccine even if Guillain-Barré syndrome is a true side effect. Such postvaccination surveillance information is not available for the recombinant hepatitis B vaccines. Early concerns about safety of plasma-derived vaccine have proven to be unfounded, particularly the concern that infectious agents such as HIV present in the donor plasma pools might contaminate the final product.

Effect of vaccination on carriers and immune persons

Hepatitis B vaccine produces neither therapeutic nor adverse effects for HBV carriers (*41*). Vaccination of individuals who possess antibodies against HBV from a previous infection is not necessary but will not cause adverse effects. Such individuals will have a postvaccination increase in their anti-HBs levels. Passively acquired antibody, whether acquired from HBIG or IG administration or from the transplacental route, will not interfere with active immunization (*42*).

Prevaccination serologic testing for susceptibility

The decision to test potential vaccine recipients for prior infection is primarily a cost-effectiveness issue and should be based on whether the costs of testing balance the costs of vaccine saved by not vaccinating individuals who have already been infected. Estimation of cost-effectiveness of testing depends on three variables: the cost of vaccination, the cost of testing for susceptibility, and the expected prevalence of immune individuals in the group.

Testing in groups with the highest risk of HBV infection (HBV marker prevalence >20%, Table 2) is usually cost-effective unless testing costs are extremely high. Cost-effectiveness of screening may be marginal for groups at intermediate risk. For groups with a low expected prevalence of HBV serologic markers, such as health professionals in their training years, prevaccination testing is not cost-effective.

For routine testing, only one antibody test is necessary (either anti-HBc or anti-HBs). Anti-HBc identifies all previously infected persons, both carriers and those who are not carriers, but does not differentiate members of the two groups. Anti-HBs identifies persons previously infected, except for carriers. Neither test has a particular advantage for groups expected to have carrier rates of <2%, such as health-care workers. Anti-HBc may be preferred to avoid unnecessary vaccination of carriers for groups with higher carrier rates. If RIA is used to test for anti-HBs, a minimum of 10 sample ratio units should be used to designate immunity (2.1 is the usual designation of a positive test). If EIA is used, the positive level recommended by manufacturers is appropriate.

Postvaccination testing for serologic response and revaccination of nonresponders

Hepatitis B vaccine, when given in the deltoid, produces protective antibody (anti-HBs) in >90% of healthy persons. Testing for immunity after vaccination is not recommended routinely but is advised for persons whose subsequent management depends on knowing their immune status (such as dialysis patients and staff). Testing for immunity is also advised for persons for whom a suboptimal response may be anticipated, such as those who have received vaccine in the buttock, persons ≥50 years of age, and persons known to have HIV infection. Postvaccination testing should also be

considered for persons at occupational risk who may have needle-stick exposures necessitating postexposure prophylaxis. When necessary, postvaccination testing should be done between 1 and 6 months after completion of the vaccine series to provide definitive information on response to the vaccine.

Revaccination of persons who do not respond to the primary series (nonresponders) produces adequate antibody in 15%-25% after one additional dose and in 30%-50% after three additional doses when the primary vaccination has been given in the deltoid (*36*). For persons who did not respond to a primary vaccine series given in the buttock, data suggest that revaccination in the arm induces adequate antibody in >75%. Revaccination with one or more additional doses should be considered for persons who fail to respond to vaccination in the deltoid and is recommended for those who have failed to respond to vaccination in the buttock.

Need for vacoine booster doses

Available data show that vaccine-induced antibody levels decline steadily with time and that up to 50% of adult vaccinees who respond adequately to vaccine may have low or undetectable antibody levels by 7 years after vaccination. Nevertheless, both adults and children with declining antibody levels are still protected against hepatitis B disease. Current data also suggest excellent protection against disease for 5 years after vaccination among infants born to hepatitis B-carrier mothers. For adults and children with normal immune status, booster doses are not routinely recommended within 7 years after vaccination, nor is routine serologic testing to assess antibody levels necessary for vaccine recipients during this period. For infants born to hepatitis B-carrier mothers, booster doses are not necessary within 5 years after vaccination. The possible need for booster doses after longer intervals will be assessed as additional information becomes available.

For hemodialysis patients, for whom vaccine-induced protection is less complete and may persist only as long as antibody levels remain above 10 m /ml, the need for booster doses should be assessed by annual antibody testing, and booster doses should be given when antibody levels decline to <10 mIU/ml.

Groups recommended for preexposure vaccination

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

1. Persons with occupational risk. HBV infection is a major infectious occupational hazard for health-care and public-safety workers. The risk of acquiring HBV infection from occupational exposures is dependent on the frequency of percutaneous and permucosal exposures to blood or blood products. Any health-care or public-safety worker may be at risk for HBV exposure depending on the tasks that he or she performs. If those tasks involve contact with blood or blood-contaminated body fluids, such workers should be vaccinated. Vaccination should be considered for other workers depending on the nature of the task (*43*).

   Risks among health-care professionals vary during the training and working career of each individual but are often highest during the professional training period. For this reason, when possible, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions before workers have their first contact with blood.
2. Clients and staff of institutions for the developmentally disabled. Susceptible clients in institutions for the developmentally disabled should be vaccinated. Staff who work closely with clients should also be vaccinated. The risk in institutional environments is associated not only with blood exposure but may also be consequent to bites and contact with skin lesions and other infective secretions. Susceptible clients and staff who live or work in smaller (group) residential settings with known HBV carriers should also receive hepatitis B vaccine. Clients discharged from residential institutions into community settings should be screened for HBsAg so that the community programs may take appropriate measures to prevent HBV transmission. These measures should include both environmental controls and appropriate use of vaccine.

   Staff of nonresidential day-care programs (e.g., schools, sheltered workshops for the developmentally disabled) attended by known HBV carriers have a risk of HBV infection comparable to that among health-care workers and therefore should be vaccinated (*44*). The risk of HBV infection for clients appears to be lower than the risk for staff. Vaccination of clients in day-care programs may be considered. Vaccination of classroom contacts is strongly encouraged if a classmate who is an HBV carrier behaves aggressively or has special medical problems that increase the risk of exposure to his/her blood or serous secretions.

3. Hemodialysis patients. Hepatitis B vaccination is recommended for susceptible hemodialysis patients. Although seroconversion rates and anti-HBs titers are lower than those for healthy persons, for those patients who do respond, hepatitis B vaccine will protect them from HBV infection and reduce the necessity for frequent serologic screening (*45*). Some studies have shown higher seroconversion rates and antibody titers for patients with uremia who were vaccinated before they required dialysis (*46*). Identification of patients for vaccination early in the course of their renal disease is encouraged.
4. Sexually active homosexual men. Susceptible sexually active homosexual men should be vaccinated regardless of their age or the duration of their homosexual practices. Persons should be vaccinated as soon as possible after their homosexual activity begins. Homosexual and bisexual men known to have HIV infection should be tested for anti-HBs response after completion of the vaccine series and should be counseled accordingly.
5. Users of illicit injectable drugs. All users of illicit injectable drugs who are susceptible to HBV should be vaccinated as early as possible after their drug abuse begins.
6. Recipients of certain blood products. Patients with clotting disorders who receive clotting-factor concentrates have an increased risk of HBV infection. Vaccination is recommended for these persons, and it should be initiated at the time their specific clotting disorder is identified. Prevaccination testing is recommended for patients who have already received multiple infusions of these products.
7. Household and sexual contacts of HBV carriers. Household contacts of HBV carriers are at high risk of HBV infection. Sexual contacts appear to be at greatest risk. When HBV carriers are identified through routine screening of donated blood, diagnostic testing in hospitals, prenatal screening, screening of refugees from certain areas, or other screening programs, they should be notified of their status. All household and sexual contacts should be tested and susceptible contacts vaccinated.
8. Adoptees from countries of high HBV endemicity. Families accepting orphans or unaccompanied minors from countries of high or intermediate HBV endemicity should have the children screened for HBsAg. If the children are HBsAg-positive, family members should be vaccinated (*47*).
9. Other contacts of HBV carriers. Persons in casual contact with carriers in settings such as schools and offices are at minimal risk of HBV infection, and vaccine is not routinely recommended for them. At child-care centers, HBV transmission between children or between children and staff has rarely been documented. Unless special circumstances exist, such as behavior problems (biting or scratching) or medical conditions (severe skin disease) that might facilitate transmission, vaccination of contacts of carriers in child care is not indicated.
10. Populations with high endemicity of HBV infection. In certain U.S. populations, including Alaskan Natives, Pacific Islanders, and refugees from HBV-endemic areas, HBV infection is highly endemic, and transmission occurs primarily during childhood. In such groups, universal hepatitis B vaccination of infants is recommended to prevent disease transmission during childhood. In addition, more extensive programs of "catch-up" childhood vaccination should be considered if resources are available.

    Immigrants and refugees from areas with highly endemic HBV disease (particularly Africa and eastern Asia) should be screened for HBV markers upon resettlement in the United States. If an HBV carrier is identified, all susceptible household contacts should be vaccinated. Even if no HBV carriers are found within a family, vaccination should be considered for susceptible children <7 years of age because of the high rate of interfamilial HBV infection that occurs among these children (*48*). Vaccination is recommended for all infants of women who were born in areas in which infection is highly endemic.
11. Inmates of long-term correctional facilities. The prison environment may provide a favorable setting for the transmission of HBV because of the use of illicit injectable drugs and because of male homosexual practices. Moreover, it provides an access point for vaccination of percutaneous drug abusers. Prison officials should consider undertaking screening and vaccination programs directed at inmates with histories of high-risk behaviors.
12. Sexually active heterosexual persons. Sexually active heterosexual persons with multiple sexual partners are at increased risk of HBV infection. Risk increases with increasing numbers of sexual partners. Vaccination is recommended for persons who are diagnosed as having recently acquired other sexually transmitted diseases, for prostitutes, and for persons who have a history of sexual activity with multiple partners in the previous 6 months.

13. International travelers. Vaccination should be considered for persons who plan to reside for more than 6 months in areas with high levels of endemic HBV and who will have close contact with the local population. Vaccination should also be considered for short-term travelers who are likely to have contact with blood from or sexual contact with residents of areas with high levels of endemic disease. Ideally, hepatitis B vaccination of travelers should begin at least 6 months before travel to allow for completion of the full vaccine series. Nevertheless, a partial series will offer some protection from HBV infection. The alternative four-dose schedule may provide better protection during travel if the first three doses can be delivered before travel (second and third doses given 1 and 2 months respectively, after first).

Postexposure Prophylaxis for Hepatitis B

Prophylactic treatment to prevent hepatitis B infection after exposure to HBV should be considered in the following situations: perinatal exposure of an infant born to an HBsAg-positive mother, accidental percutaneous or permucosal exposure to HBsAg-positive blood, sexual exposure to an HBsAg-positive person, and household exposure of an infant <12 months of age to a primary care giver who has acute hepatitis B.

Various studies have established the relative efficacies of HBIG and/or hepatitis B vaccine in different exposure situations. For an infant with perinatal exposure to an HBsAg-positive and HBeAg-positive mother, a regimen combining one dose of HBIG at birth with the hepatitis B vaccine series started soon after birth is 85%-95% effective in preventing development of the HBV carrier state (*35,49-51*). Regimens involving either multiple doses of HBIG alone, or the vaccine series alone, have 70%-85% efficacy (*52,53*).

For accidental percutaneous exposure, only regimens including HBIG and/or IG have been studied. A regimen of two doses of HBIG, one given after exposure and one a month later, is about 75% effective in preventing hepatitis B in this setting (*54,55*). For sexual exposure, a single dose of HBIG is 75% effective if given within 2 weeks of last sexual exposure (*56*). The efficacy of IG for postexposure prophylaxis is uncertain. IG no longer has a role in postexposure prophylaxis of hepatitis B because of the availability of HBIG and the wider use of hepatitis B vaccine.

Recommendations on postexposure prophylaxis are based on available efficacy data and on the likelihood of future HBV exposure of the person requiring treatment. In all exposures, a regimen combining HBIG with hepatitis B vaccine will provide both short- and long-term protection, will be less costly than the two-dose HBIG treatment alone, and is the treatment of choice.

Perinatal Exposure and Recommendations

Transmission of HBV from mother to infant during the perinatal period represents one of the most efficient modes of HBV infection and often leads to severe long-term sequelae. Infants born to HBsAg-positive and HBeAg-positive mothers have a 70%-90% chance of acquiring perinatal HBV infection, and 85%-90% of infected infants will become chronic HBV carriers. Estimates are that >25% of these carriers will die from primary hepatocellular carcinoma (PHC) or cirrhosis of the liver (*57*). Infants born to HBsAg-positive and HBeAg-negative mothers have a lower risk of acquiring perinatal infection; however, such infants have had acute disease, and fatal fulminant hepatitis has been reported (*58,59*). Based on 1987 data in the United States, an estimated 18,000 births occur to HBsAg-positive women each year, resulting in approximately 4,000 infants who become chronic HBV carriers. Prenatal screening of all pregnant women identifies those who are HBsAg-positive and allows treatment of their newborns with HBIG and hepatitis B vaccine, a regimen that is 85%-95% effective in preventing the development of the HBV chronic carrier state.

The following are perinatal recommendations:

1. All pregnant women should be routinely tested for HBsAg during an early prenatal visit in each pregnancy. This testing should be done at the same time that other routine prenatal screening tests are ordered. In special situations (e.g., when acute hepatitis is suspected, when a history of exposure to hepatitis has been reported, or when the mother has a particularly high-risk behavior, such as intravenous drug abuse), an additional HBsAg test can be ordered later in the pregnancy. No other HBV marker tests are necessary for the purpose of maternal screening, although HBsAg-positive mothers identified during screening may have HBV-related acute or chronic liver disease and should be evaluated by their physicians.
2. If a woman has not been screened prenatally or if test results are not available at the time of admission for delivery, HBsAg testing should be done at the time of admission, or as soon as

possible thereafter. If the mother is identified as HBsAg-positive >1 month after giving birth, the infant should be tested for HBsAg. If the results are negative, the infant should be given HBIG and hepatitis B vaccine.

3. Following all initial positive tests for HBsAg, a repeat test for HBsAg should be performed on the same specimen, followed by a confirmatory test using a neutralization assay. For women in labor who did not have HBsAg testing during pregnancy and who are found to be HBsAg-positive on first testing, initiation of treatment of their infants should not be delayed by more than 24 hours for repeat or confirmatory testing.
4. Infants born to HBsAg-positive mothers should receive HBIG (0.5 ml) intramuscularly once they are physiologically stable, preferably within 12 hours of birth (Table 4). Hepatitis B vaccine should be administered intramuscularly at the appropriate infant dose. The first dose should be given concurrently with HBIG but at a different site. If vaccine is not immediately available, the first dose should be given as soon as possible. Subsequent doses should be given as recommended for the specific vaccine. Testing infants for HBsAg and anti-HBs is recommended when they are 12-15 months of age to monitor the success or failure of therapy. If HBsAg is not detectable and anti-HBs is present, children can be considered protected. Testing for anti-HBc is not useful, since maternal anti-HBc can persist for >1 year. HBIG and hepatitis B vaccination do not interfere with routine childhood vaccinations. Breast-feeding poses no risk of HBV infection for infants who have begun prophylaxis.
5. Household members and sexual partners of HBV carriers identified through prenatal screening should be tested to determine susceptibility to HBV infection, and, if susceptible, should receive hepatitis B vaccine.
6. Obstetric and pediatric staff should be notified directly about HBsAg-positive mothers so that neonates can receive therapy without delay after birth and follow-up doses of vaccine can be given. Programs to coordinate the activities of persons providing prenatal care, hospital-based obstetrical services, and pediatric well-baby care must be established to assure proper follow-up and treatment both of infants born to HBsAg-positive mothers and of other susceptible household and sexual contacts.
7. In those populations under U.S. jurisdiction in which hepatitis B infection is highly endemic (including certain Alaskan Natives, Pacific Island groups, and refugees from highly endemic areas accepted for resettlement in the United States), universal vaccination of newborns with hepatitis B vaccine is the recommended strategy for hepatitis B control. HBsAg screening of mothers and use of HBIG for infants born to HBV-carrier mothers may be added to routine hepatitis B vaccination when practical, but screening and HBIG alone will not adequately protect children from HBV infection in endemic areas. In such areas, hepatitis B vaccine doses should be integrated into the childhood vaccination schedule. More extensive programs of childhood hepatitis B vaccination should be considered if resources are available.

Acute Exposure to Blood That Contains (or Might Contain) HBsAg

For accidental percutaneous (needle stick, laceration, or bite) or permucosal (ocular or mucous-membrane) exposure to blood, the decision to provide prophylaxis must include consideration of several factors: a) whether the source of the blood is available, b) the HBsAg status of the source, and c) the hepatitis B vaccination and vaccine-response status of the exposed person. Such exposures usually affect persons for whom hepatitis B vaccine is recommended. For any exposure of a person not previously vaccinated, hepatitis B vaccination is recommended.

TABLE 4. Hepatitis B virus postexposure recommendations

	HBIG		Vaccine	
Exposure	Dose	Recommended timing	Dose	Recommended timing
Perinatal	0.5 ml IM	Within 12 hours of birth	0.5 ml IM*	Within 12 hours of birth†
Sexual	0.06 ml/kg IM	Single dose within 14 days of last sexual contact	1.0 ml IM*	First dose at time of HBIG treatment†

*For appropriate age-specific doses of each vaccine, see Table 3.
†The first dose can be given the same time as the HBIG dose but in a different site; subsequent doses should be given as recommended for specific vaccine.

Following any such exposure, a blood sample should be obtained from the person who was the source of the exposure and should be tested for HBsAg. The hepatitis B vaccination status and anti-HBs response status (if known) of the exposed person should be reviewed. The outline below and Table 5 summarize prophylaxis for percutaneous or permucosal exposure to blood according to the HBsAg status of the source of exposure and the vaccination status and vaccine response of the exposed person.

For greatest effectiveness, passive prophylaxis with HBIG, when indicated, should be given as soon as possible after exposure (its value beyond 7 days after exposure is unclear).

1. Source of exposure HBsAg-positive
   a. Exposed person has not been vaccinated or has not completed vaccination. Hepatitis B vaccination should be initiated. A single dose of HBIG (0.06 ml/kg) should be given as soon as possible after exposure and within 24 hours, if possible. The first dose of hepatitis B vaccine (Table 3) should be given intramuscularly at a separate site (deltoid for adults) and can be given simultaneously with HBIG or within 7 days of exposure. Subsequent doses should be given as recommended for the specific vaccine. If the exposed person has begun but not completed vaccination, one dose of HBIG should be given immediately, and vaccination should be completed as scheduled.
   b. Exposed person has already been vaccinated against hepatitis B, and anti-HBs response status is known.
      (1) If the exposed person is known to have had adequate response in the past, the anti-HBs level should be tested unless an adequate level has been demonstrated within the last 24 months. Although current data show that vaccine-induced protection does not decrease as antibody level wanes, most experts consider the following approach to be prudent.
         a) If anti-HBs level is adequate, no treatment is necessary.
         b) If anti-HBs level is inadequate,* a booster dose of hepatitis B vaccine should be given.
      (2) If the exposed person is known not to have responded to the primary vaccine series, the exposed person should be given either a single dose of HBIG and a dose of hepatitis B vaccine as soon as possible after exposure, or two doses of HBIG (0.06 ml/kg), one given as soon as possible after exposure and the second 1 month later. The latter treatment is preferred for those who have failed to respond to at least four doses of vaccine.
   c. Exposed person has already been vaccinated against hepatitis B, and the anti-HBs response is unknown. The exposed person should be tested for anti-HBs.

*An adequate antibody level is ≥10 milliInternational Units (mIU)/ml, approximately equivalent to 10 sample ratio units (SRU) by RIA or positive by EIA.

TABLE 5. Recommendations for hepatitis B prophylaxis following percutaneous or permucosal exposure

	Treatment when source is found to be:		
Exposed person	**HBsAg-positive**	**HBsAg-negative**	**Source not tested or unknown**
Unvaccinated	HBIG x 1* and initiate HB vaccine†	Initiate HB vaccine†	Initiate HB vaccine†
Previously vaccinated	Test exposed for anti-HBs	No treatment	No treatment
Known responder	1. If adequate,§ no treatment 2. If inadequate, HB vaccine booster dose		
Known nonresponder	HBIG x 2 or HBIG x 1 plus 1 dose HB vaccine	No treatment	If known high-risk source, *may treat as if source were HBsAg-positive*
Response unknown	Test exposed for anti-HBs 1. If inadequate,§ HBIG x 1 plus HB vaccine booster dose 2. If adequate, no treatment	No treatment	Test exposed for anti-HBs 1. If inadequate§, HB vaccine booster dose 2. If adequate, no treatment

*HBIG dose 0.06 ml/kg IM.
†HB vaccine dose - see Table 3.
§Adequate anti-HBs is ≥10 SRU by RIA or positive by EIA.

(1) If the exposed person has adequate antibody, no additional treatment is necessary.
(2) If the exposed person has inadequate antibody on testing, one dose of HBIG (0.06 ml/kg) should be given immediately and a standard booster dose of vaccine (Table 3) given at a different site.

2. Source of exposure known and HBsAg-negative
   a. Exposed person has not been vaccinated or has not completed vaccination. If unvaccinated, the exposed person should be given the first dose of hepatitis B vaccine within 7 days of exposure, and vaccination should be completed as recommended. If the exposed person has not completed vaccination, vaccination should be completed as scheduled.
   b. Exposed person has already been vaccinated against hepatitis B. No treatment is necessary.
3. Source of exposure unknown or not available for testing
   a. Exposed person has not been vaccinated or has not completed vaccination. If unvaccinated, the exposed person should be given the first dose of hepatitis B vaccine within 7 days of exposure and vaccination completed as recommended. If the exposed person has not completed vaccination, vaccination should be completed as scheduled.
   b. Exposed person has already been vaccinated against hepatitis B, and anti-HBs response status is known.
      (1) If the exposed person is known to have had adequate response in the past, no treatment is necessary.
      (2) If the exposed person is known not to have responded to the vaccine, prophylaxis as described earlier in section I.b.(2) under "Source of exposure HBsAg-positive" may be considered if the source of the exposure is known to be at high risk of HBV infection.
   c. Exposed person has already been vaccinated against hepatitis B, and the anti-HBs response is unknown. The exposed person should be tested for anti-HBs.
      (1) If the exposed person has adequate anti-HBs, no treatment is necessary.
      (2) If the exposed person has inadequate anti-HBs, a standard booster dose of vaccine should be given.

Sexual Partners of Persons with Acute HBV Infection

Sexual partners of HBsAg-positive persons are at increased risk of acquiring HBV infection, and HBIG has been shown to be 75% effective in preventing such infections (*56*). Because data are limited, the period after sexual exposure during which HBIG is effective is unknown, but extrapolation from other settings makes it unlikely that this period would exceed 14 days. Before treatment; testing of sexual partners for susceptibility is recommended if it does not delay treatment beyond 14 days after last exposure. Testing for anti-HBc is the most efficient prescreening test to use in this population.

All susceptible persons whose sexual partners have acute hepatitis B infection or whose sexual partners are discovered to be hepatitis B carriers should receive a single dose of HBIG (0.06 ml/kg) and should begin the hepatitis B vaccine series if prophylaxis can be started within 14 days of the last sexual contact, or if ongoing sexual contact with the infected person will occur. Giving the vaccine with HBIG may improve the efficacy of postexposure treatment. The vaccine has the added advantage of conferring long-lasting protection.

An alternative treatment for persons who are not from a high-risk group for whom vaccine is routinely recommended and whose regular sexual partners have acute HBV infection is to give one dose of HBIG (without vaccine) and retest the sexual partner for HBsAg 3 months later. No further treatment is necessary if the sexual partner becomes HBsAg-negative. If the sexual partner remains HBsAg-positive, a second dose of HBIG should be given and the hepatitis B vaccine series started.

Household Contacts of Persons with Acute HBV Infection

Since infants have close contact with primary care givers and they have a higher risk of becoming HBV carriers after acute HBV infection, prophylaxis of an infant <12 months of age with HBIG (0.5 ml) and hepatitis B vaccine is indicated if the mother or primary care giver has acute HBV infection. Prophylaxis for other household contacts of persons with acute HBV infection is not indicated unless they have had identifiable blood exposure to the index patient, such as by sharing toothbrushes or razors. Such exposures should be treated similarly to sexual exposures. If the index patient becomes an HBV carrier, all household contacts should be given hepatitis B vaccine.

DELTA HEPATITIS

The delta virus (also known as hepatitis D virus [HDV]) is a defective virus that may cause infection only in the presence of active HBV infection. The HDV is a 35- to 37-nm viral particle, consisting of single-stranded RNA (mw 500,000) and an internal protein antigen (delta antigen [HDAg]), coated with HBsAg as the surface protein (*5*). Infection may occur as either coinfection with HBV or superinfection of an HBV carrier, each of which usually causes an episode of clinical acute hepatitis. Coinfection usually resolves, whereas superinfection frequently causes chronic HDV infection and chronic active hepatitis. Both types of infection may cause fulminant hepatitis.

HDV infection may be diagnosed by detecting HDAg in serum during early infection and by the appearance of total or IgM-specific delta antibody (anti-HDV) during or after infection. A test for detection of total anti-HDV is commercially available. Other tests (HDAg, IgM anti-HDV) are available only in research laboratories.

Routes of transmission of HDV are similar to those of HBV. In the United States, HDV infection most commonly affects persons at high risk of HBV infection, particularly parenteral drug abusers and persons with hemophilia.

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

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

NON-A, NON-B HEPATITIS

Parenterally Transmitted (PT) Non-A, Non-B Hepatitis

Parenterally transmitted non-A, non-B hepatitis accounts for 20%-40% of acute viral hepatitis in the United States and has epidemiologic characteristics similar to those of hepatitis B (*60*). Recently, a portion of the genome of a virus thought to be responsible for PT non-A, non-B hepatitis was cloned (*2*). A candidate serologic assay for antibody to this virus (proposed as hepatitis C virus) has been developed. This assay appears to detect a substantial number of persons with chronic infection and is being evaluated for screening potential blood donors (*3*). Although PT non-A, non-B hepatitis has traditionally been considered a transfusion-associated disease, most reported cases have not been associated with blood transfusion (*61-64*). Groups at high risk of acquiring this disease include transfusion recipients, parenteral drug users, and dialysis patients (*62,63*). Health-care work that entails frequent contact with blood, personal contact with others who have had hepatitis in the past, and contact with infected persons within households have also been documented in some studies as risk factors for acquiring PT non-A, non-B hepatitis (*63-65*). However, the role of person-to-person contact in disease transmission has not been well defined, and the importance of sexual activity in the transmission of this type of hepatitis is unclear.

Multiple episodes of non-A, non-B hepatitis have been observed among the same individuals and may be due to different bloodborne agents. An average of 50% of patients who have acute PT non-A, non-B hepatitis infection later develop chronic hepatitis (*66*). Experimental studies of chimpanzees have confirmed the existence of a carrier state, which may be present in 1%-3% of the population (*67,68*).

The risk and consequences of perinatal transmission of PT non-A, non-B hepatitis are not well defined. Only one small study has been published in which infants born of 12 women who had acute PT non-A, non-B hepatitis during pregnancy were followed. Six infants developed transient alanine aminotransferase (ALT) elevations at 4-8 weeks of age (*69*).

The results have been equivocal in several studies attempting to assess the value of prophylaxis with IGs against PT non-A, non-B hepatitis (*70-72*). For persons with percutaneous exposure to blood from a patient with PT non-A, non-B hepatitis, it may be reasonable to administer IG (0.06 ml/kg) as soon as possible after exposure. In other circumstances, no specific recommendations can be made.

Enterically Transmitted (ET) Non-A, Non-B Hepatitis

A distinct type of non-A, non-B hepatitis acquired by the fecal-oral route was first identified through investigations of large waterborne epidemics in developing countries. This ET non-A, non-B hepatitis, which has occurred in epidemics or sporadically in parts of Asia, North and West Africa, and Mexico, is serologically distinct from other known hepatitis viruses (*4,73*). Young to middle-aged adults are most often affected, with an unusually high mortality among pregnant women. The disease has been transmitted to experimental animals, and candidate viruses have been identified; however, no serologic tests have yet been developed (*74*).

ET non-A, non-B hepatitis has not been recognized as an endemic disease in the United States or Western Europe, and it is unknown whether the causative agent is present in these areas. Cases have been documented, however, among persons returning from travel to countries in which this disease occurs (*75*).

Travelers to areas having ET non-A, non-B hepatitis may be at some risk of acquiring this disease by close contact with infected persons or by consuming contaminated food or water. There is no evidence that U.S.-manufactured IG will prevent this infection. As with hepatitis A and other enteric infections, the best means of preventing ET non-A, non-B hepatitis is avoiding potentially contaminated food or water.

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References 70 through 75 may be obtained by writing to the Hepatitis Branch, Division of Viral and Rickettsial Diseases, Center for Infectious Diseases, Mailstop A33, Centers for Disease Control, Atlanta, Ga. 30333.

IMPORTANT INFORMATION ABOUT HEPATITIS B AND HEPATITIS B VACCINE

Please Read This Carefully

HEPATITIS B
2/1/90

WHAT IS HEPATITIS B?

Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). The term "viral hepatitis" is often used for and may include hepatitis B and other similar diseases which affect the liver but are caused by different viruses.

Acute hepatitis generally begins with mild symptoms that may or may not become severe. These symptoms may include loss of appetite, a vague feeling of oncoming illness, extreme tiredness, nausea, vomiting, stomach pain, dark urine, and jaundice (yellow eyes and skin). Skin rashes and joint pain can also occur.

In the United States about 300,000 persons, mostly young adults, catch hepatitis B each year. About one-fourth will develop jaundice, and more than 10,000 will need to be hospitalized. About 250 people die each year from severe acute hepatitis B. Between 6 and 10 of every 100 young adults who catch hepatitis B become chronic carriers (have HBV in their blood for 6 or more months) and may be able to spread the infection to others for a long period of time. Infants who catch hepatitis B are more likely to become carriers than adults. About one-fourth of these carriers go on to develop a disease called "chronic active hepatitis." Chronic active hepatitis often causes cirrhosis of the liver (liver destruction) and death due to liver failure. In addition, HBV carriers are much more likely than others to get cancer of the liver. An estimated 4,000 persons die from hepatitis B-related cirrhosis each year in the United States and more than 800 die from hepatitis B-related liver cancer.

The risk of catching hepatitis is higher in certain groups of people because of their occupation, lifestyle, or environment. Because of the risks of serious problems associated with hepatitis B infection, vaccination to help prevent infections is recommended for these groups.

HEPATITIS B VACCINE:

Hepatitis B vaccine is made two ways. Plasma-derived vaccine is made from HBV particles that have been purified from the blood of carriers. The method used to prepare the plasma-derived hepatitis vaccine kills all types of viruses found in human blood, including the virus that causes Acquired Immunodeficiency Syndrome (AIDS). Recombinant vaccines are made from common baker's yeast cells through genetic engineering. The yeast-derived vaccines do not contain human blood products. The vaccine is given by injection on three separate dates. Usually, the first two doses are given 1 month apart, and the third dose, 5 months after the second. After three doses, the hepatitis B vaccine is 85%-95% effective in preventing hepatitis B infection in those who received vaccine. An alternative schedule of 4 doses of vaccine given at 0, 1, 2, and 12 months is approved for one vaccine. Protection for normal, healthy adults and children given vaccine lasts at least 7 years. Booster doses of vaccine are not routinely recommended at the present time.

WHO SHOULD GET HEPATITIS B VACCINE?

The vaccine is recommended for persons at high risk of catching HBV infection who are or may be unprotected. These groups include:

1. **Persons with occupational risk.** Health care and public safety workers who are exposed to blood or blood products or who may get accidental needlesticks should be vaccinated.
2. **Clients and staff of institutions for the developmentally disabled.** The special behavorial and medical problems of these persons make this a high-risk setting. Risk in institutions is related to contact with blood and also with bites and contact with skin lesions and other body fluids that contain HBV. Clients and staff of group and foster homes where a carrier is known to be present should also be vaccinated.
3. **Hemodialysis patients.** Although the hepatitis B vaccine is less effective in these patients, it should still be offered to all hemodialysis patients. Higher doses and/or special preparations are required for these persons.
4. **Homosexually active men.**

(PLEASE READ OTHER SIDE)

5. **Users of unlawful injectable drugs.** Sharing needles is an extremely high-risk activity for transmitting hepatitis B.
6. **Recipients of certain blood products.** Persons such as hemophiliacs who receive special products to help their blood clot are at high risk of infection.
7. **Household and sexual contacts of HBV carriers.** When HBV carriers are identified, household and sexual contacts should be offered vaccine.
8. **Adoptees from countries with high rates of HBV infection.** Families with orphans or unaccompanied minors from such countries should have the child checked for HBV carriage, and, if positive, family members should be vaccinated.
9. **Other contacts of HBV carriers.** Vaccine use should be considered in classroom and other day settings where deinstitutionalized developmentally disabled HBV carriers behave aggressively or have special medical problems that may expose contacts to their blood or body secretions. Teachers and aides have been shown to be at significant risk in these settings. Other persons who have casual contact with carriers at schools and offices are at little risk of catching HBV infection and vaccine is not recommended for them.
10. **Special populations from areas with high rates of hepatitis B.** These groups include Alaskan natives, native Pacific islanders, immigrants and refugees from eastern Asia and sub-Saharan Africa, and their U.S. born children.
11. **Inmates of long-term correctional facilities.** The risk of inmates catching HBV infection may be due to use of unlawful injectable drugs and male homosexual practices.
12. **Heterosexuals who come in for treatment of other newly acquired sexually transmitted diseases who have histories of sexual activity with multiple sexual partners in the past 6 months.**
13. **Persons who plan to travel to areas outside the United States that have high rates of hepatitis B infection, stay in these areas for more than 6 months, and have close contact with the local population; and, persons traveling for shorter durations who may have contact with blood from or sexual contact with local persons in areas where HBV infection is common. Persons traveling abroad who will perform medical procedures in areas where HBV infection is common are at very high risk.**

ADDITIONAL VACCINEES:

Hepatitis B vaccine is also recommended as part of the therapy used to prevent hepatitis B infection *after* exposure to HBV. Postexposure use of hepatitis B vaccine is recommended for the following persons: (1) infants born to mothers who have a positive blood test for hepatitis B surface antigen (HBsAg); (2) persons having accidents involving HBsAg-positive blood where there is entry through the skin or a mucous membrane; (3) infants less than 12 months old whose mother or primary caregiver has HBV infection; and, (4) persons having sexual contact with someone who has a positive blood test for HBsAg. The hepatitis B vaccine series should be started at the same time as other therapy, primarily, treatment with hepatitis B immune globulin (HBIG).

POSSIBLE SIDE EFFECTS FROM THE VACCINE:

The most common side effect is soreness at the site of injection. Illnesses, such as neurologic reactions, have been reported after vaccine is given, but hepatitis B vaccine is not believed to be the cause of these illnesses. As with any drug or vaccine, there is a rare possibility that allergic or more serious reactions or even death could occur. No deaths, however, have been reported in persons who have received this vaccine. Giving hepatitis B vaccine to persons who are already immune or to carriers will not increase the risk of side effects.

PREGNANCY:

No information is available about the safety of the vaccine for unborn babies; however, because the vaccine contains only particles that do not cause hepatitis B infection, there should be no risk. In contrast, if a pregnant woman gets a hepatitis B infection, this may cause severe disease in the mother and chronic infection in the newborn baby. Therefore, pregnant women who are otherwise eligible can be given hepatitis B vaccine.

QUESTIONS:

If you have any questions about hepatitis B or hepatitis B vaccine, please ask us now or call your doctor or health department before you sign this form.

REACTIONS:

If the person who received the vaccine gets sick and visits a doctor, hospital, or clinic during the 4 weeks after receiving the vaccine, please report it to: 1-800-282-0546
The Ohio Department of Health

PLEASE KEEP THIS PART OF THE INFORMATION SHEET FOR YOUR RECORDS

I have read or have had explained to me the information on this form about hepatitis B and hepatitis B vaccine. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of the hepatitis B vaccine and request that it be given to me or to the person named below for whom I am authorized to make this request.

ODH 3875.11 (Rev. 2-1-90) HEPATITIS B 2/1/90

INFORMATION ABOUT PERSON TO RECEIVE VACCINE (Please Print)					FOR CLINIC USE
LastName	First Name	M	Birthdate	Age	Clinic Ident.
Address					Date Vaccinated
City	County		State	Zip	Manufacturer and Lot No.
X					
Signature of Person to receive vaccine or person authorized to make the request.			Date		Site of Injection

COMPLIANCE DIRECTIVE 88-1

Change 2

SUBJECT: Enforcement Procedures for Occupational Exposure to Hepatitis B Virus (HBV), Human Immumodeficiency Virus (HIV), and Other Blood-borne Infectious Agents in Health Care Facilities

A. Purpose. This instruction provides uniform inspection procedures and guidelines to follow when conducting inspections and issuing citations under section 2 (a) of the Executive Order 83-62 and pertinent standards for health care workers potentially exposed to HBV, HIV and other blood-borne infectious agents.

B. Scope. This instruction applies to all State Executive Departments and Agencies covered under the Executive Order.

C. Definitions.

1. Health Care Worker. An employee of a health care facility including, but not limited to, nurses, physicians, dentists and other dental workers, optometrists, podiatrists, chiropractors, laboratory and blood bank technologists and technicians, research laboratory scientists, phlebotomists, dialysis personnel, paramedics, emergency medical technicians, medical examiners, morticians, housekeepers, laundry workers and others whose work may involve direct contact with body fluids, as defined below, from living individuals or corpses.

2. [redacted] The term "universal precautions" refers to a system of infectious disease control which assumes that every direct contact with body fluids is infectious and requires every employee exposed to direct contact with body fluids to be protected as though such body fluids were HBV or HIV infected. Therefore, universal precautions are intended to prevent health care workers from parenteral, mucous membrane, and nonintact skin exposures to blood-borne pathogens.

3. Body Fluids. Fluids that have been recognized by CDC as directly linked to the transmission of HIV and/or HBV and/or to which universal precautions apply: blood, semen, blood products, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, and concentrated HIV or HBV viruses.

4. Phlebotomist. A phlebotomist is any health care worker who draws blood samples.

5. [redacted]. An IC program is the establishment's oral or written policy and implementation of procedures relating to the control of infectious disease hazards where employees may be exposed to direct

contact with body fluids. An IC Program must address all of the areas outlined in this directive.

D. Background. In September 1986, OSHA was petitioned by various unions representing health care employees to develop a standard to protect workers from occupational exposure to blood-borne diseases. As a result of recent rulemaking petitions and OSHA's evaluation of those petitions, the Agency has concluded that the risk of contracting Hepatitis B, AIDS and other blood-borne infectious diseases among members of various occupations within the health care system requires an immediate response through a variety of existing mechanisms.

1. Occupational exposure may occur in many ways, including needlestick and cut injuries. Health care workers employed in certain occupations are assumed to be at high risk for blood-borne infections due to increased exposure to blood and other body fluids from infected patients. These high risk occupations include but are not limited to surgeons, pathologists, dentists and dental technicians, phlebotomists, x-ray technicians, emergency room, intensive care and operating room nurses, laboratory and blood bank technologists and technicians. Workers in these occupations are frequently exposed to blood from patients whose disease status is often unknown. Other heath care workers who may be directly exposed to such body fluids depending on their exact work assignments include such occupations as housekeeping personnel, laundry workers, orderlies, morticians, research laboratory workers, paramedics, medical examiners. Employees in any occupation where they are directly exposed to body fluids are considered to be at substantial risk of occupational exposure to HIV and/or HBV.)

2. Ward clerks and administrators have virtually no increased risk of contact with body fluids as to a result of their employment; they are thus at no greater risk of contracting blood-borne diseases than other members of the general population.

3. Neither HBV or HIV are transmitted by casual contact in the workplace.

4. The employer's obligations are those set forth in the Occupational Safety and Health Act (OSH Act) of 1970. However, the CDC has published guidelines to protect workers from HBV and HIV (See Appendices A & B). OSHA is relying on these guidelines as reflecting an appropriate and widely recognized and accepted standard of protection to be followed by health care employers in carrying out their responsibilities under the Act.

5. The same personal protective equipment and work practices used to prevent occupational transmission of HBV should be effective in preventing occupational transmission of HIV. The CDC has recently called for use of "universal precautions" when working with blood and/or body fluids from all patients.

6. One difference between the two viruses is that there is currently a vacine to prevent HBV infection, which the CDC has recommended for persons at substantial risk of occupational exposure, including health care workers, such as those listed in paragraph D.1, but there is no vaccine for HIV.

7. The employer's obligations are those set forth in the Occupational Safety and Health Act (OSH Act) of 1970. However, the CDC has published guidelines to protect workers from HBV and HIV (see Appendices A & B). OSHA is relying or these guidelines as reflecting an appropriate and widely recognized and accepted standard of protection to be followed by health care employers in carrying out their responsibilities under the OSH Act.

E. Inspection Procedures.

1. When entering a hospital or health care facility, the SHO shall attempt to locate the Hospital Administrator, the Medical Director or the person in charge and present credentials.

2. Normal opening conference procedures shall be followed. The employer will be informed of the purpose of the inspection, anticipated scope and potential duration.

3. Health Care Facilities generally administer internal infectious disease control programs. This function may be performed by a committee or an individual. Upon entry the SHO shall request the presence of the infection control nurse(s) and/or individual(s) who is responsible for providing records pertinent to the inspection.

4. Careful examination of the facility's IC program is the core element of these inspections. Occupational injury and illness records shall be carefully scrutinized, and employees selected from all appropriate areas of the facility shall be interviewed to verify both the accuracy of the OSHA-200 records and the effectiveness of the IC program.

5. Needlesticks, like any other puncture wound, are considered injuries for recordkeeping purposes due to the instantaneous nature of the event. Only those work-related injuries that involve loss of consciousness, transfer to another job, restriction of work or motion, or medical treatment are required to be put on the OSHA 200 form. Use of prescription medication (beyond a single dose for minor injury or discomfort) is considered medical treatment. Therefore, any needlestick requiring medical treatment (e.g., gamma globulin, hepatitis B immune globulin, hepatitis B vaccine, etc.) shall be recorded. In addition, since this type of treatment is considered absolutely necessary, and must be administered by a physician or licensed medical personnel, such an injury cannot be considered minor.

6. In the event the facility being inspected does not have a formal IC program, employee interviews, combined with an inspection of appropriate areas of the facility shall be used to determine the effectiveness of the establishment's efforts to protect employees from exposure to potential infectious disease sources.

7. CSHOs shall use appropriate caution when entering patient care areas of the facility. When such visits are judged necessary for determining actual conditions in the facility, the privacy of patients shall be respected. Photographs of patients will not normally be necessary and in no event shall identifiable photographs be taken without their consent.

8. The walkaround portion of the inspection shall consist of a spot-check approach. The CSHO shall identify on the basis of professional judgment what areas should be physically checked out and to what extent. It is not expected that a comprehensive walkaround inspection of the workplace will be necessary. The CSHO is to be satisfied that an IC program is in place and judged to be effective.

9. If an inspection is conducted in an establishment outside of SIC codes 80** and 7261, and a health care unit is on site, the provisions of Sections J through T apply and shall be enforced.

F. Citation Policy. The provisions of the P.E. Occupational Safety and Health Program shall be followed when issuing citations for hazards related to blood-borne infectious diseases.

1. The following standards shall apply when citing hazards found in health care facilities. It should be emphasized that employers must comply with these provisions whenever an employee may have contact with body fluids. These provisions apply to health care workers' exposure with respect to all patients regardless of whether the patient has or is known to be infected with HBV, HIV or any other blood-borne infectious agent. This policy is based on the widespread nature of these viruses and the consequent risk to the health care workers described above. It is also based on the need to maintain patient confidentiality and HBV and HIV testing limitations.

   - 29 CFR 1910.132 -- Personal protective equipment.
   - 29 CFR 1910.22 (a) (1) and (a) (2) -- General requirements, Housekeeping.
   - 29 CFR 1910.141 (a)(4)(i) and (ii) -- Sanitation, Waste disposal.
   - 29 CFR 1910.145 -- Specifications for accident prevention signs and tags.

° Section 2 (a) Executive Order 83-62.

2. Whenever a hazardous condition exists that is not covered by one of the standards listed above, and the decision is made not to cite the condition under the Executive Order, the appropriate letter shall be sent advising the employer of the hazardous conditions and suggesting corrective action.

3. Recommendations made to employers shall be noted in the case file for special attention in subsequent inspections.

4. Multi-Employer Work Site. The following citation guidelines apply in multi-employer worksites:

   (a) Health care facilities shall be cited for standards and section (2) (a) Executive Order 83-62 violations to which their own employees are exposed.

   (b) They shall also be cited for standards (but not 2 (a) Executive Order 83-62) violations to which employees of other employers on their premises are exposed to the extent that they control the hazard. For example, they shall be cited for not providing personal protective equipment to unprotected employees of other employers on their premises.

   (c) No citation shall be issued where the only persons exposed are physicians who are sole practitioners or partners, and thus not employees under the Occupational Safety and Health Act.

G. [redacted] The IC program shall be carefully evaluated to determine compliance with OSHA requirements, as clarified by those CDC guidelines relating to health care worker safety and health. The description of the OSHA requirements in this section is based upon those guidelines. Violations of OSHA requirements will normally be classified as serious.

1. 29 CFR 1910.132 (a) and (c). The standard provides in pertinent part:

   "(a) Application. Protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, shall be provided, used, and maintained in a sanitary and reliable condition whenever it is necessary by reason of hazards of processes or environment, ... encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact."

   "(c) Design. All personal protective equipment shall be of safe design and construction for work to be performed."

The following personal protective measures shall have been addressed by the IC Program and verified by interviews and walkaround:

a. Gloves. The use of gloves will vary according to the procedure involved. The use of disposable gloves is indicated for procedures where body fluids are handled.

(1) The use of gloves is particularly important in the following circumstances:

a. If the health care worker has cuts, abraded skin, chapped hands, dermatitis or the like.
b. During instrumental examination of otopharynx, gastrointestinal tract and genitourinary tract.
c. When examining abraded or non-intact skin or patients with active bleeding.
d. During invasive procedures.
e. During all cleaning of body fluids and decontaminating procedures.

(2) Gloves must be of appropriate material, usually intact latext or intact vinyl, of appropriate quality for the procedures performed, and of appropriate size for each health care worker. Where gloves do not meet these requirements 29 CFR 1910.132 (c) shall be cited.

(3) Employers shall not wash or disinfect surgical or examination gloves for reuse.

(4) General purpose utility (rubber) gloves worn by maintenance, housekeeping, laundry or other non-medical personnel may be decontaminated and reused.

(5) No gloves shall be used if they are peeling, cracked, or discolored, or if they have punctures, tears, or other evidence of deterioration. Failure to meet these requirements shall be cited under 29 CFR 1910.132 (c).

b. Gowns. The use of gowns, aprons, or lab coats is required when splashes to skin or clothing with body fluids are likely to occur. Gowns, including surgical gowns, shall be made of or lined with impervious material and shall protect all areas of exposed skin.

c. Masks and Eye Protectors. The use of masks and protective eyewear or face shields is required when contamination of mucosal membranes (eyes, mouth or nose) with body fluids such as splashes or aerosolization of such material (e.g., during surgical or dental procedures), is likely to occur. They are not required for routine care.

d. Resuscitation Equipment. Pocket masks, resuscitation bags, or other ventilation devices shall be provided in strategic locations as well as to key personnel (e.g. paramedics) where the need for resuscitation is likely. This will minimize the need for emergency mouth-to-mouth resuscitation.

e. Invasive Procedures. Personal protective equipment as described above shall be used when performing invasive procedures to avoid exposure. When a health care worker's skin or mucious membranes may come in contact with body fluids, gowns, masks, and eye protection shall be worn, as noted above.

f. Phlebotomy. Gloves shall generally be provided to and used by phlebotomists. Employers who do not make them available shall be cited for failure to provide under 29 CFR 1910.132 (a). Employers who make gloves available, but discourage or prohibit their use shall be cited for failure to use under 29 CFR 1910.132 (a), if in fact the gloves are not being used. However, no citation for failure to use shall be issued where the phlebotomist voluntarily and without the encouragement of the employer does not wear gloves, unless the following circumstances exist:

(1) For performing phlebotomy when the health care worker has cuts, scratches, or other breaks in his/her skin.

(2) In situations where the CSHO and/or health care worker judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative patient.

(3) For performing finger and/or heel sticks in infants and children.

(4) When persons are receiving training in phlebotomy.

g. Dentistry. Gloves are required for contact with oral mucous membranes. Surgical mask and protective eyewear or chin-length plastic face shields are required during dental procedures in which splashing, spattering or aerosolization of blood, saliva or gingival fluids is likely. (Saliva and gingival fluids are included because of the likelihood that they contain blood in their setting.)

h. Laboratories. The use of gloves are required for processing body fluid specimens. Masks and protective eyewear are required when the worker's mucosal membranes may come in contact with body fluids.

i. Postmortem Procedures. Persons performing or assisting in postmortem procedures are required to wear personal protective equipment as noted above to avoid exposure to body fluids.

2. 29 CFR 1910.22 (a)(1) and (a)(2). The standard provides in pertinent part:

"(a) Housekeeping. (1) All places of employment, passageways, storerooms, and service rooms shall be kept clean and orderly and in a sanitary condition.

(2) The floor of every workroom shall be maintained in a clean and, so far as possible, a dry condition..."

The IC program shall have identified housekeeping operations involving substantial risk of direct exposure to body fluids and shall have addressed the proper precautions to be taken while cleaning rooms and blood spills. The application of these procedures shall be verified by employee interviews and the walkaround.

a. Room Cleaning Where Body Fluids are Present. Schedules shall be as frequent as necessary according to the area of the institution, type of surface to be cleaned, and the amount and type of soil present.

b. Disinfectants. Following the initial cleanup, one of the following shall be used for cleaning blood and/or body fluids:

(1) Chemical germicides that are approved for use as hospital disinfectants and are tuberculocidal when used at recommended dilutions.

(2) Products registered by the Environmental Protection Agency as being effective against HIV with an accepted "HIV (AIDS Virus)" label.

(3) A solution of 5.25 percent sodium hypochlorite (household bleach) diluted between 1:10 and 1:100 with water.

3. 29 CFR 1910.141(a)(4)(i) and (ii). The standard provides in pertinent part:

"(4) Waste disposal. (i) any receptacle used for putrescible solid or liquid waste or refuse shall be so constructed that it does not leak and may be thoroughly cleaned and maintained in a sanitary condition. Such a receptable shall be equipped with a solid, tight-fitting cover, unless it can be maintained in a sanitary condition without a cover. This requirement does not prohibit the use of receptacles which are designed to permit the maintenance of a sanitary condition without regard to the aforementioned requirements.

(ii) All sweepings, solid or liquid wastes, refuse, and garbage shall be removed in such a manner as to avoid creating a menace to health and as often as necessary or appropriate to maintain the place of employment in a sanitary condition."

The IC program shall have addressed the handling and disposal of the following potentially contaminated items. The effectiveness of the program in this regard shall be verified through employee interviews and walkaround.

(a) Sharp Instruments and Disposable Items. Needles shall not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. Resheating instruments, self sheathing needles, or forceps shall be used to prevent recapping needles by hand.

(1) After they are used, disposable syringes and needles, scalpel blades, and other sharp items shall be placed in puncture-resistant containers for disposal.

(2) Such containers shall be easily accessible to personnel needing them and located in all areas where needles are commonly used, including emergency rooms, intensive care units, and surgical suites and shall be so constructed that they will not spill their contents if knocked over and will not themselves allow injuries when handled.

(3) These containers shall also be located on patient floors and any other setting where blood is drawn and needles are used.

b. Lab Specimens. All specimens of body fluids shall be put in a well constructed container with a secure lid to prevent leaking during transport and shall be disposed of in an approved manner. 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 infectious waste.

4. 29 CFR 1910.145. The standard provides in pertinent part:

"(f)(3) Use. Tags shall be used as means to prevent accidental injury or illness to employees who are exposed to hazardous or potentially hazardous conditions, equipment or operations which are out of the ordinary, unexpected or not readily apparent. Tags shall be used until such time as the identified hazard is eliminated or the hazardous operation is completed. Tags need not be used where signs, guarding or other positive means of protection are being used.

(4) General tag criteria. All required tags shall meet the following criteria:

(i) Tags shall contain a signal word and a major message.

(a) The signal work shall be ... "BIOHAZARD," or the biological hazard symbol.

(b) The major message shall indicate the specific hazardous condition or the instruction to be communicated to the employee.

(ii) The signal word shall be readable at a minimum distance of five feet (1.52m) or such greater distance as warranted by the hazard.

(iii) The tag's major message shall be presented in either pictographs, written text or both.

(iv) The signal word and the major message shall be understandable to all employees who may be exposed to the identified hazard.

(v) All employees shall be informed as to the meaning of the various tags used throughout the workplace and what special precautions are necessary.

(vi) Tags shall be affixed as close as safely possible to their respective hazards by a positive means such as string, wire, or adhesive that prevents their loss or unintentional removal.

(f)(8) Biological hazard tags. (i) Biological hazard tags shall be used to identify the actual or potential presence of a biological hazard and to identify equipment, containers, rooms, experimental animals, or combinations thereof, that contain or are contaminated with hazardous biological agents."

The IC program shall have addressed the labeling procedures to be followed in the facility. That these procedures are followed shall be confirmed by employee interviews and the walkaround.

a. Bags or other receptacles containing articles contaminated with potentially infectious material, including contaminated disposable items, must be tagged or otherwise identified. The tag shall have the signal word "BIOHAZARD" or the biological hazard symbol. The tag shall indicate that the bag could contain infectious wastes and give any additional instructions; e.g., if the outside of the bag is contaminated with body fluids, a second outer bag should be used.

b. If tags are not used, other equally effective means of identification shall be used (e.g., red bagging).

c. Employees shall be informed of the meaning of tags. With respect to tagged material, they shall also be instructed to use double bagging where puncture or outside contamination is likely.

5. Section 2 (a). "[redacted]
;"

a. Section (2)(a) shall be cited only where the employer is failing to use abatement methods not required by the standards described above. The citation shall state: Health care workers (specify categories, such as doctors, nurses, etc.) (specify location) were exposed to the hazard of being infected by HBV and/or HIV and/or other blood-borne infectious agents through possible direct contact with blood or other body fluids. Feasible and useful abatement methods for reducing this hazard, among others, are: (List abatement methods not required by the standards which employer is not implementing.)

b. Recognition for purpose of section 2 (a) means recognition of the hazard of being infected with HBV and/or HIV and/or other infectious agents through possible direct contact with body fluids. The health care industry generally accept and, therefore, recognizes the determination of this hazard by the CDC, which is the acknowledged authority in this area. The employer's IC program can also constitute evidence of recognition.

c. The following are examples of feasible and useful abatement methods. The non-use of any of these methods is likely to result in the continued existence of a serious hazard and, may, therefore, allow citation under 2 (a) Executive Order 83-62. Consequently, all of these methods shall have been implemented. To determine whether they are being implemented, the CSHO shall evaluate the IC program and verify with employee interviews and the walkaround.

(1) [redacted]

(2) Linen. The IC program shall have identified all laundry operations involving substantial risk of direct exposure to body fluids. Linen soiled with body fluids shall be handled as little as possible and with minimum agitation to prevent contamination of the person handling the linen. All soiled linen shall be bagged at the location where it was used; it shall not be sorted or rinsed in patient-care areas. Soiled linen shall be placed and transported in bags that prevent leakage.

(3) Reusable Equipment. Standard sterilization and disinfection procedures currently recommended for hepatitis B in a variety of health care settings are adequate to sterilize or disinfect instruments, devices, or other items contaminated with body fluids. A recommended source of information is the CDC's Guidelines for Hospital Environmental Control: Cleaning, Disinfection and Sterilization of Hospital Equipment.

(4) Bagging of Articles. Objects that are contaminated with potentially infectious materials shall be placed in an impervious bag. If outside contamination of the bag is likely, a second bag shall be added.

(5) Handwashing. After removing gloves, hands or other skin surfaces shall be washed thoroughly and immediately after contact with body fluids.

(6) [redacted]

(a) [redacted] (needlestick or cut) [redacted] (splash to eye, nasal mucosa, or mouth) [redacted] the worker's skin is chapped, abraded, or otherwise nonintact, [redacted]

(b) If patient consent is refused or if the source patient tests positive, the health care worker shall be evaluated clinically and by HIV antibody testing as soon as possible and advised to report and seek medical evaluation of any acute febrile illness that occurs within 12 weeks after exposure. HIV seronegative workers shall be retested 6 weeks post-exposure and on a periodic basis thereafter (12 weeks and 6 months after exposure).

(c) Follow-up procedures shall be taken for health care workers exposed or potentially exposed to HBV. The types of procedures depends on the immunication status of the worker (i.e., whether HBV vaccination has been received and antibody response is adequate) and the HBV serologic status of the source patient. The CDC Immunication Practices Advisory Committee has published its recommendations regarding HBV postexposure prophylaxis in table format in the June 7, 1985, Morbidity and Mortality Weekly Report.

(d) If an employee refuses to submit to the procedures in (b) or (c) above when such procedures are medically indicated, no adverse action can be taken on that ground alone since the procedures are designed for the benefit of the exposed employee.

(7) [redacted]. The employer's training program shall be evaluated in accordance with Appendix C.

(a) All high risk health care workers such as those listed in D.1 shall receive education on precautionary measures, epidemiology, modes of transmission and prevention of HIV/HBV. Health care workers shall be counseled regarding possible risks to the fetus from HIV/HBV and other associated infectious agents.

(b) In addition, such high risk workers must receive training regarding the location and proper use of personal protective equipment. They shall be trained concerning proper work practices and, if the facility has implemented them, shall understand the concept of "universal precautions" as it applies to their work practices. They shall be trained about the meaning of color coding or other methods (except tags) used to designate contaminated articles or infectious waste. Where tags are used, training about tags and precautions to be used in handling contaminated articles or infectious waste is governed by 29 CFR 1910.145 (f). (See section G.4.) Workers shall receive training about procedures to be used if they are exposed to needlestick or to body fluids.

H. Other Standards.

1. The hazard communication standard, 29 CFR 1910.1200 only applies to hazardous chemicals or physical hazards in the workplace and thus does not apply to biological hazards such as blood borne diseases.

2. A record concerning employee exposure to HIV and/or HBV is an employee exposure record within the meaning of 29 CFR 1910.20. A record about HIV and/or HBV status is also an employee medical record within the meaning of 29 CFR 1910.20. However, under 29 CFR 1910.10, the CSHO may obtain these records for purposes of determining compliance with 29 CFR 1910.20.

3. Generally, 29 CFR 1910.134 does not apply since there are no respirators approved for biohazards. However, placing respirators in areas where they could be contaminated by body fluids constitutes a violation of 29CFR 1910.134(b)(6).

J. Personal Protective Equipment for CSHOs.

1. CSHOs shall not participate in activities that will require them to come into contact with body fluids, needles or other sharp instruments contaminated with blood. To evaluate such activities, CSHOs normally shall establish the existence of hazards and adequacy of work practices through employee interviews and shall observe them at a safe distance.

2. CSHOs shall take necessary precautions to avoid direct contact with body fluids. It will not normally be necessary for CSHOs actually to enter hazardous areas and, therefore, to use personal protective equipment. On the rare occasions when entry into potentially hazardous areas is judged necessary, the CSHO shall be properly equipped as required by the health care facility as well as by his/her own professional judgment, after consultation with the supervisor.

John A. Sahayda
Director of Compliance

4/2/90
Date

JAS:lt

MEMORANDUM

DATE: May 17, 1991

TO: All Immunization Staff

FROM: Joe Bronowski, Immunization Program Coordinator

SUBJECT: Attached Optional-use Orders for Hepatitis B Vaccine

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The federal contract with Merck, Sharp and Dohme for hepatitis B contains language which allows state health departments to grant optional-use status to local health jurisdictions. This will enable public employees who may have exposure to hepatitis B disease in the workplace to receive the vaccine.

The attached memorandum from Dr. Halpin specifies the terms under which the optional-use agreement can be accessed.

If you have any questions, please contact Kent or me.

Thanks.

Attachments: May 17th Memorandum from Dr. Halpin
Sample Letter
Hepatitis B Important Information Statement
List of MSD's Distribution Centers

HEPB/KW

246 N. High Street
Post Office Box 118
Columbus, Ohio 43266-0118

Telephone (614) 466-3543

GEORGE V. VOINOVICH
Governor

Merck, Sharp & Dohme
Division of Merck, Inc.
West Point, Pa. 19486

Dear Sirs:

Please be advised that the Ohio Department of Health hereby gives permission to the Health Department to directly purchase Recombivax Hepatitis B Vaccine under the consolidated federal contract (#200-91-0052).

It is my understanding that, by utilizing the contract, the purchaser has agreed to honor all terms of the contract.

Sincerely,

Thomas J. Halpin, M.D. M.P.H.
Chief,
Division of Preventive Medicine
Ohio Department of Health

HEPB/KW

246 N. High Street
Post Office Box 118
Columbus, Ohio 43266-0118

Telephone (614) 466-3543

GEORGE V. VOINOVICH
Governor

DATE: May 17, 1991

TO: Health Commissioners and Nursing Supervisors

FROM: Thomas J. Halpin, M.D. M.P.H.
Chief, Division of Preventive Medicine

SUBJECT: Optional Use Orders for Purchase of Hepatitis B Vaccine

****

The Ohio Department of Health has been informed by Merck, Sharp & Dohme Inc. that municipal governments are permitted to access the federal consolidated contract for Hepatitis B Vaccine (Recombivax). This permission is unique to the MSD hepatitis B contract and does not extend to routine pediatric vaccines. The requirements listed below must be agreed to by each municipal entity before vaccine will be shipped under this agreement:

1) The vaccine must be ordered through the local health department.

2) Only employees of governmental agencies, whose occupation places them at risk of exposure to hepatitis B disease through blood or blood products may receive hepatitis B vaccine through this agreement. These employees include physicians, nurses, communicable disease investigators who draw serologies, paramedics, emergency medical technicians, law enforcement officers, firefighters, lab technicians, and garbage collectors. Other groups not mentioned above may be included provided that exposure to blood or blood products is a job-related risk.

3) Employees of city- or county-owned hospitals and homes for the mentally retarded may be immunized when there is a risk of exposure to hepatitis B disease.

4) Persons <u>not</u> eligible to receive vaccine under this agreement include: municipal employees not routinely exposed to blood or blood products, patients in STD or other clinics, employees of private hospitals or clinics, private physicians or other medical personnel.

5) Vaccines purchased utilizing the federal contract must be administered according to instructions in the package insert. Each individual vaccine recipient must be informed of the risks and benefits of hepatitis B vaccine prior to administration. A copy of the current Important Information Statement on hepatitis B is included for your convenience in meeting this requirement. Signed Important Information Statements must be kept on file for ten (10) years following the date of administration.

6) No individual receiving this vaccine may be charged for the vaccine purchased under the federal contract, although a nominal administration fee may be charged. However, no person may be denied the vaccine for failure to pay the administration fee.

The current contract prices are listed below. Please note the minimum order requirements in the last column:

Vaccine	Packaging	Price per Package	Price per Dose	Minimum Order
HBV	1 ml vial	$29.72	$29.72	36 vials
HBV	1 ml vial	$29.42	$29.42	360 vials
HBV	3 ml vial	$89.16	$29.72	36 vials

Because of the minimum order requirement, localities may wish to pool resources to guarantee that the contract is utilized. Current contract prices are valid through February 21, 1992.

Vaccine ordered under this contract will have a minimum shelf life of 18 months. Since there is no return clause in the contract, vaccine delivered with a shelf life of less than 18 months may be refused at delivery.

Optional use orders should be sent directly to the ODH Immunization Program, 246 N. High St., P.O. Box 118, Columbus, Ohio 43266-0118, ATTN: Kent Ware. Immunization will then forward the order and letter of permission to Merck, Sharp and Dohme. All purchase orders must contain the following information:

1) Date of Order.
2) Contract number and order number.
3) Item description, quantity, and unit price.
4) Delivery date or performance date
5) Place of delivery or performance.
6) Packaging, packing, and shipping instructions, if any.
7) Accounting or appropriate data.
8) Statement to indicate if partial shipments are unacceptable.

Payment must be sent to Merck, Sharp & Dohme within 30 days of receipt of vaccine to the address listed on the individual order invoices from the manufacturer's distribution center. Failure to pay within 30 days violates the federal contract and jeopardizes this lower price. A list of distribution centers, and a sample order letter are enclosed.

Should you have any questions regarding this program, please contact Kent Ware at 614-466-4643 or your regional Immunization Representative.

Attachments: Sample Letter
Hepatitis B Important Information Statement
List of Distribution Centers

HEPB/KW

YOUR LETTERHEAD

Purchase Order #

(Health Department Name) hereby orders Recombivax hepatitis B virus vaccine at the price negotiated under Federal Contract #200-91-0052 with the manufacturer, Merck, Sharp and Dohme in the following amount:

------(# of) 3ml vials x $89.16 = $

------(# of) 1 ml vials x $29.72 = $

This agency will take all necessary steps to provide vaccine recipients with information relating to the risks and benefits of vaccination in compliance with the Duty to Warn Provisions. Important Information Statements pertaining to the vaccine will be provided to all recipients, or to a responsible party within any organization on whose behalf we purchase vaccine. This party will be advised of the necessity to comply with Duty to Warn.

Vaccine will be administered in accordance with the ACIP recommendations concerning hepatitis B and Recombivax, as summarized in MMWR No. RR-2, Vol. 39.

This agency is aware of all of the terms of this contract and agrees to guarantee that payment for the order will be made within 30 days after receipt of the invoice to the address on the invoice.

Shipment and billing should be directed to:

----(shipping address)--	------(billing address)-----

Partial shipment is ACCEPTABLE ( ) UNACCEPTABLE ( ).

No indication will be interpreted as agreement to accept partial shipment.

Administrator's (or Designee's) Signature

Date

Desired Delivery Date

DISTRIBUTION CENTERS

MSD
MERCK SHARP DOHME DIVISION OF MERCK & CO., INC.

MERCK SHARP & DOHME

GENERAL OFFICES, WEST POINT, PA 19486

BRANCH	WATS LINES AVAILABLE FOR USE
ATLANTA	Georgia only 800-282-8745
2825 Northwoods Parkway, Norcross, GA 30071	Other States 800-241-6858
BALTIMORE	Maryland only 800-492-2807
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BOSTON	Massachusetts only 800-362-4340
40 A Street, Needham Heights, MA 02194	Other States 800-225-4536
CHICAGO	Illinois only 800-942-4631
2010 Swift Drive, Oak Brook, IL 60522	Other States 800-323-7160
COLUMBUS	Ohio only 800-282-5143
4242 Janitrol Road, Columbus, OH 43228	Other States 800-848-5180
DALLAS	Texas only 800-772-5327
925 111th Street, Arlington, TX 76011	Other States 800-433-5018
DENVER	Use Kansas City Branch WATS Numbers
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KANSAS CITY	Kansas only 800-332-6268
9001 Quivira Road, Overland Park, KS 66215	Other States 800-255-6585
LOS ANGELES	California only 800-372-6249
6409 East Gayhart Street, Los Angeles, CA 90040	Other States 800-423-4007
MEMPHIS	Tennessee only 800-582-2411
1980 Latham Street, Memphis, TN 38106	Other States 800-238-2496
MINNEAPOLIS	Use Chicago Branch WATS Numbers
12955 State Highway 55, Minneapolis, MN 55441	
NEW ORLEANS	Use Dallas Branch WATS Numbers
1431 E. Airline Highway, Kenner, LA 70062	
NEW YORK	
300 Franklin Square Drive, Somerset, NJ 08873	All States 800-458-2254
PORTLAND	Oregon only 800-452-9814
717 Northeast Lombard Street, Portland, OR 97211	Other States 800-547-6706

Ohio Department of Health
Division of
Communicable Diseases
246 North High Street
Columbus, Ohio 43266-0588

SOME FACTS ABOUT HEPATITIS B

0931.11 (Rev. 4/89)

Total copies printed: 50,000
Unit cost: $.0370
Publication date: 5/89
Includes paper costs

What is hepatitis B?

Hepatitis is an inflammation of the liver. It may be caused by chemicals, drugs, or infections. One of the causes is the hepatitis B virus. This virus is found in the blood, semen, and saliva of infected persons. It is not present in the urine or bowel movement.

How do people get hepatitis B?

Hepatitis B is transmitted from person to person through blood and blood products, sexual contact, sharing unsterilized hypodermic equipment, needle-stick accidents, human bites, or contact of mucous membranes or broken skin with infected body fluids.

Of those adults who acquire hepatitis B, five to ten percent remain infectious for more than six months, and are called chronic carriers.

All blood donors are now screened for the presence of the hepatitis B virus. This action has decreased the chance of acquiring infection through transfusions.

What are the symptoms of hepatitis B?

Those who do have symptoms of hepatitis B may report: fever, fatigue, loss of appetite, abdominal discomfort, and/or jaundice (yellowing of the skin or the whites of the eyes).

What is the treatment for hepatitis B?

There is no known cure for hepatitis B, and no specific treatment — but it can be prevented.

How can the disease be prevented?

Two effective vaccines have been developed to provide active protection against hepatitis B. Both are considered safe and have no serious side effects. Both vaccines are given in a three-injection series over a six month period.

There is no evidence that the causative agent of AIDS has been transmitted by hepatitis B vaccine.

Who should get the hepatitis B vaccine?

Those persons especially at risk for hepatitis B should receive the vaccine, this includes: household members and sexual partners of hepatitis B carriers, persons having frequent contact with blood and/or blood products, and infants born to mothers that are positive for hepatitis B.

If you, or a family member, are diagnosed as having hepatitis B, please discuss the need for vaccine for others in your household with your physician.

For additional information, call your local health department, or the Ohio Department of Health, Division of Communicable Diseases at (614) 466-4643.

Cost Overview
HBV Vaccination Series

Simulation for Lancaster Post Immunization

Doctor's Office	Federal Grant Program	County Health Department
$250 per Officer	$110 per Officer	$45.88 per Officer
$2,000 Total	$880 Total	$367.04 Total

Simulation for Statewide Immunization

Doctor's Office	Federal Grant Program	County Health Department
$250 per Officer	$110 per Officer	Not Available
$150,000 Total	$66,000 Total	Not Available

Based On:

- 50%* of population desires vaccination
- Doctor's Office fees represent an average of several quotations
- Federal Grant Program fees based on cost plus $20 for time and supplies

Note:

All table information is based on best available information. The exact cost of the program will vary dependent on factors such as administration fees and supply costs. The totals provided are for comparison only, they do not represent exact cost figures.

* Estimate based on risks associated with procedure. Increased participation will DIRECTLY effect final cost.