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Texas Preventable Disease NEWS

contents:

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VIRAL HEPATITIS
PART VI: HEPATITIS B VACCINE - USAGE

VACCINE USAGE

Primary adult vaccination consists of three 1 ml (20 µg/1.0 ml) intramuscular doses of vaccine -- an initial dose followed by the second and third doses at 1 and 6 months, respectively. For patients undergoing hemodialysis and for immunosuppressed patients, three 2 ml doses (40 µg) should be used. For children under 10 years of age, three similarly spaced doses of 0.5 ml (10 µg) are sufficient. Vaccine doses administered at longer intervals than those stipulated provide equally satisfactory protection, but optimal protection is not conferred until after the third dose. Since HBV vaccine is an inactivated (non-infective) product, it is presumed that there will be no interference with other simultaneously administered vaccines. The duration of protection and the need for booster doses have not yet been determined.

VACCINATION OF IMMUNE PERSONS AND EFFECT OF VACCINATION ON CARRIERS

Vaccination of individuals who possess antibodies against HBV from a previous infection is unnecessary but will cause no adverse effects. Such individuals will have a post-vaccination increase in their anti-HBs levels. Passively acquired antibody, whether from hepatitis B immune globulin (HBIG) administration or from the transplacental route, will not interfere with active immunization. The vaccine produces neither therapeutic nor adverse effects in HBV carriers.

PRE-EXPOSURE VACCINATION (CDC/ACIP GUIDELINES)

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

1. health-care workers (medical, dental, laboratory, and support groups),
2. hospital staff,
3. clients and staff of institutions for the mentally retarded,
4. hemodialysis patients,
5. homosexually active males (Homosexually active females do not appear to be at increased risk of sexually transmitted HBV infections.),
6. illicit injectable drug users,
7. recipients of certain blood products,
8. household and sexual contacts of HBV carriers,
9. special high-risk populations (eg, Alaskan Eskimos or immigrants and refugees from areas with highly endemic disease), and
10. inmates of long-term correctional facilities.

POST-EXPOSURE VACCINATION

1. **Infants Born to HBsAg-Positive Mothers** -- Pregnant women who are HBsAg positive should be informed about the risk of HBV transmission to their infants. Infants born to these women should receive HBIG. Infants whose mothers are chronic carriers will be continuously exposed to HBV throughout their childhood; therefore, these infants should receive hepatitis B vaccine. The optimum timing for vaccination in conjunction with HBIG administration has been addressed recently by the Immunization Practices Advisory Committee (ACIP) and the Redbook Committee of the American Academy of Pediatrics. The following schedule has been proposed:

   - 0.5 ml HBIG given to the infant in the delivery room;
   - 10 µg hepatitis B vaccine given to the infant before leaving the hospital, or at one month of age;
   - 10 µg given one month after the first dose (2 months of age);
   - 10 µg six months after the first dose (7 months of age).

   NOTE: Hepatitis B immune globulin (HBIG) is specified for prophylaxis of infants born to HBsAg-positive mothers. Immune globulin (IG) should **NOT** be substituted for HBIG in this schedule.

   The infant should be screened for anti-HBs soon after the third and final dose of vaccine. If the test is negative, the infant should then be screened for HBsAg.

   The ACIP also suggests that screening the infant at birth for HBsAg may be useful especially for mothers and infants of certain population groups known to have an unusually high endemic level of hepatitis B. In these instances up to 5% of infants born may be infected in utero and will already be positive for HBsAg at birth.

   Routine childhood immunizations should be administered according to the generally accepted schedule.

2. **Sexual and Household Contacts of Acute Hepatitis B Cases and Health Workers Who Receive Needle Sticks from HBsAg-Positive Patients** -- Possible alternatives for post-exposure prophylaxis include HBIG, immune globulin (IG), HBV vaccine, or a combination of vaccine and an immune globulin. Recommendations for HBIG and IG use have been previously published (Texas Preventable Disease News, week no. 1, ending January 7, 1984). Studies are currently under way to evaluate the use of vaccine in some of these settings. No final recommendations can be made at this time for post-exposure use of HBV vaccine. However, the following schedule for post-exposure use of the vaccine is under consideration by the ACIP:

   - Give HBIG (0.6 ml/kg of body weight) immediately (PDN, week no. 1, January 7, 1984);
   - Give initial dose of HBV vaccine at the same time;
   - Continue HBV vaccine schedule as recommended.

Additional recommendations regarding hepatitis B vaccine administration and use for high risk groups can be obtained from the following sources: Texas Department of Health, The American Hospital Association, Occupational Safety and Health Administration (OSHA) [guidelines to be distributed by the Texas Hospital Association], and the Veterans Administration Medical System.

CONTRAINDICATIONS

HBV vaccine is well tolerated by healthy adults; however, it is contraindicated for:

1. individuals with a hypersensitivity to any component of the vaccine,
2. individuals with severely compromised cardiopulmonary status,
3. individuals in whom a febrile or systemic reaction could pose a significant risk,
4. pregnant women, and
5. nursing mothers.

SIDE EFFECTS AND ADVERSE REACTIONS

Data on adverse reactions to the hepatitis B vaccine are accumulated and analyzed by the CDC. Much of the following information from the Viral Hepatitis Branch, CDC, represents a pre-publication summary of some of the major points.

Approximately 450,000 individuals have received the hepatitis B vaccine since its licensure in 1981. As of December 15, 1983, 687 mild reactions or cases of illness in vaccine recipients have been reported. Of these 196 (28.5%) were deemed to be unassociated with vaccination, and 491 (71.5%) illnesses were considered to represent "background diseases" rather than adverse reactions to the vaccine.

At least 34 people exhibited severe illness following vaccination. Adverse reactions have included: joint pain (8), neurological illnesses (8), skin disorders (4), gastrointestinal symptoms (3), blood abnormalities (3), acute allergies (2), elevated liver function tests (2), fever (1), hematuria (1), chest pain (1), and congenital malformations (1). No deaths associated with vaccination have been reported.

Three cases of Guillain-Barre Syndrome (GBS) have been reported as of December 15, 1983. However, the incidence rate (3 cases per 450,000 population) does not exceed that rate resulting from chance alone (23 GBS cases per one million adults per year, $p=0.05$). The TDH received two reports of vaccine reactions in 1983, listing rash, itching, and generalized joint pain and swelling as symptoms.

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HEPATITIS B VACCINE AND AIDS

Since some plasma for hepatitis B vaccine production comes from donors belonging to population groups that are at high risk for acquired immune deficiency syndrome (AIDS), the possibility of contracting AIDS from the hepatitis B vaccine has been raised. A federal interagency committee composed of representatives from the Centers for Disease Control (CDC), National Institute of Health (NIH), and the Food and Drug Administration was convened to examine the situation. Their conclusion, published in the Morbidity and Mortality Weekly Report (Vol. 31,No. 35; September 3, 1982), supports the safety of the hepatitis B vaccine.

Clinical trials conducted in selected high risk groups during the late 1970s have been reevaluated for incidence of AIDS. It is expected that AIDS cases will be identified in a few hepatitis B vaccine recipients based on chance alone. However, the incidence rate of AIDS in this group is low compared to the rate in the nonvaccinated group. By February 1983, two cases of AIDS had been identified in 1,083 homosexual men who received the vaccine during a clinical trial conducted by the New York Blood Center in New York City (1.85 cases/1,000 population). In contrast, there were 11 cases of AIDS in 3,600 homosexual men who were not vaccinated at any time during this clinical trial (3.06 cases/1,000 population). AIDS cases have not been identified in vaccine recipients who are not members of groups at high risk for AIDS. As of December 15, 1983, 17 cases of AIDS have been reported in vaccine recipients nationwide. All of these were sexually active male homosexuals.

Since 1979, homosexual men, including those from cities with reported AIDS cases, have been the source for much of the plasma used in vaccine lots during the clinical trials and after licensure and general distribution. It is not known at this time whether any vaccine donors have subsequently developed AIDS. While a few AIDS cases have been identified in vaccine recipients, an overwhelming amount of clinical data supports the suggestion that hepatitis B vaccine does not carry an etiologic risk for AIDS.

The problem needs to be put into perspective. The average lifetime risk of acquiring a hepatitis B infection for a health care worker who has routine occupational exposur to blood can be as high as 20%. One in five workers in a high-risk health care occupation will contract hepatitis B. The potential for chronic liver disease in these individuals remains high. When compared to the occurrence of two cases of AIDS in 1,083 vaccinated homosexual males (0.18%), or the overall occurrence of 17 AIDS cases per 450,000 vaccine recipients (0.004%), the risk for acquiring hepatitis B and possible chronic liver disease is needlessly high. The risk of developing AIDS is insufficient grounds for avoiding the vaccine if the health care worker is exposed to hepatitis B.

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SELENIUM TABLETS RECALLED

"Brite Years" brand of selenium tablets, 150 microgram, used as a human food dietary supplement, has been ordered recalled by the federal Food and Drug Administration; this follows a voluntary recall instituted by the distributor on March 10, 1984. The tablets were manufactured by Superior Health Vitamin and Health Foods, Deer Park, New York, and distributed by Brite Years, Inc., Tempe, Arizona.

Texas is one of fifteen states in which bottles of 60, 90, or 180 tablets have been distributed. Affected lots are 012163, 106213, 301216, and 012161. At least one lot tested contained nearly 200 times the labeled dose, and one case of selenium poisoning from the tablets is reported in the Centers for Disease Control publication, Morbidity and Mortality Weekly Report, Vol. 33/No. 12, March 30, 1984. The most likely point-of-sale of the tablets would be health food stores or departments. Any tablets in these four lots should not be sold or consumed.

TEXAS PREVENTABLE DISEASE NEWS
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