

Review Article

HEPATITIS "B" VACCINATION: APPLICATIONS AND IMPLICATIONS

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In this review article, we have discussed different vaccines, their safety and the high risk groups which should be vaccinated. Two hepatitis "B" vaccines were licensed, the plasma derived HB Vax (Merck Sharp and Dohme Ltd) in 1982 and the recombinant Engerix "B" (Smith-Kline and French Lab Ltd) in 1987.

HB vax, prepared in U.S. has been the most widely used and researched vaccine. There has been over 15 years of experience with safety and over 12 years clinical experience. Preparation involves harvesting non-infectious sub-units from the plasma via plasmapheresis from selected chronic HBsAg +ive, HBeAg +ive, healthy carriers, which are then inactivated by triple chemical inactivation. This process inactivates all living organisms previously known to infect man, including HIV agents. Each batch is subjected to 05 weeks of purification and safety-testing.

The second type of genetically engineered vaccine "Engerix B" is prepared from human blood with whole virion particles harvested from serum of chronic carriers. There is no evidence that the two types of vaccines differ significantly with respect to safety, side effects, immunogenicity, dosage regimen, the necessity for follow-up, or the interchangeability of booster doses following initial vaccination. Choice of vaccine will ultimately depend on cost and availability.

DOSAGE:

It is given in three divided doses (3x20 ugm in adults, 3x10 ugm in neonates and children by deep I/M inj. at times nought, one and six months.

RESPONSE:

The overall safety response rate (immunogenicity) and protective rate (protective efficacy) exceeds 80% in adults and 90% in neonates and children. Improved rates can be achieved by administering the injection into deltoid or anterior thigh rather than buttocks and by choosing young (<40 yrs) vaccines).

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SAFETY AND SIDE-EFFECTS:

The licensed vaccines are completely safe and fears that they might transmit blood-borne disease including AIDS are completely unfounded. Experience with plasma derived vaccine is extensive and no serious adverse reaction unequivocally attributed to the vaccine has been reported. Soreness at the site of injection or low-grade fever (<38°C, <48 hrs) has been noted in 5%.

WHO SHOULD BE IMMUNIZED:

The public health importance of hepatitis "B" throughout the world can not be exaggerated; acute and persistent infection is common and the incidence is increasing. The world reservoir of hepatitis B is conservatively estimated to number more than 200 million people, and the carrier state may lead to chronic liver disease including chronic active hepatitis, cirrhosis and hepatocellular carcinoma.

Hepatocellular carcinoma is one of ten most common tumours in the world with over 250,000 new cases each year, and there is compelling evidence that hepatitis B is its cause in upto 80% of cases.

The wide range of parenteral and inapparent parenteral routes of transmission of hepatitis B includes the transfusion of blood and certain plasma derivatives, the use of inadequately sterilized syringes, needles and instruments and sexual contacts, particularly among homosexual men. Hepatitis B is also an occupational hazard among health care workers and lab. personnel, and infection is known to be common in residents and staff of institution for the mentally handicapped and custodial institution.

The high rates of transmission of hepatitis B from carrier mothers to their newborn infants in many areas of the world make protective immunization of susceptible mothers and infants born to carrier mothers the only practical way of interrupting transmission of the infection and preventing the establishment of the carrier state in most of infected children.

i) HIGH-RISK GROUPS:

All new born babies of HBsAg positive mothers should be immunized immediately after birth, whether or not the mother is considered of "high" (HBsAg) or "low" (anti-HBs) infectivity. Active vaccination should be administered simultaneously with passive immunization (Hep. B Immune Globulin).

- Homosexuals.
- Bisexuals.
- I/V drug abusers.
- Multiply transfused, e.g. thalassaemics, haemophilics.
- Patients with impaired immune responses.
- Mentally handicapped e.g. Down's Syndrome in institutions.

ii) **OCCUPATIONAL RISK GROUPS:**

Any health care worker who has direct and regular contact with blood/or known HBsAg positive patients should be offered vaccine. There recommendations should therefore include:

- Clinical and laboratory based hospital staff, including all clinical and dental staff and their ancillary workers and dental students.
- Midwives and surgical assistants who perform regular venepuncture, surgical or dental procedures.
- General practitioners who perform regular practical procedures e.g. venepuncture.
- Medical students and clinical staff on secondment to high-risk areas of the world.
- Policemen and members of drug-squad and staff working in prisons or institution where there are I/V drug abusers, homosexuals etc; and those working in institution for the mentally handicapped, especially with Down's Syndrome and in refugee camps.
- Other patients on long term hemodialysis, or those having surgery requiring multiple blood transfusion should also be vaccinated.
- Lastly sexual partners of patients with acute hepatitis B or carriers and other family members in close contact, and particularly promiscuous male homosexuals and female and male prostitutes should be vaccinated.

POST-EXPOSURE IMMUNOPROPHYLAXIS:

The vaccine can afford some protection even if given up to two weeks following a definite exposure for e.g. by needle stick injury or sexual contact. It is prudent to give passive (HB16) vaccination alongwith active (vaccine) under these circumstance.

ADDITIONAL BOOSTERS:

Current policy is to recommend an additional booster dose to all initial responders after 5 years from completion of vaccination. Boosting may be carried out with either plasma-derived or recombinant vaccine, since in practical terms, there are interchangeable. Finally we recommend that failure to immunize these people places them at un-necessary and unjustified risk.

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