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## *Immunization Dialogue*

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### **Plasma-derived and Recombinant Hepatitis B Vaccines**

**Q.** *At present many of us are using recombinant vaccine for hepatitis B immunization. However, this vaccine is costly and thus 90% of children can not avail it. In this context, I solicit comments on serum derived vaccine which is much cheaper and can be made available to a larger segment of population.*

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### **Reply**

Dr. Tiwari has requested for comments on the plasma-derived hepatitis B (HB) vaccine. Although not explicitly asked, the spirit of the request is for help in choosing between the two types of HB vaccines available on the market—the plasma-derived and the recombinant. In comparing the two products, safety and efficacy are the major elements, cost being a third important element. As Dr. Tiwari states, the plasma-derived vaccine is less costly than the recombinant vaccine. What about safety and efficacy?

The first HB vaccine licensed in the USA was plasma-derived, in the year 1981(1). The manufacturer used 3 purification processes (pepsin, urea, formalin) and

each process would inactivate at least  $10^5$  chimpanzee infectious doses of HB virus per milliliter and all other classes of animal viruses including retroviruses (*e.g.*, HIV; HTLV 1 and 2). Although the manufacturer of that vaccine discontinued plasma-derived production and introduced recombinant vaccine, currently there are at least 4 major manufactures, 2 in Korea, one in China and one in Taiwan producing and marketing plasma-derived vaccine in Asian countries. The purification and inactivation processes of all manufacturers are equally good and no known extraneous virus can survive them. Thus, all licensed plasma-derived vaccines are completely safe from infection with HIV, HTLV, HBV or Hepatitis C virus, *etc.* Over 30 million subjects have been given this vaccine, and the safety record is impressive(2). The overall rates of post-immunization reactions, local and systemic were not more than in placebo recipients(2).

Recombinant vaccine is manufactured in yeast cells (5 major manufacturers) or CHO cells (1 manufacturer). Their safety record is equally impressive; the side-effects, are no more than for the plasma-derived vaccine. There have been instances of Guillain-Barre syndrome following either vaccine, but causative association remains unproven. Immediate hypersensitivity reaction has been reported after the yeast-derived vaccine but it is extremely rare(2). In short, both vaccines, plasma-derived and recombinant are very safe; the World Health Organization has also stated so(3).

Both types of vaccines are also very highly immunogenic, hence effective. Over

the coming years, more recombinant vaccines will be used, as HB virus carrier pool is declining as source material for the plasma-derived vaccine. Meanwhile, either vaccine may be used-both are safe and effective.

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#### REFERENCES

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3. World Health Organization. Expanded Program on Immunization for the 1990s. WHO Bull 1992; 70: 392-393.