

Readers Forum

DTP-Hib Combination

Vaccine manufacturers promote DTP + Hib combination products for primary immunization. However, Recommended Childhood and Adolescent Immunization Schedule - United States July-December 2004 states as follows:

DtaP/Hib combination products should not be used for primary vaccination in infants but can be used as boosters after any Hib vaccine. The committee had made the same recommendation 6 months earlier. What should we do?

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Reply

It should be clearly understood that in US DTwP is not used in infant and adolescent immunization either in monovalent or combination formulation. In India all the Hib conjugate combination vaccine formulation are containing only DTwP. The efficacy and immune response of Hib component in the DTwP-Hib combination formulation have not been questioned and many other developing countries also recommend their use either in monovalent or combination formulation.

Hence in India IAP also recommends the use of DTwP-Hib combination formulation as well as DTwP-HB-Hib combination formulation wherever indicated.

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Preservatives in DPT Vaccine

Each dose of DPT vaccine contains 0.025 mg of mercury as thimersol and 1.25 mg of aluminium phosphate. Some preparations of hepatitis B vaccine, specially in multidose vials contain 0.025 mg of mercury as thimersol and 0.25 mg of aluminium hydroxide. There is still an ongoing debate whether mercury contained in the vaccine causes toxic effects on neurodevelopment of children and autism.

Cumulative doses of mercury and aluminium after three doses of DPT vaccine would be 0.075 mg and 4.5 mg of mercury and aluminium respectively. Adverse effect of mercury on the body depends on the load of mercury, period during which mercury has been administered, *i.e.*, if mercury has been administered at short or long intervals and the body mass.

A different immunization schedule for three doses of DPT vaccine administered at 8, 16 and 24 weeks would pose least harm because the metals are administered over a longer period of time, as compared to the conventional schedule at 6, 10, and 14 weeks. Also, distribution of mercury/aluminium per kg body weight would be lesser, because the infant has a higher weight in the 8, 16 and 24 weeks schedule. Studies have shown that

antibody generation is better when DPT vaccine is administered at 8, 16 and 24 weeks as compared to 6, 10 and 14 weeks.

Thus DPT vaccine administration at 8, 16 and 24 weeks should be considered. Similarly, if a mother is not a case of hepatitis B virus infection, administration of hepatitis B vaccine to her child should be deferred to the latter part of infancy or even later.

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Reply

WHO has shelved the controversy on the use of thiomersal as preservative in multi dose vaccine formulation vials. Being an ethyl mercury, it does not produce any neurotoxicity unlike methyl mercury. With 25 mcg for each vaccine administration (much less in combination formulation multi dose vials), the cumulative effect on neuro-toxicity, once feared is no more a concern. Therefore, many countries in the world use thiomersal preserved vaccine formulation in their routine National Immunization Program.

Without going into the pros and cons of 6,10,14 weeks and 8,16,24 weeks, it is worth while following the latest WHO schedule for DTwP and HB Vaccine which is highly immunogenic and has established high field efficacy since 1975 and 2000 respectively. No doubt, increasing interval between the 3 doses of the same vaccine, enhances the immunogenicity, GMT, *etc.* However, the minimum protective antibody level achieved through wider coverage at short interval with excellent field efficacy, have resulted in successful elimination/eradication of the

targeted diseases in countries world over using the WHO schedule.

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Study of Drugs in Indian Children

Regarding the use of probiotics in acute diarrhea in children, the National Task Force had stated: "Almost all the studies till now were done in developed countries except for one very small study from Pakistan. It may not be possible to extrapolate the findings of these studies to our setting where the breast feeding rates are high and the microbial colonization of the gut is different"(1). It is a logical argument. Which drugs have been introduced in the Indian market during the last five years only after evaluation on Indian children?

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REFERENCE

1. Bhatnagar S, Bhandari N, Mouli, UC, Bhan MK. Consensus Statement of IAP National Task Force: Status Report on Management of Acute Diarrhea. *Indian Pediatr* 2004; 41: 335-348.

Reply

There are some drugs for which the formulation used is global. In such situations evidence of limited efficacy is traditionally acceptable. In case of probiotics the effect on patients is dependent on the formulation used.