Readers' Forum

Q. *Japanese B Vaccine is currently available in India. Do you recommend that we pediatricians in Hyderabad start giving it as a routine? If so, which is the best time of the year to do so?*

Anita Chandna,
Secunderabad.

Reply

IAP National Consultation meeting on JE was held on 2nd October 2005 at New Delhi with participation from NICD and other partners followed by similar discussion on 2nd April 2006 during the meeting of the IAP Committee on Immunization. The consensus expert opinion follows:

1. IAP reiterates the need of introducing JE vaccine for children between 1-15 years of age in India for routine use in the endemic areas for the control of JE.
2. Based on the case load and disease incidence in the past decade, serological evidence from JE studies, and epidemiological link to known areas of transmission, 98 districts from 12 states in India, including Uttar Pradesh, Bihar, West Bengal, Assam, Andhra Pradesh, Haryana, Karnataka, Tamil Nadu, Goa, Maharashtra, Kerala and Manipur, are identified and prioritized for the introduction of JE vaccine as shown in *Fig. 1.* Of these, 11 districts from 5 states

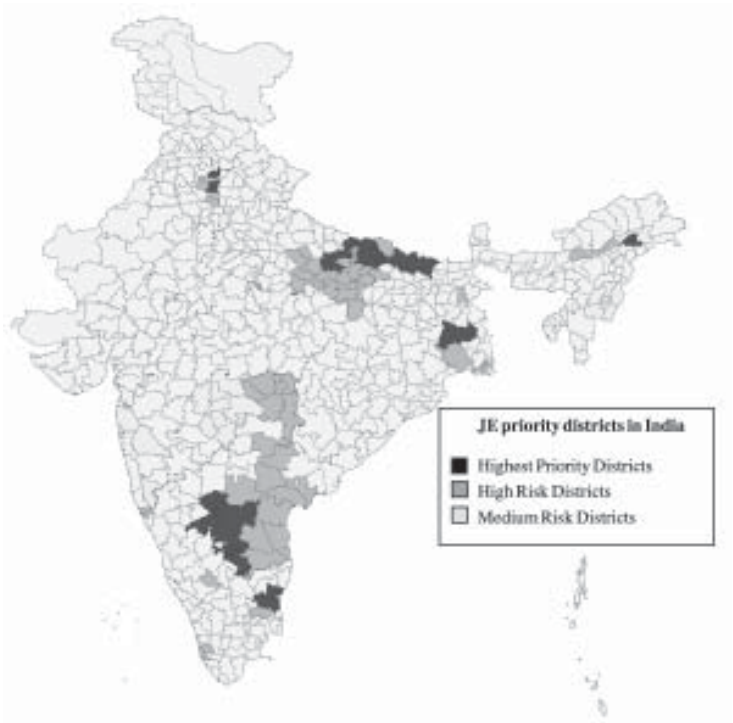

Fig 1. Priority districts for JE vaccine in India

are identified for introduction of JE vaccine in 2006-2007 as shown in *Table I.* The live SA-14-14-2 JE vaccine will be imported from Chengdu, People's Republic of China and used in all the 11 districts. This will benefit 12.2 million children from the age of 1-15 years. It will be one time campaign from village to village to give single dose of the live vaccine subcutaneously to all the children of 1-15 yeas of age in these districts to be followed by inclusion of the same in the routine immunization in these districts to cover for the new birth cohorts subsequently(1,2). ICMR will conduct safety, immunogenicity and efficacy studies simultaneously in these districts. The ongoing program of JE vaccine in Kurnool and Ananthpur districts in Andhra Pradesh and Perambulur in Tamil Nadu using the inactivated mouse brain JE vaccine will continue with the support from GAVI.

Coming to the specific question by Dr. Anita, IAP member can immunize his/her patients in private practice based strictly on the need of the vaccine as defined above. The vaccine at present is exorbitantly expensive for commercial use and may not be affordable by many. It may be better to direct such patients to public facility in the local areas for JE vaccination as and when it is made available through public health system.

TABLE I– *The List of the Districts for JE Vaccination using SA-14-14-2 vaccine in 2006 with Tentative Time Frame*

State	Districts	Number of Children /Dates
Uttarpradesh	Kushi Nagar Gorakhpur Maharajganj Deoria Kheri	(UP + Assam) 7.14 million 7-10 May 2006
Assam	Dibrugarh Sivasagar	
Bihar	Mujaffarpur Nawada	2.3 million 24th May 2006
West Bengal	Burdwan	(WB + Bellary) 4 million
Karnataka	Bellary	24th June 2006

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Q. *DPT-Hib Combination: Logical Fallacy and Circular Argument*

This is with reference to the answer given by Dr. A.Parthasarathy in reply to a question from Drs.Hemant Joshi and Archana Joshi regarding DTPw-Hib combination in the Readers' Forum of *Indian Pediatrics* of October 2005(1).

The statement by Dr. Parthasarathy that "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" is a logical fallacy and a circular argument. To say that the safety and efficacy has not been questioned may just

mean that it has not been looked for. Absence of proof is not proof of absence. The statement that other countries recommend their use is a circular argument as other countries also may be just saying that other countries also use them.

If this is the official position and the explanation for a particular recommendation by the IAP, one would have expected either a direct reference to a study showing the efficacy and safety of such use or a recommendation from any respectable and responsible organization about such use. That is, if such data and recommendations exist.

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Reply

I thank Dr. Alexander for raising an important issue of 'Safety and Immunogenicity of the Hib component in DTwP-Hib / DTwP-HB-Hib combination vaccine formulations available in India'. There are two brands of DTwP-HB-Hib combination vaccine formulations (*i*) a lyophilized formulation and (*ii*) a fully liquid formulation. Similarly there are two brands of DTwP-Hib combination vaccine formulation (*i*) a lyophilized formulation and (*ii*) fully liquid formulation respectively. There is also a third formulation in which the lyophilized Hib component in pellet form is mixed extraneously using the recommended DTwP formulation as a diluent.

1. DTwP-HB + Lyophilized PRP-T component containing Hib formulation, where the DTwP-HB liquid formulation is used as a diluent to dissolve the lyophilized pellet of PRP-T Hib component supported by studies abroad(1).
2. DTwP-HB-Hib CRM197 fully liquid pentavalent combination vaccine formulation, supported by Indian study(2).
3. DTwP + Lyophilized PRP-T component where the DTwP liquid formulation is used as a diluent to dissolve the Lyophilized pellet of PRP-T Hib component supported by Indian study(3).
4. DTwP-Hib CRM197 fully liquid formulation supported by International multicentric clinical trials(4).

Though, studies have shown that administering DTwP and Hib in combination results in reduced mean PRP antibody levels compared to giving the same components separately. However, even in those studies with statistically significant reduction, antibody levels was still high and at 90% of children (typically 95%) developed greater than 1 mcg/mL of antibody to PRP-T/ CRM197 component of Hib. This, reduced immunogenicity of Hib when given in combination with DTwP appears to be of no clinical importance. Further all the above studies have concluded that addition of Hib component to either the DTwP / DTwP HB lyophilized / liquid formulations does not affect the safety and immunogenicity of either the PRP-T / CRM197 Hib component.

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