

IAP's Immunization Time Table in Pediatrics

Over the years, the Immunization Committee of the IAP, under the able leadership of Dr. T. Jacob John, has given us practical and scientifically sound guidelines for immunizing children. The Committee has updated the older recommendations and incorporated newer vaccines in the latest schedule published in Indian Pediatrics(1).

I would, however, like a few clarifications regarding the schedule, particularly in areas where the IAP recommendations differ from those of the American Academy of Pediatrics (AAP)(2). I do appreciate that the differences are probably deliberate and arise due to varying epidemiological factors in the two countries.

1. Hepatitis B Vaccine: Is there a need for booster doses of the vaccine at 5 and 15 years? According to the AAP(2), "for children with normal immune status, routine boosters are not currently recommended. The possible need for boosters will be assessed as additional information becomes available". Considering the high cost of the vaccine, avoiding the booster doses could reduce the financial implications considerably which would have an important bearing for a country like India.

2. First Booster of DTP/OPV: Would a timing of 15-18 months be more suitable for our country compared to the recommendation of the first booster at 18-24 months? According to the AAP(2), "the 4th dose of DTP (1st booster) should be given between 15 and 18 months of age". An advantage of the 15-18 months schedule for the 1st booster would be the ability to combine it with MMR at the same visit. Simultaneous administrations of multiple

vaccines, reduces the number of patient visits and has been shown to improve immunization coverage(3). Also, an earlier schedule would confer full immunity at an earlier age.

3. The TT Booster has been advised at 10 years (5 years after the primary course). Is it necessary? According to the AAP, "A booster dose of TT should be given every 10 years after the primary immunization is completed. Routine boosters at intervals more frequent than every 10 years are not indicated and may be associated with an increased incidence and severity of the effects.

4. The recommended gap between the primary DTP and OPV doses in the new schedule is 4 weeks. In the earlier IAP Schedule as well as the AAP Schedule, the recommended gap is 8 weeks. It appears that an increased drop out rate with the 6-8 week interval schedule (4) has made the Committee revert to the UIP/EPI recommendation of OPV and DTP at 6-10-14 weeks. An increased seroconversion with a 6-8 week gap has been recommended by most authorities(2) and also by the IAP(5). If the 4 week interval has been recommended only because of poor compliance with the 8 week interval, it has two important implications: First, if a proper follow up is ensured, should we continue with the 6-8 week gap, but make a provision (in the form of an explanatory note) that in circumstances where a close follow-up is not assured, a 4 week gap would be more appropriate?

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REFERENCES

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2. American Academy of Pediatrics. Redbook: Report of the Committee on Infectious Diseases, 23rd ed. Ed. Peter G. Elk Grove Village, AAP, 1994.
3. Adhoc Working Group for the Development of Standards for Pediatric Immunization Practices. *JAMA* 1993, 269:1819.
4. Singh GR. Diphtheria, pertussis and tetanus. *In: Immunization Update*. Eds. Mittal SK, Datta A, Aggarwal V. New Delhi, CBS Publishers and Distributors, 1994, pp 15-33.
5. Immunization Advisory Committee, Indian Academy of Pediatrics, 1989.

Reply

Dr. Balsekar has raised several questions which give me an opportunity to elaborate on the thoughts behind some of the decisions made by the IAP's Immunization Committee. The IAP's Immunization Time Table, published in the December 1995 issue of *Indian Pediatrics*, is the crystallized summary of a lot of deliberations. It is not possible to reason out or justify the rationale behind every recommendation when publishing the Time Table, for several reasons. On the other hand, letters like that of Dr. Balsekar give us the opportunity to hear the views of those experts who are not on the Committee as well as to present before IAP members some of the difficult or controversial issues that we had to grapple with and arrive at a consensus.

An immunization schedule has to choose vaccines, doses and their timing in terms of the age of the vaccinee. Often there are competing pulls and demands on each of the above issues. Ultimately compromises have to be arrived at. Some of the important principles used in arriving at the compromises that are represented in the IAP Immunization Time Table will be

given below, in response to the questions raised by the very thoughtful and perceptive colleague.

1. *Hepatitis B Vaccine*

Hepatitis B Virus (HBV) infection and its consequences, including the frequency of virus carriers, are of much greater magnitude in our country than in the USA. There are approximately 36 million HBV carriers in India, while there probably less than 2 million in the USA. The magnitudes of vertical transmission and horizontal transmission during childhood are much greater in India than in the USA.

The AAP has deferred the decision on routine booster(s) of HBV vaccine. In the absence of definitive data they have chosen to go slow and make a decision later. Our view was that we should make our provisional decisions now. We have asked ourselves the optimum number of doses of HBV vaccine given during the 'pediatric' age group, which will give life-time protection, even if no further doses would be given. The Committee came up with 5 as the answer and chose this recommendation in spite of the cost, for two reasons. At the present time, while the price of HBV vaccine is high, we are recommending the vaccine only to those who can afford. If we were to make a recommendation to the Government for including HBV vaccine in the National Immunization Programme, and if the Government were to budget the cost of immunizing annual cohorts of 25 million infants, we could have perhaps come up with a different recommendation. Secondly, the Committee is confident that the price of HBV vaccine is very much negotiable and that in due course the price can (and will) come down to a fraction of what it is now.

Some 30 to 40 per cent of mothers have antibodies to HBV, either anti-HBs or anti-HBc or both. They passively transfer these antibodies to their neonates. Thus many infants in India have the slightly dampening influence of HBV antibodies

on the active response to the vaccine. This is another reason why we chose to offer 5 doses in the first 15 years of life. If new data emerge to show that we could safely avoid one of the two boosters, we should then revise our recommendation.

2. *First Booster of DTP/OPV*

What we call DPT, in the alphabetical sequence, the Americans call DTP since D and T represent toxoids and P is the odd one out! After giving a 3 dose primary course of DPT, there is no great need for an early booster at 15 months of age in order to ensure protective immunity; any time during the second year of life would suffice. Regarding OPV, if only 3 doses were given during infancy, it would be very important to give additional doses, earlier the better; 15 months would be better than 18 or 24 months. However, IAP recommends 5 doses of OPV in the primary course of immunization. Therefore, once again there is no urgent need for another dose at an early age. Therefore the Committee chose the more traditional recommendation of 18 months, aligning it with the practice in the National Immunization Programme(NIP).

The Committee also considered the question of giving more than one injectable vaccines at one clinic visit and generally tried to avoid it except when unavoidable, such as giving DPT and HBV vaccine at one session. Thus we recommended MMR vaccine at 15 months and DPT booster at 18 months. From an immunological point of view there is not much to choose between 15 and 18 months of age for a booster since the last dose in the primary course would have been some 9 to 12 months earlier.

3. *TT Booster at 10 years*

Having recognized that tetanus in adolescents and adults is a greater public

health problem, and more neglected, than neonatal tetanus, the Committee asked the question: how many doses of TT given during pediatric age would give life-long protection? In the case of HBV, there are chances of natural booster effect following exposure to infection, especially when immunity wanes with time. This is unlikely to happen in the case of tetanus, since infection with *Clostridium tetani* does not result in immune response to tetanus toxin. Although we could make recommendations of periodic boosters in adults, both for HBV vaccine and for TT, we realize that such recommendations are unlikely to be practiced in the majority of cases. If 3 doses of primary DPT are given, one booster in 2nd year of life, one booster at 5 years, one TT at 10 years and one more at 15 years of age, these would add up to 7 doses. The least likely and most expendable dose, we felt would be the one at 15 years. With at least 6 doses, the likelihood of life-long protection is very high.

It is true that repeated doses of TT (or any other vaccine) might result in side-effects such as Arthus reaction. Horses given hyper-immunization with TT or DT have a tendency to develop amyloidosis. With 6 or 7 doses spread over 10-15 years, we do not anticipate an increase in side-effects. In practice we do not see Arthus reaction with such widely spread out doses of TT. With DT, there is a greater chance of Arthus reaction since natural stimulation, and booster effect, may occur with sub-clinical infection by *Corynebacterium diphtheriae*. Therefore one had to reduce the dose of DT (denoted as dT) when given to older children or adults. This information also offers the clue as to why we do not recommend dT beyond 5 years of age.

4. Interval between primary DTP and OPV doses

The antibody levels attained after giving 2 doses of DPT at an interval of 8 weeks (2 months) are significantly higher than those attained after an interval of 4 weeks. However, the antibody levels after 3 doses are not so widely different whether the interval was 8 weeks or 4 weeks. The same phenomenon is also applicable to OPV; here the seroconversion rates should replace the antibody levels.

In fixing the 4-week interval we have used a principle of compromise. The Committee made a conscious decision not to tamper with the NIP immunization schedule, but to recommend additional doses of the same vaccines and some additional vaccines. This approach has been appreciated by the Director General of

Health Services and has avoided a potentially piquant situation when parents could quarrel with the staff of NIP arguing about the better interval between doses. Since there is not much immunological advantage for 6-8 weeks intervals when 3 doses are given, the Committee recommends 3 doses with a minimum interval of 4 weeks, between doses. The 4-week interval is qualified as minimum, leaving room for giving greater gaps, such as 6 to 8 weeks at the discretion of the pediatricians.

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NOTES AND NEWS

**2nd ANNUAL CONVENTION TWIN CITIES BRANCH AND 16th ANNUAL
CONFERENCE OF AP STATE CHAPTER, IAP**

This event is being hosted by Indian Academy of Pediatrics, Twin Cities Branch on 27th-28th July, 1996 at Gandhi Medical College, Hyderabad. For further details please contact: Dr. M. Indra Shekhar Rao, Organizing Secretary, 'Indraprastha' 106, Abhinavnagar, Padmaraoanagar, Secunderabad 500 025. Tel: 7610156.

WORKSHOP ON PEDIATRIC ENDOCRINOLOGY

This workshop is being organized by Indian Academy of Pediatrics, W.B. Branch on A 17 November, 1996 at Kothari Medical Center. For further details please contact: Dr. Tapan Kr. Ghosh, Secretary, IAP, W.B. Branch, 53, Creek Row, Calcutta 700 014.