Recommendations

Update on Immunization Policies, Guidelines and Recommendations

The Indian Academy of Pediatrics Committee on Immunization (IAPCOI) conducted its deliberations in New Delhi on 4th and 5th October, 2003 (Members, who participated in the deliberation, are listed in Annexure I). We reviewed our stand on various policies, guidelines and recommendations pertaining to childhood immunization. As has been enunciated earlier, "policies" are the decisions taken by the Academy in relation to the scientific principles and practice of immunization. "Policies" are, expected to be practiced by all members of the Academy. "Guidelines" relate to those items which are outside the purview of policy, and for which guidance is necessary. Guidelines usually pertain to newer vaccines or issues related to them. "Recommendations" are, in general, what the academy in its role of advocacy on behalf of children, requests other agencies to do. These agencies may include international funding agencies, the Government of India or other professional bodies.

It should be noted that the IAP immunization time-table is, in effect, the 'best individual practices' schedule and may be somewhat different from the national immunization schedule. This is because of the fact that the former is meant to be used for an 'individual' patient, rather than for the pediatric community at large as in the case of the latter. The two schedules are, however, not in conflict with each other. Also, as pediatricians we must be conscious of the fact that the immunization needs of children in a country are quite dynamic - a vaccine which may not be considered important today may become necessary after some time as more information about the epidemiology of the disease becomes available. Further, in developing countries affordability of the vaccines is a critical issue and any decision on incorporation of a new vaccine in the immunization schedule has to take this into consideration. The IAPCOI has based its deliberations on the best available evidence and we hope that this would become a regular feature of such meetings in the future.

It is heartening to note that some of the recommendations of the IAPCOI in the past have been instrumental in changing governmental policies and also the immunization schedules being followed by some states.

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IAP Policies on Immunization, 2003

1. On NTAGI

The IAP welcomes the establishment of the National Technical Advisory Group on Immunization (NTAGI) by the Government of India. This followed a formal recommendation from the IAP, given a couple of years ago. The Secretary, Department of Family Welfare is the Chairperson of the Committee while the Assistant Commissioner, Immunization Program is its Member Secretary. The IAPCOI now recommends that the IAP should be represented on this important committee by its incumbent President and the Chairperson/ Convener of the IAPCOI.

2. On Universal Immunization Program (UIP)

The IAP continues to endorse and reiterates its support to the national immunization schedule while recognizing the fact that much more needs to be done for meeting the current immunization requirements of the children of our country. It is a fact that except for the recent phased introduction of Hepatitis B vaccine in a few districts, no new vaccine has been introduced in the national program since the last 25 years. All vaccines under UIP should continue to be available free of charge to all eligible children.

3. On Pulse Immunization against Polio

The Academy fully supports the Government of India in the use of oral polio vaccine (OPV) for the pulse immunization program against polio. It is our considered opinion that, in spite of some operational hiccups, we must continue with this program and bring it to its logical conclusion, i.e., till wild polio virus is eradiacted from our country.

4. On DPT/OPV

The IAPCOI endorses the use of five doses of DPT/OPV at 6,10 and 14 weeks and thereafter at 15-18 months and 5 years respectively. An additional dose of OPV is to be given at birth to all institutional deliveries. It should be noted that we continue to endorse the use of DPT (rather than DT as in the national program) at 5 years.

5. On "Newer" Vaccines

The IAPCOI suggests that the UIP should be supplemented by the following vaccines: Hepatitis B (HB), MMR and Typhoid. Another important vaccine which merits active consideration is Hemophilus influenzae type b (Hib), but affordability would be an issue here. Parents, however, should be made aware of the availability of these vaccines.

Varicella and Hepatitis A vaccines are still not recommended for routine use.

(*a*) *Hepatitis B vaccine:* We wish to emphasize the fact that in our country horizontal transmission of Hepatitis B virus also appears to be an important mode of transmission of the disease along with the vertical *i.e.*, mother-to-child.

HB vaccine may be given in any of the following schedules:

(*i*) 0, 6 and 14 weeks

(*ii*) 0, 1 and 6 months

(*iii*) 6, 10 and 14 weeks

If the mother is known to be HBsAg negative, HB vaccine can be given along with DPT at 6, 10 and 14 weeks. In the latter case, there is no special requirement to start vaccination at birth itself. This schedule may be easier to implement in the context of the national immunization program, but for an optimum immune response the recommended interval between second and third doses of HB vaccine should be at least 8 weeks.

If the mother is HBsAg positive (and especially HbeAg positive), the baby should be given Hepatitis B Immune Globulin (HBIG) within 24 hours of birth, along with HB vaccine. The injections should be given at two separate sites. If HBIG is not available (or is unaffordable), HB vaccine may be given at 0, 1 and 2 months with an additional optional dose between 9-12 months.

Boosters of HB vaccine are not necessary in immunocompetent individuals. The vaccination schedule need not be changed for preterm and small-for-dates babies; in the case of extremely preterm babies, however, vaccination should only commence after initial stabilization.

(*b*) *MMR vaccine:* This vaccine should be

promoted as a universal vaccine. It should be given between 15-18 months of age *i.e*., at least 3 months after the measles vaccine. It should also be given to all adolescent girls not previously immunized as also to hospital staff likely to come in contact with pregnant mothers. There is no upper age limit for this vaccine.

(*c*) *Typhoid vaccine:* The IAPCOI strongly recommends the use of typhoid vaccine for all children. Of the 3 types of vaccines available (*viz*., Vi-polysacharide, whole cell inactivated and oral Ty-21a), only the Vi-polysacharide vaccine is freely available in our country at present. It can be given to children above 2 years of age and boosters are required after 3-5 years. The government should explore the possibility of manufacturing this vaccine in the public sector on large scale so that the costs are brought down.

(*d*) *Hib vaccine:* Hib vaccine should be offered to all children and may be given at 6,10 and 14 weeks along with DPT. A booster is given at 15-18 months. If vaccinations are started after 6 months of age, only two doses (at 2 months interval) need be given as primary schedule with a booster at 15-18 months. If vaccination is started between 12-15 months of age, only one dose need be given, with a booster at around 18 months. After 15 months of age only one dose of the vaccine needs to be given - no boosters are required under such circumstances.

Hib vaccine is also recommended for all children, irrespective of age, prior to splenectomy and also in patients with sickle cell disease.

At present the cost of this vaccine is prohibitive.

IAP Guidelines on "Newer" Vaccines, 2003

The IAP Guide Book on Immunization was last updated in the year 2001. We hope to revise it and publish the updated version shortly. It would have more complete information on the suggested IAP immunization timetable and the "newer" vaccines. This update pertains to some of the deliberations of the IAPCOI pertaining to "newer" vaccines and related maters.

1. Hepatitis A vaccine

Hepatitis A (HA) vaccine is not recommended for universal immunization in India at present. One has to emphasize the generally benign nature of and rarity of complications with, Hepatitis A infection in young children. It may be offered to children from high socio-economic strata of society after explaining the pros and cons to the parents on a one-to-one "named child" basis. It may be prescribed to adolescents who have not had viral hepatitis in childhood (or are known to be HAV-IgG negative) and are leaving home for studies in a residential school/ college. HA vaccine is indicated for all patients with chronic liver disease as well as household contacts of patients with HA virus infection - in the latter case the vaccine must be given within 10 days; it may, however, be not always effective under such circumstances if the contact has the same source of infection as the index patient. It may also be considered in children attending creches and day care centers and in travellers from abroad (*e.g*., non-resident Indians) visiting endemic areas.

It is given in a 2-dose schedule, 6 months apart. The recommended dose is 720 ELU for children in the age group 2-19 years and 1440 ELU thereafter.

2. Varicella vaccine

The IAPCOI opines that varicella vaccine is not recommended for universal immunization in India at present. One has to emphasize

the generally benign nature of and rarity of complications with, varicella infection in young children. It may be offered to children from high socio-economic strata of society after explaining the pros and cons to the parents on a one-to-one "named child" basis. It may be prescribed to adolescents who have not had varicella in childhood (or are known to be varicella IgG negative) and are leaving home for studies in a residential school/college. It is indicated in children with chronic lung/heart disease, humoral immunodeficiencies, HIV infection (but with CD 4 counts above 25% of the age related norms), leukemia (but in remission for at least 1 year) and those on long term salicylates/steroids. Varicella vaccine is also recommended in household contacts of immunocompromized children. It may also be considered in children attending creches and day care centres.

Varicella vaccine is also indicated in susceptible adolescents and adults if they are inmates of or working in the institutional set up *e.g.*, school teachers, day care center workers, military personnel, health care professionals *etc*.

A single dose suffices between the ages of 1-13 years, after which a 2-dose schedule (4-8 weeks apart) is recommended.

3. Acellular pertussis vaccine

The IAPCOI endorses the continued use of whole cell pertussis vaccine (as DPT) because of its proven efficacy and safety. Acellular pertussis vaccines may undoubtedly have fewer side-effects (like fever, local reactions at injection site and irritability), but this minor advantage does not offset the inordinate costs involved in the routine use of this vaccine. Acellular pertussis vaccines are also, by no means, more effective than the whole cell pertussis vaccine. These are, therefore, not recommended for universal immunization in our country at present. There is, however, no bar to offering these vaccines to children from well-off families who opt for the prohibitive costs for the slight advantage of fewer minor side-effects.

Use of acellular pertussis vaccine should, however, be considered in children who have had significant reactions to a previous dose of whole cell pertussis vaccine. These include:

(*i*) convulsions with/without fever occurring within 3 days.

(*ii*) persistent inconsolable crying for 3 or more hours within 48 hours.

(*iii*) collapse or shock-like state within 48 hours.

(*iv*) temperature $\geq$40.5 ºC within 48 hours.

4. Inactivated Polio vaccine (IPV)

The IAPCOI recommends that the Government should immediately license the use of inactivated polio vaccine in India. As the number of wild polio virus cases in the country decreases, it is inevitable that one would have to gradually shift from OPV to IPV in the next few years. The government should, therefore, consider incorporating IPV gradually in the national immunization schedule in a phased manner, starting from the states where polio has been eliminated.

IPV is also the vaccine of choice in patients with humoral immunodeficiencies and the preferred vaccine in children with HIV infection.

5. Japanese Encephalitis (JE) vaccine

JE vaccine should be used for universal immunization of children aged 1-3 years in all hyperendemic districts of our country. At present only limited supplies of the vaccine (inactivated mouse brain - Nakayama strain) are available from the Central Research Institute (CRI), Kasauli. The vaccine is

supplied to state governments directly by the CRI and cannot be procured from the market for use of individual patients. Primary vaccination is done with 3 doses given at 0, 7 and 30 days with boosters every 2 years till 10-15 years of age. Contrary to common belief, this vaccine is not meant to be used as an 'outbreak response' vaccine.

6. Pneumococcal and Meningococcal vaccines

Both these vaccines are not indicated for universal immunization in our country at present. The 23-valent pneumococcal vaccine (only unconjugated polysaccharide vaccine is available in India at present) may be used for patients who are under consideration for splenectomy or those with nephrotic syndrome (in remission), HIV infection, cerebrospinal fluid rhinorrhea, sickle cell anemia, asplenia, chronic lung/heart disease, diabetes mellitus and chronic renal failure. Meningococcal (A and C) vaccine is indicated for use (as an adjunct along with chemoprophylaxis) in close contacts of patients with the disease. It is also indicated in high risk individuals (*e.g.*, those with hyposplenia/asplenia, complement deficiency) during epidemics.

7. Combination vaccines

The number of vaccines in the immunization schedule is increasing every year and this trend is likely to continue for the next few years. Many parents opt for one single injection of combination vaccines at a given visit, rather than come repeatedly for the various individual vaccines that are now included in the immunization time-table. A number of combination vaccines are now available in the Indian market. The IAPCOI endorses the use of combination vaccines, but with the following cautionary statements:

(*a*) the manufacturer's recommendations should be adhered to strictly;

(*b*) "mixing" of vaccines in the same syringe (prior to injection) should not be done as far as possible, unless specifically recommended by the manufacturer; in the latter case the manufacturer's instructions should be followed strictly;

(*c*) the only advantage of a combination vaccine is the convenience of fewer clinic visits for the parents and fewer pricks for the child;

(*d*) combination vaccines should not be viewed as being more effective than vaccines given separately.

8. Adolescent vaccination

The Academy endorses the continued use of tetanus toxoid at 10 and 16 years and thereafter every 5 years. HB vaccine may be offered in the 0, 1 and 6 or 0, 1 and 2 months schedule, as mentioned earlier under individual vaccines, if the child has not received it earlier. MMR vaccine should be offered to all children who have not received it earlier - there is no upper age limit for this vaccine. The Academy encourages the use of typhoid vaccine for all adolescents. Hepatitis A and varicella vaccines should be used in selected cases as mentioned above.

9. Immunization records

Every vaccine given to a child must be documented on a card/booklet. We recommend the Immunization card of the IAP for this purpose. Parents must be instructed to keep the document safely and to present it to their doctor whenever required.

10. Advertisements in the lay media

Some of the multinational companies have been using the lay media (television, electronic media and newspapers/magazines) for placing advertisements pertaining to optional/ combination vaccines. We opine that this is

unethical. The IAP placed a formal complaint before the Drug Controller General of India and the Union Health Ministry. This led to the issuance of a letter by the Drug Controller to the concerned companies requesting them for the withdrawal of these advertisements. These advertisements have not been seen in the lay media after that. We are hopeful the companies would continue to refrain from lay advertising in the future as well.

IAP Recommendations on Immunization, 2003

The IAPCOI has formulated several specific recommendations to other agencies pertaining to immunization.

1. Recommendations to Ministry of Health, Government of India

(*a*) The IAP recommends that the Academy should be represented on NTAGI by its incumbent President and the Chairperson/ Convener of IAPCOI.

(*b*) At 5 years of age booster immunization should be done with DPT rather than DT.

(*c*) The Academy recommends that inactivated polio vaccine should be immediately licensed in the country and gradually introduced in a phased manner, starting from the states where polio has been eliminated.

(*d*) The Academy strongly recommends that Hepatitis B and MMR vaccines should be included in the national immunization schedule with immediate effect.

(*e*) The Government should actively consider inclusion of typhoid vaccine in the national immunization schedule. The Academy suggests use of Vi-polysaccharide vaccine for this purpose. However, the whole cell inactivated typhoid vaccine may also be acceptable, as it is much cheaper to produce. However, the latter vaccine does have significant side-effects.

(*f*) Another vaccine which needs serious consideration for inclusion in the national immunization schedule, while awaiting disease burden studies, is Hib vaccine. However at present the cost of this vaccine is prohibitive.

(*g*) The Academy supports the decision of the Government to discontinue production of animal brain rabies vaccine. However we need to ensure adequate supplies of indigenously produced chick embryo/ tissue culture vaccines at affordable costs.

2. Recommendation to the Federation of Obstetric and Gynecologic Societies of India

The Academy again reiterates its previous recommendations to adopt a policy of routine testing of all pregnant women for HBV infection. If the mother is HBsAg positive, the baby should be given HBIG plus HB vaccine soon after birth.

Annexure I

Members of the Indian Academy of Pediatrics Committee on Immunization (IAPCOI))

Chairperson: A.P. Dubey; *Convener:* Surjit Singh; *Members:* Mukesh Agrawal, Sunil Gomber, Ritabrata Kundu, P. Ramachandran, and A.G. Shingwekar; *Co-opted Member:* P.S. Patil; *Ex-officio:* A.K. Dutta, Tapan Kumar Ghosh, H.P.S. Sachdev, Nitin Shah, Raju C. Shah, Naveen Thacker; *Invited Experts:* T. Jacob John, Rakesh Sehgal; *Special Invitees:* Anju Aggarwal, N.K. Arora, Panna Choudhury, Seema Kapoor, Prashant Mathur, Jitender Nagpal, Sushma Nangia, Dheeraj Shah, Suvasini Sharma, Sangita Yadav.