Policy Update

IAP Committee on Immunization

Writing Committee

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The Indian Academy of Pediatrics Committee on Immunization (IAPCOI) conducted its deliberations in Mumbai on 11th of March 2007. (Members, who participated in the deliberation, are listed in Annexure I). We formulated recommendations on certain issues related to childhood immunization. The position of the IAP COI on these issues is listed below. These recommendations are an update to the latest IAP COI guide book on Immunization (2005-2006).

Inactivated Polio Virus (IPV) vaccines in individual practice

The IAP has already communicated its viewpoint on the role of IPV in the polio eradication program in a previous publication (1). However with the availability of the inactivated polio virus vaccine in the open market an urgent need was felt to issue guidelines and resolve controversies pertaining to its use in individual patient practice. The committee agreed that

- Oral polio vaccine (OPV) must be continued at present in every individual child with or without IPV (*i*) so as not to conflict with the existing national EPI schedule (*ii*) for achieving polio eradication. OPV has been highly successful in most states in the country while suboptimal performance in few districts is due to various factors and not the efficacy of the vaccine alone. Most of the countries have achieved polio eradication by use of OPV alone.
- IPV produces excellent humoral immunity as well as local pharyngeal immunity and possibly intestinal immunity. The vaccine is very safe. It is the preferred vaccine for patients with immunodeficiency and their contacts.
- As IPV gives excellent individual protection, it may be considered in addition to OPV schedules in affordable population. This implies that even if IPV is given OPV should be continued as per the EPI schedule as well as the extra doses on the national/sub national immunization days (NID's, SNID's). Shifting to an all IPV schedule at this juncture is likely to jeopardize the national polio eradication program. The risk of vaccine associated paralytic poliomyelitis (VAPP) associated with OPV is lower in India as compared to other countries due to early routine immunization with OPV and high titers of maternal antibodies(2).
- IPV cannot replace OPV at this time but it may do so over the years.
- IPV should be placed under the category of vaccines which are to be given after one to one discussion with parents on a named child basis.
- In the discussion with parents the advantages of IPV in terms of reliable immunogenicity and hence additional individual protection should be explained. The reasons for continuing OPV should be stressed (mentioned earlier).
- The ideal schedule for IPV administration is to start vaccination after 8 weeks of age and maintain an interval of 8 weeks between doses. With this time line minimum two doses are sufficient to complete primary immunization. A single booster should be given at 18 months. There are no prerequisites for spacing OPV and IPV.
- However for logistic and convenience reasons it

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would be easier to administer IPV at 6, 10 and 14 weeks with the other EPI vaccines. The immune response with three primary doses as per this schedule and a booster at 15-18 months is also satisfactory. This schedule will be particularly convenient to use when combination vaccines containing IPV become available.

- Suggested schedules are as under:

Child who has not received any polio vaccination so far:

(*i*) Birth dose of OPV, OPV at 6 weeks, OPV and IPV at 10 weeks, OPV at 14 weeks and IPV at 18 weeks. Booster of OPV and IPV at 15- 18 mths and OPV at 5 years. OPV on all NID's and SNID's.

(*ii*) Birth dose of OPV, OPV and IPV at 6, 10 and 14 weeks. Booster of OPV and IPV at 15-18 mths and booster of OPV at 5 years. OPV on all NID's and SNID's.

Child who has completed primary series of OPV

(*iii*) For a child who has completed primary immunization with OPV, IPV can be given as three doses; 2 doses at 2 month interval followed by a third dose at 15-18 months. The 1st and second booster of OPV would be given unchanged. OPV on all NID's and SNID's.

- For children with HIV and other immuno-deficiencies as well as for family members of immunodeficient children IPV should be the preferred vaccine if resources permit. OPV should be avoided. Primary vaccination should be given with either 2 doses of IPV at 10 weeks and 18 weeks OR 3 doses of IPV at 6,10 and 14 weeks. Two boosters at 15-18 months and at 5 years are necessary.
- IAP PEC and previous IAP COI has strongly recommended that IPV will be required in post eradication phase of Polio and Government of India should include this vaccine in the national immunization schedule gradually.

Combination vaccines of DTP/ DTaP with Hib/ HBV

- There are several international published trials about acceptable safety and immunogenicity of combination liquid vaccines and combination lyophilized vaccines of DTwP + Hib/HBV in the developed and developing world. Both combination lyophilized and liquid combination vaccines of DTwP + Hib/ HBV are being marketed in the developed western world.
- Published Indian trials on combination of DTwP with lyophilized Hib show acceptable immunogenicity and safety of these vaccines. As of now there are no published trials in Indian children about liquid combination vaccines (DTwP + Hib/ HBV). However the results of a combination liquid vaccine trial in Indian children which was presented at an international conference and is accepted for publication in Human Vaccines show acceptable immuno-genicity and safety of liquid combination vaccines in Indian children. Additionally there is an ongoing multicentric trial on the safety and immunogenicity of combination liquid vaccines in India the results of which are expected by the end of the year.
- Based on this information the committee at present considers both liquid and lyophilized vaccine combinations of DTwP + Hib/ HBV equally safe and effective for both primary and booster immunization. The committee will actively review the results of the ongoing multicentric trial of liquid combination vaccines in Indian children once they are available.
- The committee opined that if acellular pertussis vaccine is chosen instead of whole cell pertussis vaccine then a combination of DTaP and lyophilized Hib could be used for both primary and booster immunization. The manufacturer's instructions for combining the two vaccines should be followed.
- It is ideal to complete immunization schedule in a given child with the same brand of combination vaccine unless not available, in which case any other brand may be substituted.

Need for second dose of MMR in private practice

- In accordance with available scientific evidence as well as WHO and CDC recommendations, the committee opined that there is a need for a second dose of MMR for providing durable immunity against mumps and rubella.

- The second dose of MMR should be given at 5years of age at the time of school entry but it can be given at any point of time 8 weeks after the first dose.
- Practitioners are also urged to provide catch up immunization with a total of two doses of MMR vaccine to those children/ adolescents who have not received any dose of MMR in the past or who have received only one dose of MMR so far.

Inclusion of MMR vaccine in the National Immunization Schedule

The committee feels that MMR is an important vaccine for inclusion in the national immunization schedule as it will (*i*) provide protection from rubella and thus help in achieving control of congenital rubella syndrome (CRS). (*ii*) improve measles control by achieving seroconversion of those not protected by first dose and by giving a second opportunity to those who missed the first dose (*iii*) achieve control of mumps. The vaccine has also been shown to be cost effective in developed countries.

However with inclusion of the vaccine in the national immunization schedule may prove counterproductive in areas where the vaccine coverage is likely to be between 30%-60% by increasing the risk of congenital rubella syndrome in such areas due to epidemiologic shift.

The committee therefore suggests that

- The vaccine should only be introduced in those districts where primary coverage with the measles vaccine is consistently more than 80%.
- With the introduction of the vaccine a system for estimating the burden of rubella/ CRS should be simultaneously instituted so that the impact of vaccination on this burden may be estimated and any epidemiologic shift detected. Logistics of such a system have been enumerated in detail in WHO publications. The vaccine should not be introduced if it is not possible to institute such a monitoring system.
- All strains of the mumps vaccine are equally safe.
- The vaccine may be administered with the first booster at 15-18 months.
- In those areas where MMR is introduced in the national immunization schedule catch up vaccination of all adolescent girls (11-12 yrs age group) should be done to rapidly reduce the risk of CRS and counter any epidemiologic shift.
- Once reasonably good coverage has been achieved with the first dose of MMR there would be a need in future to assess the need for a second dose of the vaccine at school entry.

REFERENCES

1. Shah NK, John TJ, Thacker N, Vashishtha V, Kalra A, Ugra D. Polio eradication strategies in Indian recommendations under IAP Action Plan 2006. Indian Pediatr. 2006; 43: 1057-1063.
2. Kohler KA, Banerjee K, Gary Hlady W, Andrus JK, Sutter RW. Vaccine-associated paralytic poliomyelitis in India during 1999: decreased risk despite massive use of oral polio vaccine. Bull World Health Organ. 2002; 80: 210-216.

Annexure 1

Participating Members of IAP COI 2007-2008

Y.K. Amdekar (*Chairperson*)
Naveen Thacker (*Co chairperson*)
Tanu Singhal (*Convener*)
Anju Aggarwal
Jaydeep Choudhury
Parang Mehta
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