'One to One' Immunization Guidelines

We read with interest the Consensus Recommendations on Immunization, 2008 developed by the IAPCOI(1). We appreciate the efforts of the expert committee in formulating guidelines. We have a few concerns about the recommendations. The article mentions that the guidelines have primarily been developed for the pediatricians in office practice. The Indian Academy of Pediatrics being a protector of the child's rights and being committed to the improvement of the health and well being of all children(2), it would have been desirable that the guidelines were based on the needs of children rather than availability!

The other major concerns are as follows:

1. The expert committee appears to have ignored the basic principles of immunization for many vaccines especially the newer ones. The estimates of the disease burden for many diseases are flawed. The prominent being: pneumococcal pneumonia, cervical cancer due to HPV, and rotaviral diarrhea. While reasonable estimates for many of these are not available, extrapolating the data from the western world without adjusting for Indian circumstances is not an acceptable substitute. The principle of recommending the vaccine to those with highest risk has been ignored and on the contrary recommending certain vaccines only for those who can afford even when the disease epidemiology does not justify the recommendation probably serves only the commercial interests.

2. There is no justification to have the category- 'Vaccines which are to be given after one-to-one discussion with the parents'. If the current evidence does not support the use of vaccine, the same should be stated clearly. It is convenient to categorize a few vaccines specifically for the office pediatricians, but the committee has not issued any guidelines for the 'one- one discussion'. What should the parents be told- the vaccine is safe, effective, but the current epidemiologic evidence does not support the use of the vaccine. Does it imply that all vaccines that have been developed and are proven to be safe will be categorized in this category if the available evidence does not support the routine use of the vaccine? For an expert committee, the decisions about the use of the vaccines should be based on scientific merit. Therefore, mentioning the issue of affordability in the recommendations is inappropriate.

3. The committee should have only 2 categories for the recommended vaccines – one for healthy children and one for special circumstances/ scenarios that are justified on the basis of the scientific evidence. In addition, the committee should have listed the vaccines the use of which cannot be recommended at this time. This approach would have helped the government program to consider the vaccines recommended.

4. The reference for the statement in the article 'Mucosal immunity as measured by stool excretion of virus after mOPV1 challenge is superior with combination of OPV and IPV as compared to IPV alone'(3) is inappropriately used. The cited study(3) had compared the mucosal immunity induced by enhanced-potency inactivated and oral polio vaccines individually; there was no group that received the combination. In this study, mucosal immunity produced by OPV and enhanced-potency inactivated polio vaccine (E-IPV) was compared by challenging vaccinees with type 1 OPV. Fewer OPV (25%) than E-IPV (63%) vaccinees excreted OPV virus in stool after challenge. The mean stool virus titer was higher and the duration of shedding longer among E-IPV excreters(3).

5. The statement 'The risk of VAPP with this combined OPV and IPV schedule is extremely low as the child receives OPV at the time when he/she is protected against VAPP by maternal antibodies, is again without any evidence. The cited reference(4) evaluates only the use of OPV and not the combined OPV and IPV schedule.

6. If the committee is convinced about the greater efficacy of the eIPV over OPV, the same should be stated clearly and a recommendation be made to the government and the program. The committee should have clearly stated the recommendation for use of only eIPV for immunocompromised children.

7. Table II inaccurately includes Hib as an EPI vaccine. Similarly while Table II lists DTaP as a vaccine which is to be given after one-to-one discussion with the parents, the same is included in Table III as a recommended vaccine which again is misleading.

8. While varicella is listed as a category 3 vaccine, in the text the committee 'continues to recommend single dose of varicella vaccine in children aged below 13 years.', implying that it is recommended for all children; which is inaccurate. Similar is the case with Hepatitis A vaccine.

9. The recommendation of use of rabies vaccine as 'a pre-exposure prophylaxis for children at high risk of rabies' without defining 'those at high risk' is inappropriate.

10. It would have been appropriate for the committee to grade the evidence collected as is the norm for evidence based guidelines.

11. The listing of brands is not justified in a recommendation paper. It is also a deviation from the committee's earlier exercises.

We raise these issues for an academic and a healthy debate, the result of which is in the best interests of the children of the country irrespective of their economic status and in tune with the stated commitments of the IAP towards the improvement of the health and well being of all children.

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Reply

The Indian Academy of Pediatrics Committee on Immunization (IAPCOI) thanks the authors for raising the issues and is pleased to offer the following clarifications.

The IAPCOI has a clear responsibility assigned to it which is to provide guidelines on the use of licensed non EPI vaccines for the members of IAP and NOT for public, parents or children. The regulatory authority does not give guidelines for their use by health care providers. The UIP or its advisory committee (NTAGI) also does not provide guidelines for their use. The vaccine brochure gives product information and contraindications if any etc. Thus, the COI has the responsibility to help members in their choice of vaccines for children whose health care and preventive medicine is their responsibility.