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.

Therefore it is very important that IAP issues guidelines for the use of these vaccines, in a standardized way and guides its members about prioritizing the non-EPI vaccines into what are to be actively promoted (Category 2) and what need not (Category 3). Furthermore, the committee feels that on the strength of whatever data that is available none of the currently licensed vaccines can be put in the "not recommended" category. Understandably, individuals may hold their own opinions. That is precisely the reason why IAP has to evolve a consensus among the COI members and have collective guidelines.

Naturally, COI will deal with only vaccines that are licensed in the country – hence only those that are available. Conducting epidemiological research and pointing out the need for licensing unlicensed vaccines is the prerogative of all members of IAP. Similarly, creating demand for research and development of vaccines for infections without available vaccines is also for researchers to undertake.

The process of formulating the recommendations and logic behind categorization of vaccines has been adequately explained in the document and needs no further elaboration. The document explicitly states that these guidelines/ recommendations are expert opinion, based on what ever information is currently available and are subject to change as new information emerges. It should be kept in mind that these collectively made guidelines that represent the official view of the Academy are not regulations or even rules but points to guide – to help paediatrician's make the optimum choice regarding available vaccines in the best interests of the children whom they care for. Hence the aim is children's health and NOT bringing about financial gains to paediatrician's and/or vaccine manufacturers.

Another point of debate has been recommendation regarding rationale behind combined use of both OPV and IPV. It is reiterated that when a shift from OPV to IPV in most countries has been gradual with first moving towards a combined/ sequential OPV, IPV schedule to then an all IPV schedule. In fact, the switch in the national program post polio eradication is envisaged to be a gradual switch and OPV would be withdrawn under an IPV umbrella. In keeping with these strategies and to minimize any disruption of the national program the committee had recommended a combined schedule. Future committees may consider an only IPV schedule. The committee has already made a clear recommendation to the government about the role of IPV in India in the polio eradication and the post eradication era(1). A recommendation about only IPV use in immunocompromised children cannot be made as it is known that children with HIV infection can safely receive OPV(2).

The committee does not feel that there is any ambiguity in the document regarding categorization of vaccines including Hib, DTaP, varicella and hepatitis A. Such ambiguity only arises if statements are picked up and quoted out of context. Readers are referred to the recently published immunization guidebook for more detailed discussion on individual vaccines(3). The listing of brand names has been done for clarity and understanding of readers and is congruent with all international recommendations where brand names are consistently listed(4).

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Prevention of Pertussis in Adolescents and Young Adults

The IAP Committee on Immunization (COI) recommends offering Tdap vaccine instead of Td/ TT vaccine in all children / adolescents who can afford to use the vaccine(1). Tdap is a costly vaccine, which many parents may not be able to afford. There is a need for a less expensive vaccine, though slightly more reactogenic because of whole cell pertussis antigen in reduced quantity, with full dose of tetanus toxoid and reduced quantity of diphtheria antigen. I seek views of the Committee on Immunization that till such a vaccine becomes commercially available can we mix 0.1 mL of DPT vaccine from 0.5 mL ampule in a 0.5 mL of tetanus toxoid and administer 0.5 mL of this mixture to individuals above 7 years of age?

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REFERENCE

1. Consensus Recommendations on Immunization, 2008; Indian Academy of Pediatrics Committee on Immunization (IAPCOI). Indian Pediatr 2008; 45: 635 - 648.

Reply

The question is examining the feasibility of using fractional dose of the wP containing vaccine to protect adolescents and adults. In an era of combination vaccines where different antigens are being licensed for mixing with other antigen/ combination manufactured separately- some even at different production units (for example DTP+Hep B with Hib conjugate vaccine), the suggestion of Dr Paul seems quite tempting and worth considering, especially for our country where significant disease burden coupled with exorbitant cost of the aP vaccines make it impossible to even think of exercising the option of using aP vaccines at mass level. However, to recommend such a practice, we need to have evidence of safety as well as of efficacy of the revised practice that can only be obtained through clinical trials. Further, the effect of such practices on the frequency of serious adverse events and on protection against disease has not been determined earlier. Hence, in the absence of such a data, IAPCOI can not recommend this alternative practice of using fractional dose of whole-cell pertussis vaccine for adolescent and adult vaccination.

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Multidose Vaccine Vials

Do we really need multi dose vaccine vials in Indian scenario? Just today, I came accross one very big house, having major share in combination vaccines, offering 2.5 mL vaccine for Rs. 275 per dose, with a tag - if you use it properly, you will get one additional dose from the same vial, as we get additional 0.3 mL for you. Its only 0.3 mL, how can that make an additional dose? These sorts of offer encourage malpractice, less than optimal dose to the patients, leading to inadequate protection.

Isn't this the right time for our immunization committee to take a stand regarding use of multiple dose because the common practice remains the same. Even if you are getting the vaccine at lower rate, patients have to pay the price of single dose only; so where comes the question of helping the masses?

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