

Reply

We sincerely thank Dr. M Sanklecha for raising certain extremely valid points in response to the recently published policy update of the IAP committee on Immunization and giving us opportunity to dwell further on this important issue. We would like to answer points raised by him and add additional information. A point by point clarification/ rebuttal is as below.

1. Oral polio vaccine (OPV) has been successful in eradicating poliomyelitis from many countries and most regions of India. Not having the desired effect in UP and Bihar is due to several other factors and not due to the vaccine efficacy alone. Most countries have shifted to all IPV schedule only after eradicating poliomyelitis and they still continue to recommend OPV as the vaccine of choice for outbreak control (1). Additionally countries like Japan continue to use OPV even several years after eradicating poliomyelitis. Thus OPV has served the community well.
2. Compared to the risk of VAPP reported in the US of 1 per 2.4 million per doses distributed and 1 per 7,50,000 first dose the risk of VAPP in India is estimated to be 1 case per 4.1 to 4.6 million OPV doses administered and 1 case per 2.8 million first dose (1,2). The lower risk of VAPP in India is attributed to high prevalence and titer of maternal antibodies, birth dose of OPV and early immunization with OPV in the routine immunization schedule (2). We agree that the actual risk to an Indian child may be higher because of receipt of greater number of doses. Nevertheless we have to continue with OPV as it is not feasible to introduce IPV in the National Immunization Schedule at present and that wild polio virus cases exceed VAPP as of today. No case of CcVDPV has been detected in India as of today due to sustained high immunization coverage. Since administering oral polio vaccine is a national program and law of the land there is no question of any medicolegal proceedings following complications of OPV.
3. The issue is whether we are ethically justified in administering OPV to that small segment of the country's children who can afford IPV? Let us

weigh the possible harms and benefits of this approach.

4. The only possible harm with also giving OPV to these children is the risk of VAPP. But we are recommending use of OPV alone at birth followed by one of two schedules; either OPV and IPV at 6,10,14 weeks or OPV at 6 weeks, OPV and IPV at 10 weeks, OPV alone at 14 weeks and then IPV alone at 18 weeks. So in effect the child receives maximally two doses of OPV before IPV and that too before 6 weeks. At this time he/she is protected against VAPP to a large extent by maternal antibodies (there is still a small risk of VAPP; the youngest child with VAPP was 37 days old). Later he/she is protected from VAPP by IPV. Even if we adopt an all IPV schedule the child may still be at a small risk for VAPP through exposure to the oral polio vaccine virus through doses administered during pulse polio rounds (about 70 % of country receiving 4 doses per year) or contacts/ environment before the child receives the first dose of IPV.
5. The benefits of giving OPV/ harms of not giving OPV are manifold. From an individual point of view giving OPV at birth and at 6 weeks would offer some protection against wild polio virus infection at that age (wild virus cases were reported from many states in year 2006). From the community point of view giving OPV would help in polio eradication as gut immunity offered by OPV is superior to IPV. It has been shown that more infants who have received IPV alone continue to excrete wild polio virus after a wild virus challenge as compared to those receiving OPV. Another collateral benefit of administering OPV is that the vaccine virus would spread to others thus further "vaccinating" other children. Further by not giving OPV we might create confusion in the minds of the parents whose children receive only IPV about the efficacy and safety of the vaccine and interfere with its uptake on the NID's and SNID's. The aim behind pulse administration of OPV on a single day to eliminate the virus from the guts of all children may thus not be achieved. Also as a cascade effect there might be some individuals who might not give immunization with OPV due to fear of

side effects and neither give IPV due to non affordability.

6. The benefits of co administering OPV with IPV thus seem to outweigh the risks. A sequential schedule of IPV followed by OPV has been suggested and used in several countries of Eastern Europe, Cyprus and Jordan. The advantages of a sequential schedule are lower cost as compared to an all IPV schedule with minimal risk of VAPP. It may not be practically possible in India at this point of time. To call patients who have completed routine vaccination with IPV at 6, 10, 14 weeks OR at 10/ 18 weeks for OPV alone may not be successful. Also as mentioned earlier the uptake of OPV on NID's and SNID's may not be good due to non familiarization of these parents with OPV. Additionally as there would be delay in acquisition of gut immunity in these children (till they receive their first dose of OPV which will only be by 4/5 months) and they might continue to excrete and disseminate wild virus and hamper polio eradication efforts.
7. There would be no harm if one considers two booster doses of IPV at 18 months and 5 years. However IAP COI has suggested minimum additional doses of IPV required in the present scenario so that many more in the population may afford it. This does not preclude using more doses for affordable population.

As of now, children < 5 years of age are susceptible and hence last booster dose is recommended at 5 years of age. Over few years we hope to eradicate polio so that there would be no fear of shift in age prevalence of disease and so there would be no need to advance age of immunization.

8. IAP COI is concerned with offering best of protection to all children in the country without disturbing national immunization schedule and at

the same time, offering additional protection to the affordable population with minimum expenditure. Also the aim is to eradicate wild polio from the country and not be satisfied with individual protection to those who can afford better but costly vaccine. Such individual protection by IPV to only affordable population would lead to divide between different socio-economic groups and confusion arising may delay polio eradication efforts. It would then defeat very purpose of vaccination against polio.

Therefore IPV cannot replace OPV completely at this stage. However in future a shift to a sequential and/or then all IPV schedule is anticipated. Till this occurs on a programmatic basis, it is best that all IAP members follow official recommendations for the reasons mentioned above and not contribute to confusion. Surely the committee respects varied opinions from different members and welcomes them, but with a plea to keep individual views aside just to achieve our goal that we all are concerned with.

**Tanu Singhal,
Y.K. Amdekar,**

*P.D. Hinduja National Hospital and Medical,
Research Centre,
Mumbai 400 016,*

E-mail: tanusinghal@yahoo.com

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