IAP Immunization Timetable 2012 Clarifications

IAPCOI's We read the recent Consensus Recommendations on Immunization and IAP Immunization timetable 2012 [1]. We appreciate the sincerity and efforts put by IAPCOI in formulating these guidelines. Before we accept these guidelines and bring them into clinical practice, we would like to have few clarifications and share possible technical difficulties:

- 1. Omitting OPV from routine schedule at 6, 10 and 14 weeks. This is likely to create confusion among public, when one group is advised to take OPV and other group for not using OPV in routine schedule, purely on the basis of economic background. This is also likely to increase the demand of IPV, for which public sector may not be prepared yet. Wouldn't it have been wise to prepare such recommendation; while enforcing similar changes in National schedule too, when Government is prepared with enough stocks of IPV. So that confusion in public, at this vital stage of polio eradication could have been avoided.
- 2. When one decides to use IPV and not OPV in routine schedule, we are not convinced about using IPV-OPV schedule. When IPV is proved to be highly efficacious and able to provide equal mucosal immunity, why not go for only IPV schedule [2,3]? What is the justification for advising OPV later at 6 months and 9 months, knowing the difficulty in getting people at 6 months?
- 3. Regarding rotavirus vaccine, in absence of any efficacy trial on this issue from India, poor immunogenicity shown in developing countries, and prevalent strains not covered by presently available vaccines [4]; how justified are we in recommending this for routine use?
- 4. Regarding boosters of MMR and varicella, we would like to know the justification for recommending it at five years. Before recommending such boosters, we should know the status of persistence of protective antibody titres against these diseases at later ages after primary vaccination in our children. When natural infections are still likely to play a significant role in boosting immunity in our children, even if we need boosters, probably MMR and varicella boosters at 10 years would provide more robust immune response in our children rather than then giving at 5 years [5].

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REPLY

- 1. Again, we should not confuse with the committee's recommendations which are mainly for office practice. Considering the current state of polio eradication in the country, the committee believes that persisting with OPV poses significant risks both at the individual and public segment, vaccine associated paralytic polio (VAPP) at the former and circulating vaccine derived poliomyelitis (cVDPVs) at the latter. The move will also provide a timely policy 'signal' to Indian policymakers to expedite consultations on endgame and post-eradication vaccine policy. The recent SAGE April 2012 Working Group meeting confirmed early universal IPV introduction (as early as October 2013) integrated into routine immunization program (before planned April 2014 tOPV to bOPV switch) of the country [1]. So, even at the public sector, there is great pressure to introduce IPV to facilitate gradual albeit staggered OPV removal from routine immunization.
- 2. It is indeed a daunting task of how to strike a balance between individual and public sector use while formulating any recommendation on polio vaccines considering the sensitive nature of the polio eradication program in the country. Since OPV is still in use in the country and SIAs are still organized, we have decided to move gradually, hence the sequential schedule. This schedule will meet our objectives of providing immunity against VAPP and cVDPV, and at the same time permits the benefits of OPV. Even WHO has instructed to move from sequential than to all IPV schedule for countries

using OPV during pre-eradication era [2]. The new IAP Immunization timetable has slots for Hepatitis-B and Measles vaccines at 6 and 9 months, respectively. Hence, the new polio schedule will not entail extra visits.

- 3. It is true that there is no efficacy trial of available rotavirus vaccines in the country and efficacy low in other developing countries. But considering the huge burden of rotavirus disease in India, even a low efficacy should translate in to significant number of lives saved. Higher vaccine efficacy is desirable but should not delay use of an effective public health tool. Regarding proper strain match, it should be noted that there is significant amount of cross-protection offered by the rotavirus vaccines, and even RV1 provided comparable protection against non-vaccine strains in the African trial [3].
- 4. There is lack of epidemiological data on the incidence of mumps and rubella in different ages in the country but it is a common knowledge that all these diseases are more common amongst school age group of children. According to most recent unpublished data of the last 18 months (till August 16th 2012) acquired through IAP's IDSurv passive reporting system from pediatricians, school age group has now emerged as the commonest affected group for varicella and mumps in the country. Fifty-five percent of all varicella cases and 65% of all mumps cases are in the age-group of 5-12 years.

The second dose of MMR vaccine is not a "booster"; it is intended to produce immunity in the small number of persons who failed to respond to the first dose. If we delay these 'boosters' to 10 years of age, a significant number of children will be exposed to these diseases, will experience breakthrough diseases (varicella and mumps), and vaccine efficacy especially against varicella will be compromised. Besides, it is more convenient to 'catch' susceptible children before school entry than at later age.

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OPV for Children Who Have Received IPV

According to the Consensus Recommendation on Immunization 2012 [1] the Committee recommends birth dose of OPV, three primary doses of IPV at 6, 10 and 14 weeks, followed by two doses of OPV at 6 and 9 months. It further states that since IPV administered to infants in EPI schedule (*i.e.*, 6 weeks, 10 weeks and 14 weeks) results in suboptimal seroconversion, hence a supplementary dose of IPV is recommended at 15-18 months. Will administration of two doses of OPV not enhance the levels of antibodies generated by three doses of IPV so that supplementary dose of IPV at 15-18 months be eliminated?

The Committee further states that there is considerable evidence to show that sequential schedules that provide IPV first followed by OPV can prevent

VAPP while maintaining the critical benefits conferred by OPV (*i.e.*, high levels of gut immunity). In case subsequent administration of OPV is to provide 'critical benefit of gut immunity', it would be interesting to know the reasons why children from the countries which have switched over to IPV only are being deprived of 'critical benefit of gut immunity'.

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REPLY

As stated in the consensus recommendations also, this schedule is an interim arrangement to take care of VAPP cases and also to pave the way to ultimately all-IPV