IAP-ACVIP Immunization Recommendations: Focus on an 'Individual' Child in 'Office Practice' Setting

The new ACVIP recommendations [1] appear to be a mere conglomerate of various existing recommendations of the Government of India (GoI), the World Health Organization (WHO), and the industry. The main focus of the committee ought to be on issuing recommendations on the available licensed vaccines to provide the best possible protection to an individual child in an office practice setting [2]. The committee needed to appreciate the key attributes of an immunization programme designed for the 'community' *vis-à-vis* the one for 'individual' protection. While the programmatic issues, cost and economic factors are the major determinants of the former, safety and efficacy are the key considerations of the latter.

Hepatitis-B: The committee justifies four doses of hepatitis-B vaccine on 'programmatic basis' but does not address the issue of proper spacing that has a significant bearing on the long-term protection against the disease. Ideally, the final dose of any primary hepatitis-B schedule should not be administered before 24 weeks (164 days) of age; be it the fourth, fifth or sixth dose of the series [3].

Pertussis: Despite highlighting the superiority of whole-cell pertussis (wP) vaccines over acellular pertussis (aP) vaccines, the committee has accorded equal status to both the vaccines! The discussion is focused entirely on the 'public' use of the vaccine whereas the recommendations are offered for the 'individual/office' use. No new evidence is provided in favor of aP vaccines that may have emerged in recent times. There is marked variability in the performance of different component aP vaccines in different countries. It is difficult to believe that all the available aP vaccines with different components have similar efficacy.

Poliomyelitis: The ACVIP in its earlier review had expressed their reservations on the efficacy of two-dose fIPV administered at 6 and 14 weeks, and also on the single dose IM-IPV at 14 weeks [4].

Influenza: The data provided in the influenza section are comparatively old, and not India- and children-specific. The issue of vaccine efficacy and effectiveness is not discussed. There is no published data on the safety, tolerability, and effectiveness of the flu vaccines for Indian children.

MMR: IAP had strongly recommended MMR instead of MR in the UIP schedule [5]. Therefore, there should not be any issue about non-availability of MR vaccine in private set-up.

Typhoid: The committee has endorsed WHO guidelines, meant for country-level mass use of the vaccines. Recent age-stratified data on typhoid burden in India should have also been mentioned. The issue of boosters with conjugate vaccines is still debatable. Considering the immaturity of the immune system, gradual waning of immunity 6-12 months after vaccination, and limited opportunity for natural boosting below two years, a booster dose may be required for the children vaccinated below two years of age.

Rotavirus: The change in the administration schedule of RV-1 for office use is not well-supported by the recent data. The data on per dose efficacy of RV-1 when co-administered with OPV at 6 and 10 weeks, particularly among Indian children, is also missing. No new India-specific data is provided that may have emerged since the publication of ACVIP's 2014 recommendations on RV-1 schedule [5]. Figure 1 is showing catch-up with rotavirus vaccine till 12 months, whereas in the text, the upper limit is restricted to 8 months.

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AUTHORS' REPLY

The Advisory committee for vaccines and immunization practices (ACVIP) recommendations of 2018-19 are a mix of best practices for individual children, and for community use, based on published studies, World Health Organization (WHO) recommendations, and National immunization program.

Author cites the Centre for Disease Control (CDC), USA recommendation that the fourth dose of Hepatitis B vaccine should not be administered before 24 weeks whereas WHO recommends birth dose (using monovalent vaccine) to all infants followed by 2 or 3 additional doses (monovalent or combined vaccines) to complete the primary series with minimum 4 weeks' interval between doses [1]. CDC recommends primary vaccination at 2,4,6 months whereas WHO recommends primary vaccination at 6,10,14 weeks and the ACVIP recommends the latter. Indian studies using different schedules as 0,6,14 weeks and 0,1,2 months [2] and 6,10,14 weeks [3,4] have also reported adequate immunogenicity. All the 3-dose hepatitis schedules protect from the disease for as long as 15-20 years. Even if protective antibody titers decline with time, long-term protection relies on immunological memory that allows a protective anamnestic response after exposure to Hepatitis-B virus.

The effectiveness of licensed acellular pertussis (aP) and whole cell pertussis (wP) vaccines in preventing disease is similar in the first year of life [5], and hence the committee accorded near equal status to both types of the vaccines [6]. Clinical phase III studies in India demonstrated that the aP containing vaccines elicit a robust immune response in Indian children following a primary immunization schedule at 6, 10 and 14 weeks of age [7,8].

In view of limited manufacturing capacity for IPV, WHO has supported fractional IPV (fIPV) use and hence government has adopted the same. ACVIP recommends administration of full dose of IPV at 6,10,14 weeks as preferred option, and when this is not feasible the fIPV at 6 and 14 weeks along with bOPV at 6,10,14 weeks.

Reasons for introduction of influenza vaccine have been clearly detailed in the ACVIP recommendations [9].

As Measles-Rubella (MR) vaccine has been introduced in the national immunization schedule and in MR campaign, the same was mentioned. ACVIP supports the national MR campaign. We have not changed the earlier recommendations at all on Measles Mumps Rubella (MMR) vaccine.

Regarding TCV, the committee has brought down the age for the vaccination based on adequate immunogenicity data from earlier studies. The recommendation from 6 months onwards is to suit the convenience and avoid overcrowding of vaccinations around 9 months. The need for second dose of TCV has not been convincingly established though most studies indicate that a single dose might provide adequate antibody titres for up to 5 years. Until hard data is generated or available, we have endorsed the WHO recommendation of a single dose as of now. Antibody titres have been reported to be sufficient for 30 months after one dose and enough data is not there as of now to justify a booster at 2 years. It should be noted that no international scientific body has endorsed booster doses.

Infants in developing countries are at risk of developing rotavirus gastroenteritis at an earlier age than those in developed countries. Hence, it is ideal if immunization schedule is completed early. A recent meta-analysis [10] showed that 6,10 weeks' schedule for rotavirus 1 (RV1) is immunologically inferior to 10,14 weeks' schedule. However, the authors mentioned that the correlates of protection of anti-rotavirus IgA levels are not known and "the association between vaccine schedule and immunogenicity does not provide evidence of a difference in disease protection" [9]. The upper age limit of 12 months follows the same in National immunization schedule which recommends beginning of RV immunization up to 1 year of age. This age limit is for catch-up immunization.

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