Consensus Recommendations on Immunization and IAP Immunization Timetable 2012

INDIAN ACADEMY OF PEDIATRICS COMMITTEE ON IMMUNIZATION (IAPCOI)

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Justification: Vaccinology today is a rapidly changing specialty of medical science where new developments are regularly taking place. There is a need to review/revise recommendations about existing vaccines in the light of recent information.

Process: Following an IAPCOI meeting in December 2011, a draft statement was prepared and circulated among the meeting participants to arrive at a consensus.

Objectives: To review and issue recommendations on the recent contentious issues pertaining to rotavirus, Hib, and pneumococcal conjugate vaccines, and to revise recommendations for 2012 Immunization timetable for pediatricians in office practice.

Recommendations: IAPCOI abolished the earlier categorization of vaccines in four categories. On rotavirus, the committee stresses the need of having more data on disease burden in India. Further, there is a need to optimize use of rotavirus vaccines in India to achieve higher yields in term of protective efficacy. For the want of adequate data, the committee is not able to issue any specific recommendation on the suitability of a particular rotavirus vaccine (monovalent *vs* multivalent) for the country. The committee also acknowledges a small risk of acute intussusception following use of current generation of rotavirus vaccines and recommends inclusion of the history of intussusception in the past as an absolute contraindication. The committee concludes that there are no safety concerns of Hib vaccines as reported frequently in lay media. On the disease burden of pneumococcal diseases, the committee concludes that there is a need of conducting more community based studies to gather more evidence. Similarly, the data on prevalence of different pneumococcal serotypes in the country is sparse and limited to few hospital based studies. There is need of establishing real-time multisite pneumococcal disease surveillance in the country. Due to scarcity of data on the prevalence of pneumococcal serotypes and non-typeable hemophilus influenza (NTHi) in India, it is difficult to comment on the superiority of one pneumococcal conjugate vaccine over other. The committee also revised the recommendations for the year 2012.

Key words: *Committee on Immunization, India, Indian Academy of Pediatrics.*

The Indian Academy of Pediatrics Committee on Immunization (IAPCOI) met on 24th and 25th December 2011 in Mumbai. IAPCOI members and invitees who attended the meeting are listed in *Annexure* 1. The aim of the meeting was to discuss and debate recent developments in the field and to issue recommendations based on them, and to revise IAP Immunization Timetable for the year 2012. This document presents the consensus recommendations, which arrived out of that meeting.

Process for Issuing Recommendations

The process involves review of recent published literature including standard text books, vaccine trials, recommendations of reputed international bodies like ACIP of CDC, World Health Organization (WHO) etc, post-marketing surveillance reports from industry, cost-effective analysis, etc. More reliance is given to studies emanating from India, especially on disease epidemiology, and vaccines' immunogenicity, efficacy, and safety studies. If knowledge gaps are present then expert opinion is sought to fill the gaps. The existing national immunization schedule and government policies are also taken in to account while drafting recommendations. The recommendations of IAPCOI are primarily for pediatricians in office practice. In addition, IAPCOI also submits its position on incorporation of various new vaccines in the national immunization schedule.

I. PROCEEDINGS AND RECOMMENDATIONS

The IAPCOI has taken following key decisions:

1. **Categorization of vaccines:** IAPCOI has abolished the earlier categorization of vaccines in four categories [1]. Now there will be only two categories: one, the vaccines recommended by IAP for routine use; two, the vaccines to be used in special circumstances only.

2. **IAP immunization timetable:** Since immunization schedules ought to be dynamic—adaptable to ongoing

epidemiological changes and rapid developments in vaccine sciences, it is unanimously resolved to revise immunization timetable every year rather than every two years as has been practiced so far.

3. **Revised process for issuing recommendations:** It is decided to develop a uniform approach to making explicit the evidence base for IAPCOI recommendations. The committee will adopt a new evidence-based methodology, *e.g.* GRADE (Grades of Recommendation Assessment, Development and Evaluation, for issuing not only the future recommendations but to apply to existing recommendations also, especially on newer vaccines. A subcommittee is also constituted that will devise a new model based entirely on evidence to grade the available evidences and on its basis decide the strength of recommendations in 2-3 different categories. The main focus will be on scientific evidence and transparency so that the system can be reproducible and can also be reviewed by other experts.

4. **Position papers:** It is also decided to prepare position papers on important vaccines and vaccine preventable diseases highlighting committee's stand on various issues on the format of WHO position papers. Hib diseases and vaccines have been chosen for the inaugural papers.

II. AIMS AND OBJECTIVES

- To review and issue recommendations on the recent contentious issues pertaining to rotavirus, Hib, and pneumococcal conjugate vaccines.
- To revise IAP Immunization Timetable for the year 2012.

III. SPECIFIC RECOMMENDATIONS

A. ROTAVIRUS VACCINE

In the light of recent publications and developments, the following issues are considered for discussion:

1. Burden of rotavirus disease in India

According to most recent global estimates, India accounts roughly 22% of deaths (98 621 deaths) due to rotavirus out of global estimates of 453 000 deaths [2]. Along with India, Democratic Republic of the Congo, Ethiopia, Nigeria, and Pakistan account for more than half of all deaths attributable to rotavirus infections globally [2]. Most of Indian studies are hospital-based. However, according to one review that collated data from 46 epidemiological studies conducted between 1990-2005, rotavirus positivity rates varied greatly between different settings - diarrhea hospitalizations (20%), neonatal infections (35%), symptomatic and asymptomatic infections in the community (15.1% and 6.3%, respectively) and nosocomial enteric infections (22.5%) [3]. The incidence of rotavirus positivity amongst hospitalized children varies from 6-45% (20.8%) [3]. According to the Indian Rotavirus Strain Surveillance Network (IRSN), established with 4 laboratories and 10 hospitals in 7 different regions of India, rotavirus was found in approximately 39% of 4243 enrolled patients from December 2005 through November 2007 with greatest incidence seen among children aged 6-23 months [4].

2. Efficacy of current rotavirus vaccines in India

There are no efficacy trials of the licensed rotavirus vaccines available in India. The data from other developing countries shows efficacy ranging from 17.6% (in Mali) to 61.2% (in South Africa and Malawi) [5-9]. There is definite gradient in the efficacies of these vaccines when different regions of the world are compared-highest in US and Europe, moderate in Latin America, and low in Africa and Asia (5-12). IAPCOI still believes that in developing countries with high rotavirus disease incidence, even moderate to low vaccine efficacy translates into significant numbers of severe rotavirus gastroenteritis cases prevented and into significant public health impact. More rotavirus deaths may be prevented in developing countries despite lower vaccine efficacy than in countries with low rotavirus disease burden and higher vaccine efficacy [13]. However, considering that oral vaccines elicit diminished immune responses or have lower efficacy in developing countries than in developed countries [14], and since India is having history of poor performance of other oral vaccines, notably OPV in recent past [15-17], it would not be prudent to extrapolate data from other countries having comparable epidemiologic, economic, and demographic indices.

3. Administration schedule of rotavirus vaccines

In a recent community-based study from Vellore, it was noted that rotavirus infection generally occurred early in life, levels of re-infection were high and even three natural infections were able to provide only 79% protection against moderate or severe disease, with no evidence of homotypic protection as believed so far [18]. Therefore, there may be a need for modification of the rotavirus vaccination strategy in India, by increasing the dose or increasing the number of doses or delaying the doses or even considering neonatal immunization. These considerations were further supported by the immunogenicity study of another live attenuated human oral rotavirus vaccine 116E in Indian infants, where administration of higher (1×10^4 ffu Vs 1×10^5 ffu) and more frequent (2 *vs* 3) doses resulted in more robust immune responses [19]. Consequently, the ongoing phase

III efficacy trial with this strain is conducted with higher dose (10^5 ffu) and a 3 dose schedule (6, 10 and 14 weeks) [19]. It can be argued that one study in South Africa and Malawi with monovalent rotavirus vaccine (RV1, marketed as Rotarix) did not detect significant differences in vaccine immunogenicity or efficacy on pooled analysis between the cohort receiving two vaccine doses and the cohort receiving three doses [7]. However, there was a slight but non-significant trend toward higher sero-conversion rates and vaccine efficacy with the three-dose schedule, and these differences were more marked in South Africa (81.5 [55.1–93.7] *vs* 72.2 [40.4–88.3]) than in Malawi (49.7 [11.3–72.2] *vs* 49.2 [11.1–71.7]) [7]. The two-dose schedule used in this trial was 10 and 14 weeks instead of 6 and 10 weeks [7].

Administering rotavirus vaccines at younger ages could further lower the immunogenicity of the vaccines, because of the potential for greater interference of maternal antibody and enhanced replication of the oral poliovirus vaccine [7]. In the above African study with RV-1, the researchers accepted that the study was not powered to detect differences in dose schedule [7]. Furthermore, there have been low seroconversion rates (58.3%; 95% CI: 48.7; 67.4) with two doses of RV1 in comparison with three-dose schedule of RV5 (82.4% (CI; 75; 90%) and 116E (89.7% (42.4; 80.6%) in immunogenicity studies in India [19-21]. In the RV1 trial, the first dose was administered between 8-10 weeks (mean age-8.7 weeks) and the second dose between 12-16 weeks (mean age-13.4 weeks) [20]. Hence, there is no immunogenicity data for 6 and 10 weeks administration or data on interference with simultaneous OPV administration from India. It is important when examining immunogenicity data to point out that although seroconversion is not a direct proxy for efficacy, it does demonstrate that the virus is able to colonize the infant gut and induce a robust immune response.

According to the WHO Ad-hoc Group of Experts on rotavirus vaccines [22], most countries with high rotavirus disease incidence or high under-5 mortality rates (where children would particularly benefit from robust protection from rotavirus infection) have 6, 10, 14 week EPI schedules. If rotavirus vaccines are to be co-administered with OPV in a setting with an EPI vaccination schedule beginning at 6 weeks of age, the second dose of RV1 may not be sufficient to provide adequate immunity against severe rotavirus disease [22]. A 2-dose schedule at 10 and 14 weeks is also assumed to be programmatically problematic, since this would likely result in a failure in administration of the full course of vaccines to children in developing countries due to the restrictive upper age limit for rotavirus vaccine administration, resulting from the approach of attempting to avoid administration of rotavirus vaccines during the ages when there is a heightened risk of intussusceptions [22]. After debating intensely, the committee thinks that there is a need to seriously relook at the proper administration schedule of rotavirus vaccines in India in order to achieve higher yields in term of protective efficacy.

4. **Homotypic *vs*. heterotypic protection and potential impact of vaccination on Rotavirus strain diversity**

Distribution of rotavirus genotypes exhibits distinctive changes, both due to natural cyclical changes or due to selective pressures imposed by vaccines. There is currently much interest in elucidating the strain dynamics of rotavirus to determine whether vaccination may lead to the replacement of vaccine-type strains. According to a new modeling study, the predicted frequency of cycling depends on the relative strength of homotypic *vs*. heterotypic immunity. Vaccination that provides strong protection against G1 and weaker protection against other strains will likely lead to an increase in the relative prevalence of non-G1 strains, whereas a vaccine that provides equally strong immunity against all strains may promote the continued predominance of G1 [23]. Overall, however, disease incidence is expected to be substantially reduced under both scenarios and remain below pre-vaccination levels despite the possible emergence of new strains. The committee concludes that better understanding of homotypic *vs*. heterotypic immunity, both natural and vaccine-induced, will be critical in deciding the inclusion of a particular rotavirus vaccine in the national immunization program and predicting the impact of vaccination. It also urges the need of effective strain monitoring prospectively in different zones to determine changes in circulating strains over a period of time.

5. **Safety of rotavirus vaccines and post-marketing surveillance data on acute intussusception in India**

The committee reviewed the emerging data on intussusception related to current rotavirus vaccines following large-scale use of these vaccines in Mexico, Brazil, Australia and US [24-27]. The post-marketing surveillance (PMS) data from India by the manufacturers of two rotavirus vaccines licensed in India was also reviewed.

Based on PMS data, the current rotavirus vaccines have been associated with an increased risk of intussusceptions (about 1–2/100,000 infants vaccinated) for a short period after administration of the first dose in some populations [24]. This risk is 5–10 times lower than

that observed with the previously licensed vaccine (1 case per 10,000 doses). There are no published reports on incidence/rates of acute intussusception following rotavirus vaccination in India. However, the PMS data (unpublished) of Indian manufacturers revealed 13 cases of acute intussusceptions associated (causality not yet proved) with rotavirus vaccines administration since the launch of RV1 in India till December 2011, and two cases following RV5 during a five-month surveillance period (May-September 2011) in India.

There is limited information on the incidence of intussusception and its risk factors in India. No large-scale trials of rotavirus vaccines have been conducted in the country to assess whether there is an increased risk of intussusception associated with the vaccination. Data on background rates of intussusception in developing countries are required to facilitate informed decision making about use of new rotavirus vaccines. These background rates are also needed for estimation of the sample size needed for studies to demonstrate safety both before and after licensure of new rotavirus vaccines. Such population-based data are not available in most developing countries, including India. However, a recent study from Delhi found the incidence of intussusception requiring hospitalization was 17.7 cases per 100,000 infant-years of follow-up (95% CI: 5.9-41.4 cases per 100,000 infant-years) [28]. The study also concluded that natural rotavirus infection did not appear to be a major cause of intussusception in Indian infants. This incidence appears to be lower than that reported in other middle- and high-income countries. Another retrospective study from a tertiary-care hospital from south India identified 31 children with definite intussusception during the study period of 1 January 2001-30 June 2004 [29].

After reviewing recent data, the committee concludes that there is definite albeit a small risk of acute intussusceptions following use of current generation of rotavirus vaccines. However, the benefits of rotavirus vaccination against severe diarrhea and death from rotavirus infection far exceed the miniscule risk of intussusceptions. It urges the manufacturers to actively monitor the risk of intussusceptions as the usage of these vaccines is bound to go up. This will also require strengthening of AEFI surveillance in the country. Information about the possible risk of intussusceptions associated with rotavirus vaccination needs to be communicated clearly to the national decision-makers, health-care providers, and parents. The committee also stresses that while prescribing them in office practice; there is a need to strictly adhere to the set upper age-limits, *i.e.* the first dose of either RV1 or RV5 be administered between the ages of 6 weeks and 14 weeks 6 days, and that the maximum age for administering the last dose of either vaccine should be 32 weeks [30]. The committee has recommended inclusion of the history of intussusception in the past as an absolute contraindication for rotavirus vaccines (RV1 and RV5) administration.

B. HEMOPHILUS INFLUENZAE TYPE B VACCINE

The committee discussed the recent reports on the safety of Hib-containing pentavalent vaccines including a new PIL against its introduction in two southern states [31, 32]. It also reviewed the disease burden of Hib disease in India and PMS data on Hib and Hib containing combination vaccines. The committee decided to publish a detailed position paper on Hib-disease and Hib-vaccines. According to PMS data of one Indian manufacturer, a total of 98 (46 serious and 49 non-serious) AEFI episodes have been reported for 53.51 million doses (overall frequency 1.83/million doses, and for serious AEFI 0.85/million) from October 2004 through December 2011. The committee expressed satisfaction on impressive performance of Hib and Hib-containing vaccines as far as safety issues are concerned. The committee concluded that there was no safety concerns of Hib vaccines as reported frequently in lay media. It strongly supports the Government of India's efforts to introduce this vaccine in all the states of the country.

C. PNEUMOCOCCAL CONJUGATE VACCINES

1. Burden of pneumococcal diseases in India

The committee reviewed the available data on the incidence of pneumococcal diseases (PD) in India and found that there was no nationally representative study of pneumonia incidence from the community. Most studies of severe pneumonia were hospital-based; hence, may have missed cases. There were few older studies, based on parental reporting of symptoms that again showed lower incidence. Most of the available data on PD was from hospitals and on meningitis.

According to the WHO's Child Health Epidemiology Reference Group (CHERG) pneumonia working group, incidence of clinical pneumonia among children <5 years in India for the year 2004, was estimated to be 0.37 episodes per child year [33]. One Indian study reported that the incidence of severe clinical pneumonia ranged from 0.03 to 0.08 per child-year at three study sites [34]. Another Indian study finds that Indian children <5 years of age suffer ~3 episodes of respiratory infection per year, with heavier burden on younger children. Approximately, 1 in 5 episodes is a lower or severe lower respiratory infection [35].

There is no systematic review or nation-wide study of etiology of childhood pneumonia in India. The incidence of pneumonia (ALRI) in India was found to be 290-536 and of severe pneumonia (severe ALRI) was 27-96 per 1000 child-years India. Out of these cases, 18-59% of all pneumonia (ALRI) and 53% of all severe pneumonia (severe ALRI) were of bacterial origin [36]. Viruses mainly respiratory syncytial virus (RSV), influenza A and B, para influenza 1, 2 and 3, and adenovirus are responsible for 22.1% of under five year old children patients with ARI, but only RSV and para-influenza 3 were seen to cause severe ALRI disease [35]. Pneumococci accounted for 5-12% of all severe pneumonia cases across studies; 12-30% of pneumonia cases with a confirmed etiology [36]. A recent systematic review reported that about 12-35% of childhood pneumonias were caused by pneumococci and 10-15% by H. *influenzae* and RSV each [37].

Another India-specific estimate for the year 2005 found 136,000 deaths (46,000-253,000) caused by pneumococcal diseases comprising 10% of deaths in Indian children aged 1-59 months [38]. The death rate for pneumococci was 106 per 100,000 (range 36-197), and more than two-thirds of pneumococcal deaths were pneumonia-related. Central and Eastern regions of the country had highest pneumococcal mortality with more than half of all Indian deaths occurring in four states: Bihar, Madhya Pradesh, Rajasthan, and Uttar Pradesh [38]. According to a two year prospective study at three Bengaluru hospitals in south India, incidence of invasive pneumococcal disease (IPD) in the first year of study among less than 2-year old children was found to be 28.28 cases per 100,000 population in which pneumonia contributed 15.91 and acute bacterial meningitis (ABM) 6.82 cases [39].

There is also lack of community-based studies on incidence of acute bacterial meningitis in India. There was only limited data from prospective population-based incidence studies not only from India but from entire Asia. A study from Vellore found an annual incidence of 'possible', 'probable' and 'proven' ABM as 86, 37.4 and 15.9 per 100,000 children per year, respectively [40]. Assuming that the probable and proven cases were truly ABM, the burden of disease was 53/100,000/year in under-five children [40]. According to the recent review on epidemiology of pneumococcal infections in India, pneumococci were responsible for 27-39% of all cases of ABM in children [36].

2. **Distribution and prevalence of different pneumococcal serotypes in India**

The committee reiterated its stand on the significance of knowing prevalence of distribution of different pneumococcal serotypes in the community since each serotype had a distinct 'personality' and represented a distinct disease.

The committee reviewed studies [41-49] on the distribution and prevalence of different pneumococcal serotypes in the country, including some recent studies done by vaccine manufacturers in India like Pneumonet by M/s Pfizer [39] and Alliance for Surveillance of Invasive Pneumococci (ASIP) by M/s GSK (unpublished). The committee concluded that the data on prevalence of different pneumococcal serotypes in the country was sparse and limited to few hospital based studies. On the basis of available data, it is difficult to evaluate the coverage of serotypes included in the existing Pneumococcal conjugate vaccine (PCV) formulations. There were only handful of small hospital-based studies mostly from south India [41, 43], and the only comparatively large multi-centric study (Invasive Bacterial Infection Surveillance (IBIS) multi-centric study from six centers across India in 1994-1997) was more than a decade old [42]; however, it is the one which is most frequently cited. The large studies from Asian and other neighboring countries like PneumoAdip [44], ANSORP [45, 46], SAPNA [47], etc. did not have adequate representation of isolates from India.

Though a limited number of serotypes cause most invasive pneumococcal disease (IPD) worldwide and the serotypes included in existing PCV formulations responsible for 49%-88% of deaths in developing countries of Africa and Asia where PD morbidity and mortality are the highest [49], still there is a need of establishing a real-time multi-site comprehensive pneumococcal disease surveillance including both population and hospital-based surveillance arms. This ongoing project should also include data on zonal distribution and prevalence of different serotypes on annual basis. There is need to consolidate all ongoing surveillance projects run by different vaccine manufacturers to accord more credibility and avoid bias in the results. There is need to incorporate more sophisticated diagnostic tests like immune-chromatography (ICT), latex particle agglutination (LPA), and real-time polymerase chain reaction (PCR) apart from cultures to increase the yields. Since few serotypes are difficult to grow and under diagnosed by culture (such as serotype 3), the PCR can be used to pick serotypes from culture negative cases as done in few European countries [50]. The surveillance should not be a one-time project but should be an ongoing initiative to pick natural variations in the sero-epidemiology. For example, in Bangladesh, there were differences in the

serotypes profile of hospital-based and population-based surveillance [51-53]. Further, the ongoing surveillance project picked a new serotype, type 2 as the predominant serotypes, not covered by the existing PCV formulations [53]. Hence, surveillance should be prolonged enough to pick the changing epidemiology over the years.

The surveillance project should have three important objectives-to collect data on serotype distribution to guide appropriate pneumococcal conjugate vaccine formulations, to identify trend of antimicrobial resistance amongst different serotypes, and lastly, to assess the impact of vaccine introduction (in national immunization program [NIP] on the serotype distribution and replacement, if any. The committee urges the Government of India (GoI) to take the initiative and launch this project all over the country.

3. **Suitability of PCV13 *vs* PCV10 for Indian children**

The committee studied the recent data on PCV13 and PCV10. The committee also reviewed the reports of PCV13 studies done worldwide on immune responses (IgG - GMC, OPA – GMT) and boostability for the serotype 3 capsular antigen [54], and the immune responses following post-primary and post-booster series against serotype 19A infections, with PCV10 and PCV13 [55, 56]. It has reviewed the interim data of COMPAS trial done in three Latin American countries with PCV10 [57] and effectiveness of PCV 10 in Brazil [58].

The committee also reviewed available data on the efficacy of the new serotypes in the PCV13. In England and Wales [59], vaccine effectiveness (VE) for the new serotypes for 2 doses under a year was 78% (95% CI -18-96%) and 77% (CI: 38-91%) for one dose over a year. VE for 7F and 19A was 76% (CI: 21-93%) and 70% (CI: 10-90%), respectively for one or more than one dose, for serotypes 1 and 3 was 62% and 66%, respectively although confidence intervals spanned zero. IPD due to PCV13-only serotypes halved in children under 2 years in the study period [59].

The committee believes that the direct protection rendered by the serotype included in a vaccine formulation is definitely superior to any cross protection offered by the unrelated serotypes even of the same group in a PCV formulation. However, the committee is not convinced about the clinical efficacy of serotype 3 contained in PCV13 despite multiple studies showing good functional immune responses after the infant series and reasonably good effectiveness. There has been no consistent PCV13 impact on serotype 3 IPD or carriage reported so far.

Similarly, the committee thinks that despite using a different conjugation method (cyanylation *versus* reductive amination) [60], PCV10 is yet to demonstrate a better clinical efficacy (cross protection) against serotype 19A than shown by PCV7. Though current seroprevalence of type 19A in India is not known, but its presence is confirmed by almost all the recent studies [39, 45, 46]. Since this serotype is increasing in many other Asian countries and has got higher antimicrobial resistance characteristics than other serotypes [45, 46], the committee believes that protection against 19A will be critical to determine which vaccine is appropriate to use in the country. Recent data has now shown that PCV13 provides protection against 19A [59], while it is unknown if the presence of 'novel' 19F in PCV10 will provide cross protection against 19A [61]. On the other hand, the committee is convinced about the adequate cross-protection rendered by serotype 6B to 6A based on performance of PCV7 in many European countries and US in decreasing IPDs caused by 6A. However, the exact role and significance of 6C which is clearly emerging as replacement serotype is yet to be determined.

The committee thinks that though non-typeable *Haemophilus influenzae* (NTHi), a co-pathogen plays some role in the pathogenesis of mucosal disease with *Streptococcal pneumoniae*, its role in childhood pneumonia is still not proven.

After appraising in detail all the available relevant data, the committee concludes that since there is scarcity of data on the prevalence of pneumococcal serotypes including serotypes 3, 6A and 19A, and NTHi in India, it is almost impossible to comment on the exact superiority of one product over other. Further, in the absence of head to head trials, it is difficult to determine if either vaccine has a clear advantage over other. Although recent publications [49] state that the same few serotypes are responsible for a large proportion of PD in all geographic regions and new PCVs cover almost 70% of serotypes prevailing in India, the committee believes that it is critical to know what percentage of pneumonia, meningitis and other IPDs are caused by the pneumococcal serotypes not included in existing formulations.

4. **Recommendations for premature and low birth weight infants**

The committee has now stressed the need of treating prematurity and very-low birth weight (VLBW) infants as another high risk category for pneumococcal vaccination. VLBW infants have up to 9-fold higher incidence of invasive pneumococcal diseases (IPD) as compared to full size babies [62]. The risk ratio for LBW infants compared with normal birth weight infants was

2.6, and for premature infants compared with full-term infants was 1.6 [62]. PCV must be offered to these babies on priority basis. PCV was as immunogenic in low birth weight and preterm infants as in normal birthweight and fullterm infants; the vaccine efficacy for both groups was found 100% [62].

RECOMMENDATIONS FOR IAP IMMUNIZATION TIMETABLE, 2012

The IAPCOI has issued recommendations for the IAP Immunization Timetable (***Table* I, *Fig.* 1,2**) for the year 2012 that includes the following major changes from last year:

A. Poliovirus immunization

In the light of remarkable achievement in the field of polio eradication in India over the last one year [63], the committee has now decided to adopt a sequential IPV-OPV schedule. This will pave the way to ultimate adoption of all-IPV schedule in future considering the inevitable cessation of OPV from immunization schedules owing to its safety issues (VAPP and cVDPVs). This policy is in accordance with the recent decision taken by GPEI where phased removal of Sabin viruses, beginning with highest risk (type 2) would be undertaken [64]. This will result in elimination of VDPV type 2 in 'parallel' with eradication of last wild polioviruses by switching from tOPV to bOPV for routine EPI and campaigns. This switch will result in much early introduction of IPV than anticipated, at least in high risk areas for VDPVs, to provide type 2 protection [64].

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). Data from several studies show that sequential schedules considerably decrease the risk of VAPP [65-68]. There is moderate level of scientific evidence that sequential immunization schedules starting with two or more doses of IPV and followed by two or more doses of OPV(at an interval of 4-8 weeks) induce protective immunological responses to all three poliovirus serotypes in more than 90% of vaccinees [69]. However, the committee has retained the birth dose of OPV as recommended earlier. Providing the first OPV dose at a time when the infant is still protected by maternally-derived antibodies may, at least theoretically, also prevent VAPP. A birth dose of OPV is considered necessary in countries where the risk of poliovirus transmission is high [70].

The primary schedule

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, another dose (booster) of IPV at 15-18 months and OPV at 5 yrs. Alternatively, two doses of IPV can be used for primary series at 8 and 16 weeks, though this schedule is immunologically superior to EPI schedule and the number of IPV doses is reduced, but will be more cumbersome due to extra visits and incompatibility with combination formulations. Further, the child would be susceptible to WPV infection for the first two months of life considering the epidemiology of WPV in India till quite recently.

Since IPV administered to infants in EPI schedule (i.e. 6 weeks, 10 weeks and 14 weeks) results in suboptimal seroconversion [70], hence, a supplementary dose of IPV is recommended at 15-18 months. IPV should be given intramuscularly (preferably) or subcutaneously and may be offered as a component of fixed combinations of vaccines. However, the committee recommends that if IPV is unaffordable or unavailable, the primary series must be completed with three doses of OPV given at 6, 10, and 14 weeks. No child should be left without adequate protection against wild polio virus (*i.e.* three doses of either vaccine). All OPV doses (mono-, bi- or trivalent) offered through supplemental immunization activities (SIAs), should also be provided.

Catch-up schedule

IPV may be offered as 'catch up vaccination' for children less than 5 years of age who have completed primary immunization with OPV. IPV can be given as three doses; two doses at two months interval followed by a third dose after 6 months. This schedule will ensure a long lasting protection against poliovirus disease.

Recommendations for travelers

The committee has now issued the following recommendations for travelers to polio-endemic countries or areas:

- For those who have previously received at least 3 doses of OPV or IPV should be offered another dose of polio vaccine as a once-only dose before departure.
- Non-immunized individuals should complete a primary schedule of polio vaccine, using either IPV or OPV. Primary series includes at least three doses of either vaccine.
- For people who travel frequently to polio-endemic areas but who stay only for brief periods, a one-time only additional dose of a polio vaccine after the primary series should be sufficient to prevent disease [70].

Major Changes in Recommendations for IAP Immunization Timetable, 2012

- *Polio:* Sequential IPV-OPV schedule is recommended for primary polio immunization in place of combined OPV+IPV schedule.
- *Hepatitis-B:* 'Birth-6 weeks-6 months' is recommended as most preferred schedule instead of earlier '0- 6 weeks-14 weeks' schedule.
- History of intussusception in the past is added as an absolute contraindication for rotavirus vaccine administration.
- Prematurity and very-low birth weight are added as another high risk category for pneumococcal vaccination.
- Guidelines are provided for influenza vaccination.

B. **Hepatitis B immunization**

The committee has now recommended the following schedule for routine Hepatitis-B vaccination in office practice for children: the first dose of a three-dose schedule should be administered at birth, second dose at 6 weeks, and third dose at 6 months (*i.e.* 0–6 week–6 month). This schedule is not only more closer to immunologically ideal and most widely used 0-1-6 months schedule, but also confirms to latest ACIP recommendations wherein the final (third or fourth) dose in the Hepatitis-B vaccine series should be administered no earlier than age 24 weeks and at least 16 weeks after the first dose [71]. It will replace the existing schedule of 0–6 week–14 week. However, the Hepatitis-B vaccine may be given through other schedules, considering the programmatic implications and logistic issues. The committee stresses the significance and need of birth dose.

C. **Influenza vaccination**

The committee reviewed the WHO recommendations regarding composition of flu vaccines for the southern and northern hemisphere for use in the 2012-2013 influenza seasons [72-73]. For the northern hemisphere, it will contain the following strains: an A/California/7/2009 (H1N1) pdm09-like virus; an A/Victoria/361/2011 (H3N2)-like virus; and a B/Wisconsin/1/2010-like virus [72]. The last two strains will be different from the last year's vaccine for the region; however, there will be no change in the composition of influenza vaccines for the southern hemisphere for 2012 [73]. Last year, the strains were similar for both the hemispheres. This will have impact on the types of vaccines to be used in coming season.

As far as the influenza virus circulation in India is concerned, the data since 2004 suggests a clear peaking of circulation during the rainy season across the country- 'June to August' in north (Delhi), west (Pune) and east (Kolkata), and 'October to December' in south (Chennai) [74]. This data is also consistent with the WHO circulation patterns for 2010 and 2011 for India which also shows a clear peak coinciding with the rainy season across the country. These data illustrate the difficulty in having effective uniform vaccination timing for a vast country like India and have implications when formulating vaccination policies. The evidence of antigenic drifts of circulating influenza viruses in India, together with the temporal peaks in seasonality of influenza in different parts of the country; illustrate the need for a staggered approach in vaccination timing. Hence, the best time for offering vaccine for individuals residing in southern states would be just before the onset of rainy season, i.e. before October while for rest of the country, it should be before June. Though, the committee acknowledges that this issue is still contentious and unresolved.

This is to be noted that WHO convenes two meetings to provide recommendations for the usage of influenza vaccine in February and September each year. The vaccine for the February recommendations (Northern hemisphere) and September recommendations (Southern hemisphere) becomes available after 6 months of each recommendation. With the above background the vaccine that shall be available in March-April 2012 (Southern hemisphere) this year is based on the recommendation made in September 2011 which took into account the data from the past year i.e. August 2010 to Sept 2011 (thus covering India's rainy season peak last year from June to August 2011). Whereas the vaccine that shall be available in August 2012 (Northern hemisphere, with the 2 new strains) shall be based on the recommendation made in February 2012 which took into account the data from the past year i.e. March 2011 to Feb 2012 which means that by the time it is available in August 2012, the most of the country barring southern states may have already passed the peak influenza activity.

TABLE I IAP IMMUNIZATION TIMETABLE 2012 (IAP RECOMMENDED VACCINES FOR ROUTINE USE)

Age	*Vaccines*	*Comments*
Birth	BCG, OPV 0, Hep-B 1	**Hepatitis-B:** Administer Hep-B vaccine to all newborns before hospital discharge.
6 weeks	DTwP 1/DTaP 1, IPV 1, Hep-B 2, Hib 1, Rotavirus 1, PCV 1	**Polio:** All doses of IPV may be replaced with OPV if former is unaffordable/ unavailable; Additional doses of OPV on all "Supplementary immunization activities" (SIAs); Two doses IPV instead of 3 for primary series if started at 8 weeks, and 8 weeks interval between the doses. **Rotavirus:** 2 doses of RV-1 (monovalent) and 3 doses of RV-5 (pentavalent).
10 weeks	DTwP 2/DTaP 2, IPV 2, Hib 2, Rotavirus 2, PCV 2	
14 weeks	DTwP 3/DTaP 3, IPV 3, Hib 3, Rotavirus 3, PCV 3	**Rotavirus:** Only 2 doses of RV1 are recommended at present.
6 months	OPV 1, Hep-B 3	**Hepatitis-B:** The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks and at least 16 weeks after the first dose.
9 months	OPV 2, Measles	
12 months	Hep-A 1	**Hepatitis A:** For both killed and live hepatitis-A vaccines 2 doses are recommended.
15 months	MMR 1,Varicella 1, PCV booster	**Varicella:** The risk of breakthrough varicella is lower if given 15 months onwards.
16 to 18 months	DTwP B1/DTaP B1, IPV B1, Hib B1	The first booster (4th dose) may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
18 months	Hep-A 2	**Hepatitis A:** For both killed and live hepatitis-A vaccines, 2 doses are recommended.
2 years	Typhoid 1	**Typhoid:** Typhoid revaccination every 3 years, if Vi-polysaccharide vaccine is used.
4 ½ to 5 years	DTwP B2/DTaP B2, OPV 3, MMR 2, Varicella 2, Typhoid 2	**MMR:** The 2nd dose can be given at anytime 4-8 weeks after the 1st dose. **Varicella:** The 2nd dose can be given at anytime 3 months after the 1st dose.
10 to 12 years	Tdap/Td	**Tdap:** Preferred to Td followed by Td every 10 years.
	HPV	**HPV:** Only for females, 3 doses at 0, 1-2 (depending on brands) and 6 months.

IAP recommended vaccines for High-risk* children (Vaccines under special circumstances): *1. Influenza Vaccine, 2. Meningococcal Vaccine, 3. Japanese Encephalitis Vaccine, 4. Cholera Vaccine, 5. Rabies Vaccine, 6. Yellow Fever Vaccine, 7. Pneumococcal Polysaccharide vaccine (PPSV 23).*

****High-risk category of children:***

- Congenital or acquired immunodeficiency (including HIV infection)
- Chronic cardiac, pulmonary (including asthma if treated with prolonged high-dose oral corticosteroids), hematologic, renal (including nephrotic syndrome), liver disease and diabetes mellitus
- Children on long term steroids, salicylates, immunosuppressive or radiation therapy
- Diabetes mellitus, Cerebrospinal fluid leak, Cochlear implant, Malignancies
- Children with functional/anatomic asplenia/hyposplenia
- During disease outbreaks
- Laboratory personnel and healthcare workers
- Travelers

Age ▶ / Vaccine ▼	Birth	6 wk	10 wk	14 wk	18 wk	6 mo	9 mo	12 mo	15 mo	18 mo	2-3 Yr	4-6 Yr
BCG	BCG											
Hep B	Hep B1	Hep B2*				Hep B3*						
Polio†	OPV0	IPV1	IPV2	IPV3*		OPV1	OPV2	IPV B1*				OPV3*
DTP		DTP 1	DTP 2	DTP 3					DTP B1*			DTP B2*
Hib		Hib 1	Hib 2	Hib 3				Hib-booster*				
Pneumococcal		PCV 1	PCV 2	PCV 3				PCV -booster*			PPSV$	
Rotavirus††		RV 1	RV 2	RV† 3								
Measles							Measles*					
MMR								MMR 1*				MMR 2*
Varicella									Varicella 1*			Varicella 2*
Hep A								Hep A 1*			Hep A 2*	
Typhoid											Typhoid*	
Influenza						Influenza (yearly)$						
Meningococcal											Meningococcal$	
Cholera								Cholera 1 & 2$				
JE							JE$					

**Range of recommended ages for all children ; $Range of recommended ages for certain high-risk groups*

(This schedule includes recommendations in effect as of April 2012. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines).

FIG.1 *IAP Recommended immunization schedule for children aged 0-6 years (with range), 2012.*

1. *BCG Vaccine*
   • Should be given at birth or at first contact • Catch up may be given up to 5 years
2. *Hepatitis B (HepB) vaccine*
   • Minimum age: birth • Administer monovalent HepB vaccine to all newborns before hospital discharge • Mono- valent HepB vaccine should be used for doses administered before age 6 weeks • Administration of a total of 4 doses of HepB vaccine is permissible when a combination vaccine containing HepB is administered after the birth dose • Infants who did not receive a birth dose should receive 3 doses of a HepB containing vaccine starting as soon as feasible • The ideal minimum interval between dose 1 and dose 2 is 4 weeks, and between dose 2 and 3 is 8 weeks • Ideally, the final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks and at least 16 weeks after the first dose • Hep B vaccine may also be given in any of the following schedules: Birth, 1, & 6 mo, Birth, 6 and 14 weeks; 6, 10 and 14 weeks; Birth, 6 weeks,10 weeks, 14 weeks, etc.
3. *Poliovirus vaccines*†
   • OPV in place of IPV If IPV is unaffordable/unavailable, minimum 3 doses • Additional doses of OPV on all SIAs • IPV: Minimum age: 6 weeks • IPV: 2 instead of 3 doses can be also used if primary series started at 8 weeks and the interval between the doses is kept 8 weeks • IPV catch-up schedule: 2 doses at 2 months apart followed by a booster after 6 months
4. *Diphtheria and tetanus toxoids and pertussis (DTP) vaccine*
   • Minimum age: 6 weeks • The first booster (4thth dose) may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose • DTwP/DTaP/Tdap/Td: Catch up below 7 years: DTwP/DTaP at 0, 1 and 6 months; • Catch up above 7 years: Tdap, Td, Td at 0, 1 and 6 months.
5. *Haemophilus influenzae type b (Hib) conjugate vaccine*
   • Minimum age: 6 weeks • Catch up in 6-12 months; 2 doses 1 month apart and 1 booster; 12-15 months: 1 primary and 1 booster; above 15 months single dose.
6. *Pneumococcal vaccines*
   • Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV] • Administer 1 dose of PCV to all healthy children aged 24 through 59 months who are not completely vaccinated for their age • For children who have received an age-appropriate series of 7-valent PCV (PCV7), a single supplemental dose of 13-valent PCV (PCV13) is recommended for:
   • All children aged 14 through 59 months • Children aged 60 through 71 months with underlying medical conditions • Administer PPSV at least 8 weeks after last dose of PCV to children aged 2 years or older with certain underlying medical conditions (certain high-risk • PCV: Catch up in 6-12 months: 2 doses 1 month apart and 1 booster; 12-23 months: 2 doses 2 months apart; 24 mo & above: single dose • PPSV: Revaccination only once after 3-5 years only in certain high risk patients.
7. *Rotavirus (RV) vaccines*† †
   • Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [Rota Teq]) • Only two doses of RV-1 are recommended at present • The maximum age for the first dose in the series is 14 weeks, 6 days; and 8 months, 0 days for the final dose in the series • Vaccination should not be initiated for infants aged 15 weeks, 0 days or older.
8. *Measles*
   • Minimum age: At completed months/270 completed days • Catch up vaccination beyond 12 months should be MMR • Measles vaccine can be administered to infants aged 6 through 11 months during outbreaks. These children should be revaccinated with 2 doses of measles containing vaccines, the first at ages 12 through 15 months and at least 4 weeks after the previous dose, and the second at ages 4 through 6 years.
9. *Measles, mumps, and rubella (MMR) vaccine*
   • Minimum age: 12 months • The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
10. *Varicella vaccine*
    • Minimum age: 12 months • The risk of breakthrough varicella is lower if given 15 months onwards • The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose • For children aged 12 months through 12 years, the recommended minimum interval between doses is 3 months. However, if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.
11. *Hepatitis A (HepA) vaccine*
    • Minimum age: 12 months • Two doses of both killed and live HepA vaccines • Administer the second (final) dose 6 to18 months after the first.
12. *Typhoid vaccine*
    • Only Vi-PS (polysaccharide) vaccine is recommended • Minimum age: 2 years; Revaccination every 3 years • Vi-PS conjugate vaccine: data not sufficient to recommend for routine use of currently available vaccine
13. *Influenza vaccine*
    • Minimum age: 6 months for trivalent inactivated influenza vaccine • First time vaccination: 6 months to below 9 years: two doses 1 month apart; 9 years and above single dose; Annual revaccination with single dose • For children aged 6 months to below 9 years: For the 2012 season, administer 2 doses (separated by at least 4 weeks) to those who did not receive at least 1 dose of the 2010–11 vaccine. Those who received at least 1 dose of the 2010–11 vaccine require 1 dose for the 2011–12 season • Best time to vaccinate: as soon as the new vaccine is released and available in the market & just before the onset of rainy season;
14. *Meningococcal vaccine*
    • Only meningococcal polysaccharide vaccine (MPSV) is available • Minimum age: 2 years • Revaccination only once after 3 years in those at continued high risk
15. *Cholera Vaccine*
    • Minimum age: one year (killed whole cell vibrio cholera (Shanchol) • Two doses 2 weeks apart for >1 year old
16. *Japanese encephalitis (JE) vaccine*
    • Recommended in endemic areas only • Live attenuated, cell culture derived SA-14-14-2 vaccine is preferred • Minimum age: 8 months; can be co-administered with measles vaccine at 9 months; single dose • Catch up vaccination: all susceptible children up to 15 yrs should be administered during disease outbreak/ahead of anticipated outbreak in campaigns.

Vaccine ▼ / Age ►	7-10 years	11-12 years	13-18 year
Tdap[1]	1 dose (if indicated)	1 dose*	1 dose (if indicated)
HPV[2]	See footnote 2	3 doses*	Complete 3-dose series
MMR[3]	Complete 2-dose series		
Varicella[4]	Complete 2-dose series		
Hepatitis B[5]	Complete 3-dose series		
Hepatitis A[6]	Complete 2-dose series		
Typhoid[7]	1 dose every 3 years		
Influenza Vaccine[8]	One dose every year[$]		
Japanese Encephalitis Vaccine[9]	Catch-up up to 15 years[$]		
Pneumococcal Vaccine[10]	See footnote 10[$]		
Meningococcal Vaccine[11]	See footnote 11[$]		

*Range of recommended ages for all children; *Range of recommended ages for catch-up immunization; [$]Range of recommended ages for certain high-risk groups.*

FIG. 2 *IAPCOI recommended immunization schedule for persons aged 7 through 18 years, 2012 (with range).*

1. *Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine:* • Minimum age: 10 years for Boostrix and 11 years for Adacel • Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter • Tdap vaccine should be substituted for a single dose of Td in the catch-up series for children aged 7 through 10 years • Tdap vaccine can be administered regardless of the interval since the last tetanus and diphtheria toxoid–containing vaccine • Catch up above 7 years: Tdap, Td, Td at 0, 1 and 6 months • Tdap can also be administered safely to pregnant women.
2. *Human papillomavirus (HPV) vaccines:* • HPV4 [Gardasil] and HPV2 [Cervarix] • Minimum age: 9 years • Either HPV4 (0, 2, 6 months) or HPV2 (0, 1, 6 months) is recommended in a 3-dose series for females aged 11 or 12 years • HPV4 can also be given in a 3-dose series for males aged 11 or 12 years • The vaccine series can be started beginning at age 9 years • Administer the second dose 1 to 2 months after the first dose and the third dose 6 months after the first dose (at least 24 weeks after the first dose).
3. *Measles, mumps, and rubella (MMR) vaccine:* • The minimum interval between the 2 doses of MMR vaccine is 4 weeks • One dose if previously vaccinated with one dose.
4. *Varicella (VAR) vaccine:* • For persons without evidence of immunity, administer 2 doses if not previously vaccinated or the second dose if only 1 dose has been administered • For persons aged 7 through 12 years, the recommended minimum interval between doses is 3 months. However, if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid • For persons aged 13 years and older, the minimum interval between doses is 4 weeks.
5. *Hepatitis B (HepB) vaccine:* • Administer the 3-dose series to those not previously vaccinated • For those with incomplete vaccination, the recommended minimum interval between dose 1 and dose 2 is 4 weeks, and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered at least 16 weeks after the first dose.
6. *Hepatitis A (Hep A) vaccine:* • Administer 2 doses at least 6 months apart to unvaccinated persons • For catch up vaccination, pre vaccination screening for Hepatitis A antibody is recommended in children older than 10 years as at this age the estimated sero-positive rates exceed 50% • Combination of Hep B and Hep A may be used in 0, 1, 6 schedule.
7. *Typhoid vaccine* : • Only Vi-PS (polysaccharide) vaccine is recommended • Vi-PS conjugate vaccine: data not sufficient to recommend for routine use of currently available vaccine • A minimum interval of 3 years should be observed between 2 doses of typhoid vaccine.
8. *Influenza Vaccine* : • Administer 1 dose to persons aged 9 years and older • For children aged 6 months through 8 years • For the 2012 season, administer 2 doses (separated by at least 4 weeks) to those who did not receive at least 1 dose of the 2010-11 vaccine. Those who received at least 1 dose of the 2010-11 vaccine require 1 dose for the 2011–12 season • Annual revaccination with single dose • Best time to vaccinate: as soon as the new vaccine is released and available in the market & just before the onset of rainy season;
9. *Japanese Encephalitis (JE) Vaccine* : • Only in endemic area as catch up • Currently no type of JE vaccine available in private Indian market • Live attenuated, cell culture derived SA-14-14-2 JE vaccine should be preferred • Dose: 0.5 ml, SC, single dose up to 15 yrs.
10. *Pneumococcal Vaccines* : • Pneumococcal conjugate vaccine [PCV] and pneumococcal polysaccharide vaccine [PPSV] both are used in certain high risk group of children • A single dose of PCV may be administered to children aged 6 through 18 years who have anatomic/functional asplenia, HIV infection or other immunocompromising condition, cochlear implant, or cerebral spinal fluid leak • Administer PPSV at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant • A single re-vaccination (with PPSV) should be administered after 5 years to children with anatomic/functional asplenia or an immunocompromising condition.
11. *Meningococcal Vaccine:* • Recommended only for certain high risk group of children, during outbreaks, travelers to endemic areas, and students going for study abroad; • Only meningococcal polysaccharide vaccine (MPSV) is available; • Minimum age: 2 years; • Dose schedule: a single dose 0.5 ml SC/ IM is recommended; • Revaccination only once after 3 yrs in those at continued high risk.

In addition to this, WHO classifies India under the 'South Asia' transmission zone of Influenza circulation. This along with summary review of the 2011 southern hemisphere winter influenza season [73] strongly points India's alignment with the availability of Southern hemisphere vaccine (March-April) to ensure we have the latest available strains for early vaccination to prevent the peak of circulation of Influenza in the rainy season across the country.

D. Updated and consolidated footnotes of all IAPCOI recommended vaccines

The committee has decided to update and consolidate all the footnotes of IAP recommended vaccines. The readers can access them at the committee's official website at www.iapcoi.com

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ANNEXURE 1

Participants

IAPCOI members: TU Sukumaran; Rohit Agrawal; Vipin M Vashishtha; A Parthasarathy; Nitin Shah; Raju Shah; Naveen Thacker; Panna Choudhury; Suhas Prabhu; SG Kasi; S Sanjay; AJ Chitkara; Monjori Mitra; Vijay Yewale and Pravin Mehta (Rapporteur).

Following were the special invitees who attended the meeting during their respective sessions only:

Ashish Bavdekar, Pune; Krishna Ella (Bharat Biotech); Sai D Prasad (Bharat Biotech); Shailesh Mehta (GSK vaccines); Swashraya Shah (MSD); Sudhanshu Pandey (MSD); Rohit Arora (Sanofi Pasteur); Shafi Kolhapure (Chiron Panacea); Gautam Rambhad (Wyeth).

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