

INDIAN ACADEMY OF PEDIATRICS
Kailas Darshan, Kennedy Bridge, Mumbai-400007

Minutes of the meeting of the IAP COMMITTEE ON IMMUNIZATION (IAPCOI) of Indian Academy of Pediatrics held on 24th & 25th August 2012 at Hyatt Regency Hotel, Sahar, Mumbai from 09.00 am onwards.

The following IAP members were present at the meeting:

Chairperson - Dr Tu Sukumaran
Chairperson - Dr Rohit C Agrawal
Convener - Dr Vipin M Vashishtha
President-Elect- Dr. C. P. Bansal
Secretary General- Dr. Sailesh G. Gupta
Member – Dr Amarjeet Chitkara
Member – Dr Manjori Mitra
Member – Dr S Sanjay
Member – Dr SG Kasi
Member – Dr Suhas V.Prabhu
Adviser - Dr Nitin K. Shah
Adviser - Dr Raju C. Shah
Adviser - Dr Naveen Thacker
Adviser - Dr A Parthasarathy
Ex-Officio - Dr Panna Choudhury
Ex-Officio - Dr Vijay N Yewale
Ex-Officio - Dr Abhaya K.Shah
Rapporteur: Dr. Pravin J. Mehta

Dr. Ritabrata Kundu, Chairperson of IAP ID chapter, an ex-officio member of IAPCOI expressed his inability to attend due to personal reasons.

Friday, 24th Aug 2012

The President, Dr. Rohit C. Agrawal welcomed the members present in IAPCOI meeting and requested their cooperation in smooth conduct of the meeting. He thanked the entire committee for their monumental contribution in IAPCOI and also congratulated the committee members, especially the National Convener Dr Vipin M Vashishtha for their commendable job for the successful completion of more than one year of IAPCOI committee. He then requested Dr Vipin M Vashishtha to proceed with the transaction of the business as per the agenda circulated earlier.

Agenda: 1) ATR on the minutes of last meetings

- Issue was raised regarding the “Limitations/scope of activities to be taken up by the of IAP committee on Immunization”, where Dr. Sailesh G. Gupta suggested the following points:
 - Suggestion can come from all IAP committee and that should be ratify in October EB meeting
 - TOR should be decided for all IAP committees
 - IAP committees can recommend suggestion to IAP executive board (EB) but it should not be binding.

- The committee member suggested that the Copy of IAPCOI survey / report / conclusion (dissemination plan, publication, & free reprint) should be circulated to all IAPCOI members.

- The committee also expressed satisfaction on publishing its detailed recommendations based on last meeting’s proceeding at Mumbai and also on publishing the new timetable for the year 2012.

- Dr. Sailesh G. Gupta apprised the members about the current status of ‘Immunize India’ program which was earlier a part of activities of IAPCOI. This program, now the core activity of IAP President’s Action Plan 2012, deals with reminder of vaccination via SMS to each registered parent. The plan was recently launched all over the country and the committee is requested to actively participate in this activity.

- The convener also briefly apprized the house about the key developments in regard to working of COI’s subcommittees on EBR and AEFI since separate sessions were kept for both these sub-committees. Dr Vashishtha informed the house that the work on EBR of Rotavirus has already underway and one group of researchers at Varanasi performing it. Dr Panna Choudhury, convener of IAP sub-committee on EBR informed the house that the final review shall be available by the mid-October after which the EBR sub-committee will frame the recommendations based on GRADE methodology. Dr Vipin Vashishtha informed the committee that this exercise was going to be an expensive one and the committee would need to spend a significant amount to sustain this activity in future too. Dr Naveen Thacker and Dr A.J. Chitkara, the chairperson and convener of the sub-committee, respectively informed briefly the key developments in this regard. The committee applauded both of them for their exceptional work in this regard.

- Dr Vipin M Vashishtha informed the house about the current status of IAPCOI’s ambitious project of IAP Textbook of Vaccines. It was suggested by the office-bearers that the book should be approved by IAP-EB before it is published.

- There was also some discussion on the issue of replying to the FAQ’s posted to the IAP and IAPCOI websites. Dr Panna Choudhury and Dr. Sailesh G. Gupta suggested

that a sub-committee should be formed where one official spoke-person and one member from each zone (total 10 members) should be appointed and authorized to reply the queries posted there. Dr. Sailesh also suggested Dr A Parthasarathy's name as an official spoke-person and requested committee to appoint the zonal members.

- Dr S.G. Kasi informed the committee members about the status of BD-IAPCOI joint venture on '**Time & Motion study**'.
- Dr Vashishtha informed the house that the KAP survey of paediatrician was completed and a paper was under final stages of submission to a reputed peer reviewed journal.
- Regarding publication of IAP position papers on Measles and Hib disease by Dr S. Sanjay and Dr Raju Shah, respectively, the duo were requested to do the needful within four weeks.
- In the end, Dr Vashishtha shared few of the achievements of current committee with members. The laurels included WHO accreditation of IAPCOI website in to the list of websites that adhere to the credibility and content criteria of good information practices, and felicitation of IAPCOI at the 15th International Congress of Infectious Diseases at Bangkok for its exemplary work in the field of global typhoid prevention and control.

Agenda: 2) Conflict of Interest issues

- Dr Vipin M Vashishtha requested every member to go through IAPCOI website and check the updated Conflict of Interest policy.
- Dr Vashistha informed the house that the conflict of interest issues were indeed a very serious matter and since the committee had embarked upon issuing evidence-based recommendation, this issue cannot be left unaddressed. He further stated that the new 'code of conduct' prepared by the committee in lieu with MCI recommendations would be mandatory to sign by every member, advisor, and office-bearer of the committee. However, since the current committee members were not aware of this formality, he suggested that this code would come in force from the subsequent terms. It will not be appropriate to enforce it now retrospectively. The members, advisors and office-bearers were requested to declare their conflict of interests on a uniform proforma prepared and circulated in advance to each member. The members complied and submitted the duly filled and signed forms to the committee.
- The convener further stated that a 'three- member committee' should be appointed by EB which will go into the details of conflict of interest and should recommend appropriate action for resolving the issue of conflict of interest.

- The committee shall examine the declared conflicts, and decide whether a member has got 'significant' conflicts and whether he/she should be allowed to remain a part of the committee or of the decision making body.
- Many members were of the opinion that this code and arrangement should be uniformly applied to all committees of the parent body.

Agenda: 3) Symposium on Typhoid vaccination

Dr Vipin M Vashishtha presented an overview of IAPCOI perspectives on typhoid disease and vaccination. He briefly presented the disease burden of typhoid fever in India along with certain contentious issues related to large scale typhoid vaccination in India.

Dr Vipin M Vashishtha welcomed Dr R Leon Ochiai, M.H.S. an internationally acclaimed expert on epidemiology of typhoid fever in Asia and a research scientist at the International Vaccine Institute (IVI), Korea. Dr Ochiai presented an overview of the global, regional and national Typhoid burden. He also participated in a discussion with members and answered their queries.

Dr Vipin M Vashishtha also welcomed Dr. Sushant Sahastrabuddhe, IVI Korea; who presented a brief overview of currently available typhoid vaccines, and also shared the status of new conjugate typhoid vaccine being developed by his institute.

Dr. Raju C Shah was the lead discussant and very ably moderated the discussion on typhoid vaccination that followed the presentations.

Agenda: 4) Symposium on Rotavirus Vaccination

Dr Vipin M Vashishtha projected the contentious issues related with current rotavirus vaccines and also presented IAPCOI's perspectives on Rotavirus disease and vaccines.

To carry forward the symposium Dr Vipin M Vashishtha invited Dr Gagandeep Kang, a renowned expert in the field of Rotavirus disease and vaccines from CMC Vellore, who quite patiently and diligently answered all the queries raised by the committee members with evidence based explanation. She also presented recent scientific data on various studies going on in the field of Rotavirus disease and vaccines.

Dr Rohit Agarwal moderated the entire discussion.

In the end, the entire house acknowledged her contribution with an impromptu standing ovation.

Agenda: 5) Symposium on Hepatitis-A vaccination

Dr. Manjori Mitra presented the contentious issues faced by the committee regarding Hepatitis-A vaccines.

Dr Nitin K Shah, advisor of the committee, discussed the issue of live Hep-A vaccine one dose v/s two doses and also the use of a single dose of inactivated Hep-A vaccine in public sector. An intense yet healthy discussion followed his presentations, and the matter regarding single dose of a live, H-2 hep-A vaccine instead of currently recommended and practiced remained unresolved despite seeking a division of the vote on the issue. In the end, it was decided to wait for publication of more long term data on the persistence of protective efficacy beyond three years before any change is made to current recommendations. The matter was postponed for the next meeting of the committee which shall be convened in December this year.

In the end, Dr Vipin M Vashishtha appreciated the wonderful work done by Dr Nitin K Shah.

Dr. Vijay Yewale moderated and summarised the discussions on this vaccine.

Agenda: 6) Symposium on Polio End-game strategies

Dr Vipin M Vashishtha presented the IAPCOI's perspective on 'end game' and post-eradication polio vaccination policy.

Dr. Raju C Shah briefly discussed about the concept, need and implications of polio 'end-game'. He also apprized the house about the current status of global polio eradication initiative, especially the cVDPVs.

Dr. A. Parthasarthy shared the current thinking and probable timeline of global 'end-game' initiative. He suggested the feasibility of developing a hexavalent combo-vaccine formulation containing DTPw-HB-Hib-Sabin IPV by indigenous vaccine manufacturers of India with technology transfer, should also be examined in future. Whether to go in for an ALL IPV doses in 2 doses schedule in routine immunization and route of administration (IM/ID) will also be discussed in due course.

Dr. Naveen Thacker who moderated the entire session discussed various implications of 'end-game' strategies to IAPCOI. The house unanimously adopted that at least two doses of IPV should be used, preferably all over the country. Intra-dermal route should only be preferred if local data support its effectiveness at indigenously conducted trials. The committee believes that though bio-safety issues are important, but India should be allowed to produce IPV indigenously to take care of demand and cost issues pending Sabin IPV efficacy results.

Agenda 7). Miscellaneous issues

1- Dr M Kuppuswami , Managing Director of Tergene Biotech, India presented the details of a new 15-valent pneumococcal conjugate vaccine (PCV 15) which is being developed indigenously with the support of Department of Biotechnology, GoI.

2- Dr. Manjori Mitra presented the details of existing and newer JE vaccine. She shared few early results of an ongoing clinical trial of an Indian JE vaccine being developed by M/s Bharat Biotech. The issue of comparatively poor efficacy of Chinese live attenuated SA-14-14-2 JE vaccine in India was also discussed. The committee debated the issue of issuing new recommendation of providing two doses of this vaccine.

Meeting was adjourned for the day and remaining part of this agenda was scheduled for the next day.

Day 2, Saturday, 25th August 2012

Agenda 7). Miscellaneous issues (contd)

3-Dr Panna Chaudhary presented details of a software developed by Institute of Medicine (IOM) called “ SMART (Strategic Multi-attribute Ranking Tool for Vaccines) Vaccine Beta.” This software is a novel tool to assist various stakeholders in prioritization of vaccine, i.e. which vaccines most need to be developed. He also presented its utility for our policymakers and vaccine industry.

Agenda 8). IAPCOI subcommittees’ reports

1- EBR subcommittee report:

Dr Panna Choudhury presented the activities of IAP subcommittee of EBR. One exclusive meeting of the committee was held on 19th February 2012 at New Delhi. Dr Panna Choudhury shared the minutes of the meeting which stressed the need of devising an impeccable ‘conflict of interests’ policy at the outset. He also informed the current status of the EBR on Rotavirus disease and vaccines. He also informed the office-bearers about the financial implications of undertaking these projects. Dr Yewale suggested that some other institutions including professional companies, involved in this process should also be approached.

2-AEFI subcommittee report:

The convener of this committee, Dr. A.J. Chitkara presented the report of the subcommittee. He also informed the house about the initiatives taken by the committee with the Government so far. The house applauded the efforts of Drs Chitkara and Naveen Thacker (Chairperson) in this regard. Dr Naveen Thacker presented brief information regarding the use of IDSurv for

AEFI reporting and informed the house that online IDSurv can now be used for AEFI reporting. The GoI has also approved this type of reporting.

The following suggestions were made during discussion

- Five IAP members (paediatricians) should be selected for observation of AEFI reporting
- Continue with same AEFI system as before
- The reporting forms will be uniform and approved by the government

The president and chairperson of IAPCOI, Dr Rohit C Agrawal welcomed Dr. Ajay Khera, Deputy Commissioner, Child Health & Immunization, GoI.

Dr. Ajay Khera discussed in brief the background of adverse event following immunization (AEFI) in India and also highlighted the need and its importance in a developing country like India. He said that, among 6 critical indicators of WHO assessment, one of the important assessments before GoI is to pass the AEFI system, particularly in context of vaccines and keeping its sensitivity in the mind, GoI has now decided to pay highest attention to proper AEFI reporting. According to him, the current reporting of AEFI is indeed very dismal. He requested IAP to start with only 'serious' types of AEFI reporting. The purpose behind this is to understand the reasons along with 'programmatic errors' occurring during the process of vaccination. He also shared the few 'serious AEFIs' that had made big media impact in recent times. According to him, the science of 'causality assessment' is an evolving specialty in the country for which a specialized kind of training is needed. And despite undertaking all the investigations, sometimes it is not possible to arrive at a correct diagnosis and many a times the cause may remain undetermined.

He sought IAP's support in following aspects:

- Reporting of AEFI and helping GoI in developing an effective AEFI reporting system in the country, and strengthening the national regulatory authority (NRA) of the country;
- Handling media effectively after occurrence of any serious AEFI
- Tackling any misinformation campaign against national immunization programs by anti-vaccine lobby;

He also assured house that he will request the state authority to nominate an IAP member as a committee member in State AEFI committee. He invited the convener of the committee, Dr. A. J. Chitkara to discuss this issue further in their next meeting.

In the end, he complemented IAP for doing good work to improve the AEFI system.

Dr Rohit C Agrawal suggested following points:

- One IAP member be elected as a National nodal person who shall remain in contact with GoI and be responsible for the appointment of state nodal members from each state;
- Workshops shall be conducted where training will be given regarding AEFI reporting and media handling;
- Such trained person will be labelled as a ‘State nodal person’ who will be in charge to deal with these issues in their respective states,
- A proposal will be sent to GoI in this regard.

Ms Anuradha Gupta, IAS, Mission Director, NRHM, Ministry of Health & Family Welfare, GoI also joined the COI meeting and interacted with the committee members on various issues related to national vaccination program. Dr Rohit Agarwal, and president-elect, Dr C.P. Bansal welcomed Ms Anuradha Gupta. She discussed about the current vaccination policy of GoI including its strategy on introduction of new vaccines in to national immunization program. She informed the house that there was no scarcity of funds as far as introduction of newer antigens is concerned and the government is not very interested on this particular option as far as GAVI’s proposal of financing new vaccines is concerned. However, the major concern is how to develop an effective health infrastructure in the country to support such major initiatives. She further informed that the government was looking for technical inputs and support from international agencies and institutions like GAVI to take care of its plan of investing and later developing an effective health infrastructure to effectively utilize such introductions of newer vaccines. She also expressed her concerns on current state of RI in the country where 40% of eligible population is still not provided full immunization.

Later, Ms Anuradha Gupta also addressed a media conclave jointly with the office-bearers of IAP and IAPCOI on current government perspectives on immunization..

Agenda 9). Symposium on VPD Surveillance

Dr. Naveen Thacker presented the recent initiatives of surveillance subcommittee. The innovative passive VPD surveillance program of IAP, IDSurv was also officially launched in the National ToT, Vaccicon that immediately followed the COI meeting at the same venue. Dr. Thacker also apprized the house on new proposed features of IDSurv that included AEFI reporting and generation of ‘VPD Alert’.

He also sought committee’s instructions on how to utilize, synthesize and analyze available data on 10 VPDs through this system. He also underlined the need of inducting full-time professionals to streamline its functioning. There is a need to expand its base so that entire country gets representation and more useful data is generated by the year end.

Later, following members made presented epidemiological data on ten VPDs reported through IDSurv so far:

Pneumonia and Diphtheria

Dr. Vijay Yewale

Pertussis and Hepatitis	Dr. A J Chitkara
Measles and Mumps	Dr. S. Sanjay
Dengue Fever	Dr. S G Kasi
Chicken Pox and ABM	Dr. Suhas Prabhu
Typhoid	Dr. Pravin Mehta

Agenda 10). Open house

(Discussion on contentious issues/communications, etc)

1-The issue of conflict of interests was again taken up for discussion and it was resolved that a request will be made to IAP EB to form 'a three member committee' to examine the disclosures made by the members.

2-The issue of recent misrepresentation/distortion of IAP immunization Timetable by M/s Sanofi Pasteur was also taken up for discussion with the representatives of the latter. The executives of M/s Sanofi Pasteur offered unconditional apology and promised not to repeat this misdemeanour again.

3-Dr. Yash Paul, a senior expert on vaccine science, made a brief presentation on the need of offering an affordable low dose-pertussis, diphtheria and tetanus vaccine to poor adolescents/adults/pregnant women who are unable to afford current Tdap vaccine which is quite expensive. The committee assured him of pursuing this matter with appropriate authorities.

4-Some other issues like IV Hep-B immunoglobulin for HBsAg-positive mothers, Serum Institute of India's plea on inappropriately published information on their rabies human diploid cell vaccine in IAP Guidebook, and age limits recommendations on Adacel were also taken up for discussion.

Meeting ended with a vote of thanks to the chair.

Rapporteur: Dr Pravin J. Mehta