# Report of the National Consultative Meeting

# on Hepatitis-B & The Polio Eradication Initiative



New Delhi 14<sup>th</sup> May, 2006

#### About IMA

The Indian Medical Association was established in the year 1928. It has a membership of over 1.64 lakhs modern medicine doctors spread over 33 states and UTs. It has more than 1600 branches; even in the remotest corners of the country. Improvement of public health, maintenance of the honour and dignity of the profession while keeping the interest of general public in mind are important objectives of IMA, among other things. The Association has empowered itself to consider and express its views on all questions on the laws of India or proposed legislation affecting public health, medical profession and medical education and to initiate or watch over or take such steps and adopt such measures from time to time regarding the same, as may be deemed expedient or necessary

#### About Plan International

Plan is a transnational, humanitarian, child centered community development organization without religious, political or governmental affiliations.

Children are at the heart of everything we do. Our vision is of a world in which all children realise their full potential in societies which respect people's rights and dignity. Plan has programmes in 62 countries. In communities we work with, children are often involved directly in planning, implementing and monitoring projects which benefit them, their families and the community at large.

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Plan International (India) reaches out to vulnerable children in remote areas and facilitates development processes that would result in increased security for children, their families and communities.

#### Organising Committee

**Indian Medical Association** 

National President **Dr. Sanjiv Malik** 

Hony. Secretary General **Dr. Vinay Aggarwal** 

Hony. Joint Secretary & Convenor **Dr. Dharam Prakash** 

**Sub-Committee** 

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Prof. S.K. Mittal

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Dr. Jacob Pulivel

Dr. Onkar Mittal

Members

Dr. C. Satyamala

Dr. Joseph Mathew

Dr. Tarun Gera

Dr. Ajay Gambhir

The issues related to introducing Hepatitis B immunisation and controversies regarding the polio eradication program have been causing concern among medical professionals in the country. The National President of the Indian Medical Association (2005-2006), Dr Sudipto Roy set up a committee under the Chairmanship of Prof S.K.Mittal with Dr. Dharam Prakash as Convener, to look into the issues involved. The Committee first met on 19 October 2005. It was decided to hold a national level consultation on 14 May 2006 to discuss the issues related to Hepatitis-B immunization and polio eradication in India. It was resolved that prior to this, the sub committee must draft position documents.

Dr Jacob Puliyel prepared the draft on position paper on Hepatitis B while Dr. Onkar Mittal and Dr C. Sathyamala, prepared the same for Polio eradication. The drafts were discussed in several meetings of the sub-committee and adopted as position papers by it after careful consideration of available literature.

The background papers were circulated to a host of eminent experts in the country, spanning several specialties including Paediatrics, Gastroenterology, Public Health, Biostatistics and Social Sciences. The experts studied the



Dr. Dharam Prakash, Convenor & Hony. Jt. Secretary, IMA



Dr. Sanjiv Malik, National President of IMA

documents and met together for a workshop on May 14, 2006 at New Delhi. Besides researchers, Dr. P. M. Bhargav, Vice Chairman of the National Knowledge Commission, Dr.Jay Wenger, Project Manager of the WHO National Poliomyelitis Surveillance Project. representatives of the Indian Academy of Paediatrics (IAP) and India Expert Advisory Group on Polio Eradication were invited. The background papers were presented and each member present was asked to respond. The comments of all members were tape recorded. A tentative set of conclusions were drawn by consensus at the end of the day. Thereafter, the summary of the proceedings was circulated by e-mail to all participants who were again invited to suggest further modifications.

These responses, along with the proceedings of the workshop were used to develop a set of final conclusions and recommendations. The full text of the two White papers presented and the discussion at the consultation is available online on the IMA website www.imanational.com. This booklet contains a short summary of the proceedings of the day and the recommendations of the IMA Sub-Committee on Immunization on the issues of Hepatitis B vaccination and Polio eradication in India.

#### IMA National Consultation of Experts on Immunization

A national consultation of experts was held on 14 May 2006 co-sponsored by Plan International (India). Plan International (India) was represented by the Country Health Advisor, Dr Nalini Abraham. The President of the IMA Dr Sanjiv Malik, and Honorary Secretary General, Dr Vinay Aggarwal were dignitaries present from the IMA.

The program was inaugurated with a welcome address by Dr Vinay Aggarwal. The inaugural address was given by the IMA President Dr. Sanjiv Malik. Professor S.K. Mittal, as Chairperson of the Subcommittee on Immunization spoke on the objectives of the workshop.

#### Workshop on Hepatitis-B in India

The first session was on Hepatitis-B. Professor S.K. Mittal was the Moderator and Dr Joseph Mathew was the Rapporteur. Dr Jacob M Puliyel presented the draft White Paper. The White Paper was based on a systematic review of literature and a meta-analysis of the point prevalence data on Hepatitis-B and data on resultant deaths from Hepatocellular carcinoma. Also a search of literature using broad and inclusive search terms was performed for studies evaluating the pilot project in India. Systematic search of international literature for efficacy of the 6, 10, 14 week schedule was also presented.

The experts were invited to add references which were missed in the systematic review. Each expert was invited to respond. The entire White paper and discussions are available on the IMA website www.imanational.com. A summary of the systematic review and the final recommendations are presented in this brief report.



Inaugural meeting held on 14th May at New Delhi



Dr. Vinay Aggarwal, Hony. Secretary General, IMA

### Workshop on the Global Polio Eradication Initiative in India

This second session was held after lunch. The moderator of the session was Professor S K Mittal. Dr Tarun Gera was the Rapporteur.

Dr. J.Wenger, National Polio Surveillance Project spoke first on the current status of polio eradication in India. He also responded in writing to the position document. His written response is being published unedited on our web site.

Dr Onkar Mittal and Dr C Sathyamala presented the position document. They discussed the strides made in control of the disease and the costs, both monetory and to other public health initiatives. They highlighted the problems of vaccine induced poliomyelitis and the unexplained & unprecedented increase in non-polio acute flaccid paralysis. The issue of the use of monovalent polio vaccine as part of a Phase 4 trial without following established national guidelines evoked expressions of concern.

#### Conclusion

Immediately after this session was a short break for tea. A draft of recommendations was formulated having incorporated the opinion of all the experts and presented to the group. A more formal set of recommendations was later emailed to the experts. This booklet summarizes the position papers and the final recommendations.

#### **Vote of Thanks**

Dr. Ajay Gambhir Hony. Secretary, IMA Academy of Medical Specialities HQs, gave the vote of thanks to the sponsors, and participants.

#### Systematic Review & Meta-analysis of Papers related to Hepatitis-B in India

#### **Objectives**

- To assess the prevalence of Hepatitis-B in the country, and collect available data on deaths from hepatocellular carcinoma.
- To evaluate what the immunization program will cost the country.
- To look for evidence of the success of the pilot project.
- To collect evidence from world wide literature on the results of Hepatitis-B vaccination starting at 6 weeks

#### Search strategy

Library and Best bets and previous reviews, including cross references.

#### Data analysis

Done using standard Meta analysis software

#### Main results

- 1. The true prevalence of Hepatitis-B, in non-tribal populations in India is 2.1 (95% CI 1.8-2.5). This corresponds to a chronic carrier rate of approximately 1.6%. Among tribal populations it is 19.4 (95% CI 15.3–23.5)
- 2. The death rate from Hepatocellular carcinoma is very low in the country and constitutes 1.6% of all cancer deaths.
- 3. The pilot project has not been evaluated
- 4. The proposed schedule of immunization starting at 6 weeks has not been shown to be



Dr. Rakesh Agarwal & Dr. B.N. Tandon



Dr. S.K. Mittal, Chairman, Sub Committee & Dr. Jacob Puliyel, Co-Chairman, Sub Committee

efficacious (in reducing prevalence) in any country in the world.

Searches were made of the Medline, Cochrane 5. The cost outlay for universal immunization with Hepatis B Vaccine in India is Rs.500 crores each year.

#### **Author's conclusions**

An evaluation of the pilot project is required before the Government of India decides to incorporate Hepatitis B immunization in the EPI. The data required are:

- 1. Coverage (with 3 doses of Hepatitis B vaccine) in the pilot area.
- 2. The fall in carrier rate in the pilot study area
- 3. Carrier rate among those immunized at 6 weeks compared to those immunized at birth

This is essential because the proposed schedule of immunization starting at 6 weeks, has not been shown to be efficacious (in reducing prevalence) in any country in the world.

#### Professors S K Mittal on the importance of preventing vertical transmission:

Vertically acquired Hepatitis-B results in chronic carrier state in 90% compared to only 5% when infection is acquired after 6 year of age. It is also responsible for most cases of HCC due to Hepatitis-B infection. It is important to know the extent of vertical transmission before formulating Public Health Policies for Universal Infant Immunization In China, horizontal transmission is important. QuZy reported that the number of chronic carriers

increases from infancy to childhood. Prevalence of HBsAg +ve in China:

> 0-1 yr 3.2 % 1-4 yr 8.9% 5-9 yr 10%

In India however there is no significant difference in prevalence of Hepatitis-B markers among infants 0-6 months old and children 4-5 years old (Jain V. et al., Tandon BN et al.) Thus there is little evidence to support hypothesis of the acquisition of Hepatitis-B infection in infancy/early childhood by horizontal transmission in India. Most children are carriers by 5 years of age in India. 2/3rd of all carriers probably occur due to vertical transmission.

#### Synopsis of comments of the experts

**Dr Anand Phadke** pointed out that point prevalence must be multiplied by 0.67 to get the carrier rate. He said the meta-analysis showed India was a low endemicity country.

**Dr Ashok Gupta** cited a thesis where no vertical transmission was recorded

**Dr Ashok Kale** said the previous estimate of 4.7% carrier rate was an arithmetic mean.

**Dr** C **Sathyamala** said that the forest plots in the white paper showed very narrow CI suggesting the data is well powered to interpret it reliably.

**Dr CP Bansal** also wanted vaccines to cover both vertical and horizontal transmission.

**Dr Joseph L Mathew** said that the HBV program must be looked at against other pressing health care needs.

**Dr Naveen Thaker** said that the major route of transmission was horizontal but the most important was vertical transmission.

**Dr Panna Choudhury** said deaths from cirrhosis due to HBV must be studied. He also favored a study in the pilot areas of Delhi and Andhra Pradesh. He said the present evidence was insufficient to decide on a vaccination policy.

**Dr Raju Shah** suggested that cost efficacy be compared with other vaccines. He said one third carriers were due to vertical transmission. He felt the program may cost only Rs 135 crores.

**Dr Ritu Priya** said 1% of all deaths were due to chronic liver disease. She wanted clarity on what

proportion of this was due to HBV.

**Dr Tarun Gera** said that there was indeed no study in world literature where the 6,10,14 week schedule was found efficacious.

**Dr V Sreenivas** said that the ICMR cancer registry was reliable and accepted the world over. He also said evidence based medicine was the best approach although traditional wisdom has its own place.

**Dr V N Tripathi** strongly supported the birth dose. **Dr. Rakesh Aggarwal:** The review of literature appears to be somewhat biased. Off hand it is difficult to quote any literature but there are studies that have shown better cost efficacy of universal Hepatitis B vaccination then suggested in the position paper. Also horizontal transmission is the major route of acquiring infection rather than vertical transmission.

**Dr. S.K. Mittal:** Even if vertical transmission is responsible for only 10% of infections, still it will be the major cause of chronic carriers as 90% of vertically infected infants become chronic carriers while only a small proportion of later infected individuals develop chronic carrier stage.

**Prof B N Tandon** felt that academic discussions need to be abandoned and we need to get on with immunization but it must be decided whether to vaccine universally or selectively. He too thought the cirrhosis deaths due to HBV need to be studied. He thought we had become slaves to evidence based medicine.

**Prof Parthasarthy** suggested routine testing of pregnant mothers and birth dose to babies born to positive mothers.

**Prof** U **Jhamb** said 0.5% admissions in children were due to Chronic liver disease and 20% of this was due to HBV.

Professor Nirmal Kumar felt Evidence Based Medicine was not the way to arrive at right answers. He felt that vertical transmission needs to be prevented. He felt that if costs of vaccine came down people would buy their \own vaccine. None of the experts cited papers that had been missed out from the systematic review.

#### Recommendation on Hepatitis B vaccination in India

Conclusion 1: On meta-analysis the true prevalence of Hepatitis-B in India among nontribals is 2.1% (95% CI 1.8 - 2.5). This is the meta analysis of data of point prevalence not carrier rate. It was pointed out that chronic carriers have to be positive on repeat testing in two tests at least 6 months apart. The carrier rate is approximately 80% of the point prevalence rate. This corresponds to a chronic carrier rate of 1.6%



Dr. Anant Phadke of Pune

Conclusion 2: "Hepatocellular carcinoma constitutes only 1.6% of all cancers in India, hence is very rare." However, it is not clear how many of these are related to Hepatitis-B. The estimated annual deaths attributable to hepatocellular carcinoma due to hepatitis B are only 5000. A better marker of burden of Hepatitis-B may be obtained by a registry counting cases of cirrhosis as about a third of cases of cirrhosis in adults is related to Hepatitis-B. Reliable data on this is not available.

**Recommendation:** In view of these estimates, the cost efficacy of universal immunization with Hepatitis-B needs to be re-evaluated.



Dr. A. Parthasarthy of Chennai

Conclusion 3: Vertical transmission of infection from mother to child is an important mode of acquiring Hepatitis-B infection, especially in establishing chronic Hepatitis-B carriers. The exact incidence of vertical transmission is not known in our country but it may be contributing between 30% to 40% of the pool of chronic Hepatitis-B carriers.

Recommendation: Before launching any national program it would be vital to assess the contribution of vertical transmission to the overall Hepatitis-B carrier pool. If universal Hepatitis-B vaccination is to be carried out, currently available data, though inadequate, would strongly favour initiation of Hepatitis-B vaccination starting at birth, to derive maximum benefit from the programme.

**Conclusion 4:** There is no scientific data from **Recommendation:** It will not be advisable to anywhere in the world that the schedule of 6,10 and 14 weeks has been found to be effective in reducing the carrier rates of Hepatitis-B. The pilot project carried out in Andhra Pradesh and Delhi with 6, 10 and 14 weeks has not been evaluated for its efficacy. We need to know the effect on carrier rates among the children who received the vaccine at 6, 10 and 14 weeks compared to the unvaccinated children.

initiate a National/Sub-national immunization program without proper evaluation of the pilot project.



Dr. Sanjiv Malik (right) & Dr. S.K. Mittal



Dr. Panna Chaudhary, MAMC, Delhi



Dr. Raju C. Shah, Past President, IAP



Dr. Naveen Thacker, President-Elect, IAP

chronic carrier rate among the tribal population is very high (19.4%) (95% CI 15.3 – 23.5) which is comparable to those living in the East **Asian Countries** 

Conclusion 5: The overall prevalence of Recommendation: A well designed epidemiological study is needed in this population to study the natural history of the disease. If necessary, a vaccination program, with first dose being given at birth, could be considered in these population groups.

#### Global Polio Eradication Initiative in India-1995- 2006

#### **Main Points**

- 1. Polio eradication initiative has helped to dramatically decrease the incidence of paralytic poliomyelitis from over 40,000 cases per year to less than 200 cases per year now. Only 4 states continue to have wild polio cases and very few districts are reporting cases. P<sub>2</sub> virus has been eliminated and P<sub>3</sub> has also been largely contained. Only two lineages of P<sub>1</sub> virus continue to circulate. Despite these positive gains, continued circulation of Wild Polio Virus (WPV) despite 12 years of intensive efforts, is a cause of deep concern.
- 2. There has been a dramatic increase in the number of AFP cases in the last 2-3 years, with a national average rate of 6.3/1,00,000 and even higher incidence of 12-13/1,00,000 in endemic states of UP and Bihar, against an international average of 1/1, 00,000.
- 3. There is an urgent need for a complete epidemiologic investigation into the cases of AFP with a view to find out the reason for the rising incidence, to know the exact cases



Dr. C. Sathyamala, Member, Sub-Committee



Participants in attention

- and nature of these AFP cases, and to provide appropriate treatment and rehabilitation
- 4. Strategy of increasing the number of pulse polio rounds each year (the NIDs and SNIDs) to meet the challenge of continuing transmission of WPV does not seem to be meeting the desired objective of stopping the transmission of WPV and needs to be reviewed.
- 5. The monovalent Oral Polio Vaccine-1 (mOPV1) has been introduced in India since last two years, through the polio eradication programme. More than 5-6 pulse polio rounds have been undertaken in the states of UP and Bihar with mOPV1. Impact of these multiple rounds of mOPV1 needs to be assessed.
- Inactivated Polio Vaccine (IPV) has been introduced in many developed countries, to tackle the problem of Vaccine Associated Polio Paralysis (VAPP) due to OPV, while maintaining the immunity against wild polio virus. Desirability, feasibility and cost efficacy

- of this strategy needs to be discussed in the national context.
- 7. Strategies that need to be adopted, if we fail to stop the transmission of WPV, need to be discussed as much as the 'post-eradication-strategies' which would be required only if we are able to stop the wild polio virus transmission.

#### **One Way Forward**

- 1. The year 2006 should be the year of the phased withdrawal and ultimate closure of the National Pulse Polio Program.
- 2. Urgent investigation should be carried out on the actual incidence of Post Polio Residual Paralysis (PPRP) in the cases of reported AFP in the last 10 years.
- 3. The activities of the polio-immunization should be re-integrated into the Universal Immunization Program.
- 4. An expert committee should review the present evidence base on efficacy of the IPV and cost—benefit-ratio of substituting IPV for OPV and other issues related to the relative merits of these programs in the prevention of the transmission of WPV.
- 5. The improvement of sanitation and hygiene



Dr. J. Wenger Head of Dept, National Polio Survellence Project, WHO



Dr. Onkar Mittal, Consultant-Health Policy & Governance, Delhi

- should be taken up as the highest priority, specially, in those urban and rural pockets of UP and Bihar, which have been reporting the cases of WPV in the last three years.
- 6. An independent commission should be appointed to review all aspects of National Pulse Polio Program in the last ten years and appropriate lessons should be drawn for the health policy formulation, program implementation and health governance in this country.
- 7. A comprehensive policy and program for the rehabilitation of the children who have been paralyzed during the period of the polio eradication initiative should be worked out.

#### Synopsis of comments of the experts

**Dr A D Tiwari** said that his personal experience was that there was a lot of under reporting from Bihar.

**Dr A Kale** spoke of the threat of bioterrorism with polio virus.

**Dr A Phadke** Thought that polio was not eradicable

**Dr Ajay Gambhir** said doctors were developing apathy to PEI He said there was no attention being paid to water supply and sanitation.

**Dr Ashok gupta** said water and sanitation need to be looked at and the possibility of using IPV.

**Dr CP Bansal** felt workers at the grass root level were poorly paid and not motivated.

**Dr Jay Wenger's** response was that big progress was already made with polio eradication. He felt that the 1/100,000 rate of non polio AFP was only a minimum target not the international average. He felt that once OPV is stopped VDPV and IVPDV will disappear after some time. He felt that the authors must tone down the "experimental drug rhetoric." The full text of his response is published on the web site.

**Dr.Joseph Mathew** felt evaluation of surveillance must be done by an external agency independent of the NPSP/WHO.

**Dr Mahesh** thought there was fatigue among PEI workers.

**Dr Naveen Thacker** said WPV was localized to a few pockets. He said the IEAG had recommended IPV in these areas.

**Dr P M Bhargava** spoke of the plan in 1980 to manufacture IPV in India and how the plan was shelved for no explicit reason. He spoke of his experience of the poor condition of the cold chain in district hospitals.



Regional Coordinator-North, NPSP, WHO



Dr. P. M. Bhargav Vice Chairman, National Knowledge Commission

**Dr Panna Choudhury** felt that dissemination of information by the NPSP was selective leading to confusion and concern.

**Dr Parthasarthy** felt that looking at the numbers we might be looking at a resurgence of WPV. He felt IPV must be used.

**Dr R N Srivastava** said the problem in western UP was lack of political will. He said that 45 - 49% of non polio AFP were not in fact AFP.

**Dr Rajeev Tandon** said we should aim at eradication not control.

**Dr Raju Shah** felt that IPV was not affordable and that eradication was still possible. He said VAPP was not a big issue.

**Dr Ritu Priya** said that by epidemiological classification the agencies were not aiming for eradication.

**Dr. Harish Verma**, Regional Coordinator-North, NPSP felt polio eradication was the only option available. He said that mOPV was being used as phase 4 trial. Professor Mittal wondered why consent from parents, as for a phase 4 trial, was not being obtained.

**Dr Yash Paul** wondered if the population in North India was resistant in its response to OPV or genetically predisposed to WPV.

#### **Polio Eradication: Current Status**

#### Gains achieved by the programme:

- Confirmed wild polio cases down significantly.
- Number of 'infected' states has decreased.
- Very focal transmission now.
- · P3 almost absent.
- Less genetic bio-diversity now.
- Coverage during pulse polio rounds is 'improving'.
- "Excellent" surveillance system in place.
- Large scale social mobilization operation in India that cut across several barriers (during pulse polio rounds).

#### The costs:

- More than Rs 5,000 crores have already been spent.
- Higher priority health problems have receded to the background.
- Even routine immunization has suffered, as evidenced by higher number of cases of traditional VPDs.
- No mention of VAPP at all in the grand

- reports of covering 170 million per NID and 67 million per SNID.
- Fatigue at all levels.
- Confidence of public and professionals shaken
- A close look shows that with the current strategy "polio cannot be eradicated". (Please see point made to Dr. Wenger's comments)
- No definite plan available for post eradication scenario or if there is a failure to achieve zero WPV status.



Dr Joseph Mathew Assistant Professor, Dept. of Pediatrics, PGI, Chandigarh

Conclusion 1: Continuing circulation of the wild **Recommendation**: Strategies need to be polio virus in a few states, despite intensified reviewed by setting up a National Expert group. pulse polio activities, with multiple changes in Possible use of IPV( alone or in combination strategies and interventions, is a matter of serious concern. At the same time a large number of (See also Conclusion /recommendation 4). states which have been free of WPV for last several years are being unnecessarily being exposed to hazards of VAPP due to OPV.

with OPV) needs to be considered strongly.

the number of clinical AFP cases, particularly in the states of UP and Bihar. Such high incidence of non-polio AFP has not been reported from anywhere else in the world.

Conclusion 3: Administration of multiple doses of mOPV1 in a pulse manner to a very large number of children in different states of the country is unprecedented. It is alarming that the same is being done as phase IV clinical trial without following the established national guidelines for such trials.

**Conclusion 4:** At present, there does not appear to be a coherent policy for the future keeping in mind the possibilities of

a) Pockets of continuing circulation of WPV;

Ultimate cessation of circulation of WPV b)



Dr. Gopal Dabade President, Drug Action Forum

**Conclusion 5:** The number of cases of VAPP is not available in the public domain. It is not known whether any effort is even being made to delineate cases of VAPP.

**Conclusion 2:** There is an alarming increase in **Recommendation:** These reported cases need thorough evaluation, including clinical follow-up, to assess the possible causes, and sequelae thereof. There is also an urgent need of establishing an independent agency (separate from NPSP) for carrying out surveillance activities and their review

> Recommendation: There is a need to immediately evaluate the impact and side effects, if any, of the use of multiple doses of mOPV1.

> **Recommendation:** There is a need for an independent National Expert Group to consider future strategies, which would be best, suited to our country within the overall objectives of the Global Polio Eradication Initiative. The feasibility and desirability of introducing IPV and the suitable timing for the same also needs to be examined by this expert group. There is urgency for deciding on these issues with a view to establish and achieve self sufficiency in manufacturing of IPV in the country, if it is considered desirable to introduce IPV in the immunization program.

> **Recommendation:** District wise and state wise data on VAPP should be made available on a regular basis. Efforts must also be made to asses VAPP among contacts of Vaccinnees. It is also important that the state initiates a comprehensive program of rehabilitation and possibly compensation for the victims of VAPP.

## List of experts invited to the expert consultation and to whom the draft White Papers circulated for comments

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