Recommendations of 2nd National Consultative Meeting of Indian Academy of Pediatrics (IAP) on Polio Eradication and Improvement of Routine Immunization

POLIO ERADICATION COMMITTEE,
INDIAN ACADEMY OF PEDIATRICS

ABSTRACT

Justification: *Persistence of intense wild poliovirus (WPV) transmission, particularly type 3 in northern India necessitated the Indian Academy of Pediatrics (IAP) to convene a National Consultative Meeting to review its earlier recommendations on polio eradication and improvement of routine immunization.* ***Process:*** *More than thirty experts were invited and intense deliberations were held over two days to draw consensus statements on various issues related with polio eradication.* ***Objectives:*** *To review the ongoing strategy,identify the existing challenges, and suggest modifications to the current strategy for eradication of poliomyelitis in India.* ***Recommendations:*** *IAP reiterates its support to ongoing efforts on polio eradication but demand some flexibility in the strategy. The immediate challenges identified include persistent WPV type 1 transmission in Uttar Pradesh (UP) and Bihar, intense type 3 transmission also in UP and Bihar, and maintaining polio-free status of all other states. Circulating vaccine derived poliovirus (cVDPV), particularly type 2, was identified as a great future threat. Neglect of routine immunization (RI), poor efficacy of oral polio vaccine (OPV), operational issues, and inadequate uptake of OPV in the 2 endemic states are the main reasons of failure to interrupt transmission of WPV 1 and 3. However, for the first time in history the intensity of WPV 1 circulation is very low in western UP. IAP suggests that high-quality, uniform and consistent performance of supplementary immunization activities (SIAs) in all districts of western UP, particularly using mOPV-1(monovalent OPV-1) should be maintained to avoid re-establishment of circulation of type 1 poliovirus. A judicious mix of mOPV-1 and mOPV-3, given sequentially or even simultaneously (after validating the efficacies) will be necessary to address the upsurge of WPV-3. Re-establishing routine immunization should be the foremost priority. IAP strongly recommends to Government of India (GOI) to take urgent measures to attain coverage of a minimum of 90% against all UIP antigens in all the states by the end of 2008. In view of the need to simultaneously raise immunity levels to protect against WPVs 1, 3 and cVDPV-2, IPV may be given immediate consideration as an additional tool. IPV will be essential in the post-WPV-eradication phase; it can play a useful role even in the current WPV eradication phase. IAP urges the GOI to urgently sort out various issues associated with implementation of the proposal to use IPV. More transparency is needed on cases of vaccine associated paralytic poliomyelitis (VAPP). Further improvement in stool collection rates is also warranted to minimize the tally of 'compatible' cases. IAP urges the social mobilization network to address the issues of waning interest and shifting focus and negative media coverage. Alternate tactics like reduced numbers of SIAs applied in the low transmission season, along with IPV-DTP combination vaccine in RI can also be considered. IAP believes it will be risky to stop vaccination against poliomyelitis in post-WPV-eradication phase. The best option is to gradually introduce IPV starting now, so that a switch to IPV following high-performance national immunization days (NIDs) can be made to ensure sustained high immunity against all polioviruses, wild and vaccine-derived. IAP requests the global polio eradication initiative (GPEI) to continue relevant research to inform on various aspects related to polio eradication, defined as zero incidence of any poliovirus infection. IAP also urges GOI to take immediate measures for improvement of environmental sanitation.*

Key words: *Immunization, Indian Academy of Pediatrics, Polio eradication, Post-eradication strategies, Recommendations.*

Correspondence to: Dr Vipin M. Vashishtha, Convener, Polio Eradication Committee, Indian Academy of Pediatrics, Mangla Hospital, Shakti Chowk, Bijnor, UP, India. E-mail: vipin@iappec.com

I. INTRODUCTION

The Indian Academy of Pediatrics (IAP) held its second National Consultative Meeting on Polio Eradication and Improvement of Routine Immunization (RI) on November 24th and 25th, 2007

at New Delhi. List of experts present at the meeting is given in *Annexure 1*. The recommendations of its first National Consultative Meeting held on October 1, 2006 are already published(1).

II. AIMS AND OBJECTIVE

Polio eradication efforts have resulted in handsome gains since inception in 1988 with more than 90% reduction in the incidence of wild poliovirus (WPV) cases. Moreover, type 2 WPV has been eliminated in the whole country. The four-pronged strategy of polio eradication (high and sustained coverage of routine immunization, supplementary immunization activity [SIA], clinical and virological surveillance of acute flaccid paralysis [AFP] and lastly mop-up immunization to interrupt any stray chains of transmission), has succeeded to eliminate WPV 1 and 3 also in the rest of the country except the two states of Uttar Pradesh (UP) and Bihar. The failure in these two states has caused concern not only to the IAP but experts all over the world. Therefore, the consultative meeting was held with the intention of reviewing the strategy and ongoing efforts, identifying the existing challenges or hurdles and suggesting modifications or additions to the current interventions.

III. OVERALL CONCLUSIONS

Feasibility of Eradication and Eradication Strategies

Notwithstanding the recent publications of a spate of articles questioning the very concept or feasibility of eradication(2-6), IAP believes polio can be eradicated provided all the resources are utilized in an intelligent and evidence-based way. IAP reiterates its support to the ongoing efforts; however, it also demands some flexibility and urgency in the approach and greater emphasis on certain neglected aspects of the four-pronged strategy.

Current Scenario

Despite achieving a fair degree of control over the intense transmission of WPV type 1 in western UP , the large outbreak of WPV type 3 (which in the second half of the year spread not only to neighboring states but also to some far flung southern states) is reason of great concern. Further, WPV type 1 transmission still remains unabated in Bihar and central and eastern parts of UP.

Globally, India along with Nigeria, Pakistan and Afghanistan (all still remaining endemic for WPV 1 and 3) is offering the greatest challenge to the eradication initiative(7). The nature of challenges is different in these countries.

Reasons Behind the Delay in Achieving the Goal

IAP has identified four major reasons for this problem in the affected areas, namely (*i*) neglect of RI, (*ii*) extremely poor vaccine efficacy of OPV, (*iii*) extremely high force of transmission (FOT) of WPV types 1 and 3, and (*iv*) operational and political issues(8-15). Neglect of RI is a governance deficiency. Poor vaccine efficacy was denied for too long, although it had been documented earlier and evident from field data over a decade(12-14). WPV transmission is highly contagious and the high FOT appears to be due to the overcrowding of infants and young children (on account of high population density plus high birth rate)(13). The effects if any, of the particular demography and specifically substandard sanitation-hygiene milieu of UP and the high incidences of diarrhea, non-polio enteroviral infections and malnutrition have not been explored scientifically. Data from the affected WPV-endemic areas show that there may be differences in the causes of failures in UP and Bihar. In UP, both vaccine-failure and failure to vaccinate seem to be operative, but vaccine-failure is more important. In Bihar also both adverse factors play, but failure to vaccinate is more important, on account of the inaccessible terrain in which a large proportion of the population live. In both states RI coverages are sub-optimal and underserved communities have a tendency to suspect the intentions of the specific focus on polio and excessive use of OPV, while the community demands measles and DPT vaccinations (9,10).

Current Challenges to the Global Polio Eradication Initiative

Globally, interrupting transmission of WPV 1 and 3 in the last four endemic countries, dealing

with outbreaks of circulating vaccine-derived polioviruses (VDPV) and meeting the funding gap are the major challenges in front of the Global Polio Eradication Initiative (GPEI)(7). At the national level, the immediate challenge is to break WPV type 1 transmission in UP and Bihar and also to control the WPV type 3 outbreak in western UP and Bihar, and progress towards interrupting its transmission also. How to keep polio-free states free from importing polio is another challenge. How to deal with the issue of very low vaccine efficacy of OPV in endemic states in the face of very high FOT of type 1 in western UP, and how to balance between RI and SIAs as well as between trivalent and monovalent OPVs in the endemic states are the other challenges in front of the GPEI and GOI.

ISSUES RELATED TO OPV

A. *Efficacy:* IAP acknowledges the role played by trivalent OPV (tOPV) in halting WPV 1 and 3 transmissions in almost all the states of the country barring two. However, in all other states there were helpful factors–such as high RI coverage and / or low FOT due to low population density. IAP believes that poor efficacy of OPV, very low RI coverage and high FOT of WPVs were the main reasons for the lack of success in UP and Bihar, apart from operational issues that further contributed to the difficulties. Failure of the GPEI to take notice of many earlier reports from the country pointing to these issues also resulted in delay in addressing them(11-18). The recent studies sponsored by the WHO(19, 20) only confirmed the earlier conclusions reached by other researchers that were available for a long time. One interesting aspect of OPV-induced immunity was that despite having comparable 'gut immunity' as reflected by low intestinal shedding of vaccine viruses in endemic districts and in all other districts of India and the world, it failed to exhibit appreciable 'herd effect' (or 'herd protection' defined as reduction of incidence of disease in unvaccinated segment due to vaccinating a section of population) (21) in endemic regions(22). Hence, it can safely be assumed that it is systemic immunity *i.e.*, neutralizing antibodies that ultimately determines the efficacy of a vaccine and not the mucosal immunity, which is short-lived and wanes over time.

The number of OPV doses required to confer immunity in an optimum proportion of children is much higher than the three doses recommended from the very early stages of the program(9,13,15). The GPEI and GOI did not conduct any verification of these old data. While a mean of 8-10 doses of tOPV was sufficient in other states, in UP and Bihar, it was inadequate. Either the vaccine efficiacy is lower than elsewhere, or the FOT of WPV is higher than elsewhere, or the contribution of RI was lower than elsewhere, or a combination of these factors was operative. Only in 2006 the GPEI conducted an analysis of data to identify these adverse factors(19,20).

The administration of the required number of doses of OPV – sometimes as many as 10 in first year of life required to confer the necessary immunity is a challenge, especially when motivation and acceptance of parents and health workers are likely to decrease(9,15).

B. *Safety*: Apart from low efficacy of OPV, IAP is concerned with the potential safety problems of OPV. It has been widely known for a long time that OPV may cause vaccine-associated paralytic polio (VAPP) in an occasional child given the vaccine. Vaccine viruses may be even transmitted to other children, resulting in VAPP in contacts (contact VAPP). Both these adverse reactions confirm the reversibility of attenuation, owing to the genetically unstable nature of vaccine viruses and propensity to revert to neurovirulence and transmission efficiency. While VAPP in the vaccinated children and contact VAPP are sporadic, outbreaks of VAPP may occur due to VDPVs. IAP believes that the degree of risks of such adverse events is unknown for widespread use of monovalent type-specific OPVs (mOPV). While mOPV-1 and mOPV-3 are increasingly used in the endemic states, there may be increased risk of emergence of cVDPV type 2. Particular note was made of the recently diagnosed large outbreak of type 2 cVDPV that caused more than 100 cases of VAPP in northern Nigeria during the past 2 years (23). With almost 1 or 2 outbreaks of VAPP due to VDPV reported every year in recent times(23), cVDPV will pose the greatest challenge to the success of eradication initiative in the future. IAP appreciates that the GPEI has endorsed the view that

continued use of OPV during post-WPV-eradication would be incompatible with the concept of polio eradication (24,25).

ROUTINE IMMUNIZATION: THE WEAKEST LINK

India has some of the lowest immunization rates in the world(26). WHO/UNICEF estimates from 2001 indicate that only 38% of children of age 12-23 months were fully immunized (received BCG, measles vaccine, and 3 doses of DPT and OPV), whereas 25% had received no vaccination at all(27). Recent estimates based on the 2005-2006 India National Family Health Survey (NFHS) show little improvement – only 43.5% of children of age 12-23 months were fully immunized(28).

The IAP feels that the "imbalance" between RI and SIAs is the main reason why many disease-free districts became re-infected in the endemic states. There is no micro-planning for RI, apparently for want of time and manpower, and government health machinery is over-occupied with planning of SIAs. IAP advises that the foremost task of the state governments is to strengthen routine immunization which has suffered the most, and has become the weakest link in the polio eradication program. This situation is highlighted by the fact that between NFHS2 and NFHS3, while the number of children fully covered by immunization had increased in 19 states, it has declined in 10 states - an indication of the increasing complacence even in the states like Kerala, Tamil Nadu and Gujarat(28). The current figures of 22.9% and 32.8% for 'fully immunized' children in UP and Bihar(28), respectively are indeed intolerable. IAP thinks that unless RI is bolstered, the elimination of wild virus may not be sustained for long and the elusive zero polio status, even if attained, may not last long. IAP strongly recommends that Government of India (GOI) take urgent measures to attain at least 90% coverage against all UIP antigens in all the states, both for the goal of polio eradication to be achieved and for its benefits to be made permanent. Special efforts should be made to reach children at very young age (below 6 months) by immunizing them with at least four doses (at birth, 6, 10, and 14 weeks) of OPV to counteract the high force of WPV transmission in infants. The success of polio eradication efforts in Bangladesh and Sri Lanka is attributed to the very high rate of RI coverage, a platform upon which SIAs were mounted. Had there been high coverage of OPV under RI in our country, it would have been very likely that we also would have been polio-free by now(28). Even after WPV eradication is achieved, universal RI coverage with polio vaccine (OPV initially and IPV eventually) will be necessary to prevent reintroduction of WPV or emergence and spread of cVDPV.

The IAP pledges its support to the government for its renewed efforts to strengthen RI using various measures (such as fixed and outreach sessions). The gravity of situation calls for urgent and vigorous approach. RI should become a part of basic policy of the government, aiming at full (100%) coverage. It must be linked with delivery of basic health care and management of common, minor problems. This will lead to it being accepted as a part of "growing up" of children. Eventually, the community will realize the need and benefits and immunization practices will get established as the norm.

The onus of having the child vaccinated does not lie exclusively on the parents, especially if they are illiterate and uninformed. In the rural areas, the recently empowered village 'panchayats' must shoulder shared responsibilities regarding RI. The village panchayat personnel may be made accountable for ensuring that every child in the village is adequately vaccinated. They need to be informed about the benefits of vaccination and, they can, along with the health officials, correct mis-information and other local problems. Villages in which every child is fully immunized could be offered incentives. In the urban areas, especially in the slums and in children of migrant families, the responsibility should be assigned to local government personnel, elected representatives and community leaders(29).

The members of IAP have also been exhorted to devote one day in a week for free RI in their clinics. Vaccination camps and such crash activities would have an immediate effect but for a lasting impact, RI must become established as a standard practice in the community. IAP also pledges to spread the message of RI at various forums and to conduct countrywide

immunization updates for its members and also for members of sister associations. IAP has decided to bring out a detailed strategic position paper on Polio Eradication and Routine Immunization in India.

The IAP also reiterates its commitments to extend a helping hand to IEC activity by offering assistance for interpersonal communication to the individual beneficiaries, the opinion leaders, the decision makers and the community leaders to achieve a high and sustained RI coverage including the newborns.

ROLE OF INACTIVATED POLIOVIRUS VACCINE (IPV)

It is prudent to look at other tools which can help in achieving the goal of eradication of polio as a disease. In this respect, the IAP feels that use of IPV as an additional/adjunct tool along with OPV needs urgent consideration. IAP believes that in the post-WPV-eradication phase its use will be indispensable(30). During the current phase of pre-eradication also, IPV will be a valuable tool in the endemic states, to hasten the interruption of WPV transmission(31). IPV is best suited in developing countries with high RI coverage, continuing WPV 1 and 3 transmission, paralytic cases in children vaccinated with many doses of OPV, poor sanitation, high population density and wide immunity gap in infants(32). IPV offers not only very high vaccine efficacy but also exceptionally good pharyngeal and reasonably adequate and long-lasting intestinal immunity(33,34). There are enough evidences from studies on IPV in tropical country settings. At least 54 trials (70 study arms) have been done with IPV or IPV-containing vaccines in 24 tropical countries, since 1977, and out of them 30 studies were in low income countries(32,33).

More recent reports from a few developing countries(35-37) have confirmed the high effectiveness of IPV in tropical country settings and vaccination with 2 or 3 doses of IPV results in at least 90% seroconversion to all 3 serotypes(36). Considering the very low efficacy of OPV and almost negligible herd effect against predictable high immunogenicity of IPV particularly against type 1 and 3, pharyngeal immunity, well-documented herd effect in other countries(31,33) and uniformity of response in the vaccinees irrespective of geography or environmental conditions(31,33), IAP believes that there is a strong case for the use of IPV even during pre-eradication phase in the endemic states with intense or persisting WPV type 1 and 3 transmission. However, operational issues, financial implications and other logistics should be sorted out by GOI and GPEI. IAP recommends its use initially in a few blocks of western UP, as pilot projects to assess the feasibility of wide-scale use.

There are a few reports to suggest that even one dose of IPV following multiple doses of OPV in a tropical setting helps to narrow the humoral immunity gaps to all three polio virus serotypes(38-40). Similarly, mucosal immunity is also boosted following one or two doses of IPV after history of multiple doses of OPV(33,41). Hence, there is all the more justification for using it in the endemic areas of western UP and Bihar to interrupt the WPV transmission. However, considering the reported failure of a single dose of IPV in some tropical countries(42,43), IAP recommends at least two doses of IPV after 2 months of age should be adequate to assess its utility in campaign mode. The Expert group of ICMR on "Potential use of IPV for interrupting wild poliovirus in UP" has also recommended that IPV be used as an adjunct to OPV as an approach to boost mucosal immunity in OPV primed children and increase seroconversion in non-immune infants and young children(44).

The IAP, therefore, reiterates its earlier recommendations made in the year 2006(1): "Based on the data available, IAP recommends that IPV should be used in campaign mode to interrupt transmission of wild polio virus in areas where such transmission continues. It should be given as two doses of IPV at two month interval to children from two months to two years of age."

Such a strategy of introducing IPV in the campaign mode in one district would act as a pilot project and serve the purpose of providing useful data for further evaluation. Subsequently, IPV can be introduced as a part of RI in these areas. However, it will be a daunting task for the enforcing agencies to reach a target of at least 85% in endemic areas. IAP

believes that it is not impossible to attain adequate coverage even in the worst affected districts of western UP. The recent experience of successful campaign of Japanese Encephalitis vaccine (an injectable vaccine) in Saharanpur district in wUP showed that coverage of 88% was achieved (Government of UP, UNICEF and PATH joint action). In western UP, 9.28 lakhs children out of the target of 10.6 lakhs aged 1-15 yrs were immunized during May and June 2007 (unpublished data). Hence, the practical issue is mainly operational and depends not only upon how the community perceives the risk of the disease prevented through vaccination but also on the effectiveness of the preventive intervention as well as how effectively an Information-Education-Communication (IEC) campaign is devised and employed.

IAP reiterates its suggestion to introduce IPV in RI along with DTP, preferably in combination, in the states free of WPV transmission(1). Again, logistically this is feasible as with the increased emphasis on RI, the same manpower and money can deliver the job. This approach will pave the way for eventual universal use of IPV as a prelude to withdrawing all OPV.

AFP AND VIROLOGICAL SURVEILLANCE

Although IAP expressed satisfaction on the performance of AFP surveillance, it is concerned about the reporting of unusually large numbers of 'compatible' cases. It urges the GOI to provide regular periodic and annual data on actual incidence of VAPP cases, both vaccinated and contact. It also requests the National Polio Surveillance Project (NPSP) to strengthen molecular virology surveillance to immediately pick up emergence or transmission of cVDPV. IAP requests the GOI and state governments to issue uniform guidelines to all states to start "Outbreak Response Immunization" (ORI) rounds at the earliest on detecting a 'hot case' to contain dissemination of the wild virus.

SOCIAL MOBILIZATION

IAP lauds the efforts of SMNet of UNICEF in 2007 particularly in western UP that resulted in a reduction in the number of 'missed' children from houses marked X during house to house immunization, increased immunization rates at fixed site booth, higher numbers of newborns immunized, and an absolute decline in the number of 'resistant' households. Still, ensuring maximum participation of all families and communities remains the key challenge. IAP cautions the social mobilization network of UNICEF to remain vigilant against complacency or fatigue. Media management should be given top priority especially in endemic states. IAP reiterates its unstinted support to counter negative or false media stories against the eradication initiative. The community appears resistant to the concept of increasing the frequency of national immunization days (NIDs) or introducing new elements including IPV. There is a felt need for identification of novel social mobilization strategies(45). IAP urges the social mobilization network to address the relevant issues related to introduction of a new tool, *i.e.*, IPV in future.

RESEARCH ON CURRENT AND FUTURE NEEDS

IAP highlights that one of the flaws of current eradication strategies is poor reliance on available scientific data and low priority given to generate new data through continuing research on the many issues associated with failure to finish the job on time. For example, it took GPEI almost ten years to document extremely low efficacy of OPV in endemic areas. IAP feels that non-utilization of our own 'resources'– available evidence, indigenous data and views of many home-bred experts – has cost the program dearly. There was no plan 'B' (alternate or contingency plan) in case of failure of the original plan of action, as happened in India.

IAP welcomes the new recommendations of IEAG to look for seroprevalence among children with AFP and seroconversion response to OPV in endemic regions(46). However, it believes there are many more issues that deserve immediate research.

There are two broad areas that demand urgent attention, "What are the knowledge gaps in achieving polio eradication and the gaps in current research activities being undertaken to understand them?" and, "What further research activities are required?" Research is urgently required to provide local evidence for modifying the on-going polio

eradication efforts. However, this research should be conducted simultaneously and not at the expense of ongoing activities for polio eradication based on international experience and particularly the need for urgently improving the RI coverage. The regions with persistent WPV transmission should be targeted for research. The studies in these areas should be carried out in the form of pilot projects and should focus on the end point of polio eradication rather than seroconversion only.

The following research questions deserve immediate priority:

- The mOPV-1 and 3 have never been combined in a bivalent OPV in the past; will the immunogenicity of both given in one sitting be equivalent to that when given alone at an interval of 4 weeks or more?
- Role of IPV in interrupting WPV type 1 and 3 transmission in endemic areas?
- Optimal schedule and doses of IPV in campaign mode and also in RI in disease free states?
- How best to utilize IPV in boosting mucosal immunity?
- How to assess impact of IPV when simultaneous OPV is still in use?
- What are the alternative strategies to be adopted in the endemic areas?
- What are the community perceptions regarding the current strategy, and proposed alternatives?
- What alternative strategies are required for social mobilization along with valuation and field testing of these novel strategies?
- Should Universal Immunization Program (UIP) schedule be revised considering the future incorporation of IPV in it?
- How effective will improved sanitation and safe water supply be, in addition to immunization?

END-GAME AND POST-ERADICATION ISSUES

IAP reiterates many of its earlier recommendation on post-eradication strategies(1). In the absence of any available guidelines from the WHO, IAP believes that onus will be on GOI to design an effective post-eradication vaccination strategy to not only maintain the disease free status but also to thwart any future incidence of re-introduction of the poliovirus.

Considering the increasing incidents of cVDPV outbreaks and risk of VAPP, it would be unwise and unethical to abandon all polio immunization and also to use OPV during post-eradication phase. But, OPV will still be in use to check outbreaks even during early post-eradication phase. Globally, each country should be given ample time to plan their own individual strategy to implement during post-eradication phase. "Regional synchronization" (WHO regions) should be preferred over "global synchronization" when OPV is discontinued.

The issues related to end-game and post-eradication are complex ones that include matters related to withdrawal of OPV, (when and how?, coordinated cessation globally versus Regional or country-wise decision?), use of IPV (when and how?), dealing with future outbreaks of cVDPVs (by mOPV or IPV?), bio-safety issues like leakage from IPV production sites, future of AFP-surveillance (when to stop?), threat of bioterrorism, etc. IAP reiterates its stand that India should gradually switch to IPV, preferably as IPV-DTP combination product in RI in disease-free states like north-eastern and southern states having robust RI(1). IAP further requests GPEI to restart research projects on safe and effective novel polio vaccines for post-eradication era and not to merely discard it as an unrealistic approach.

According to many IAP experts, the future of eradication depends on how quickly the WPV transmission in the four endemic countries is broken, how safely and effectively OPV is withdrawn, how will the world respond to an outbreak if one occurs following WPV interruption and after OPV cessation, how effectively we will deal with the threat of cVDPVs, can mOPV be used safely after eradication of WPV, how quickly can we produce affordable IPV, how quickly any novel safe polio vaccines for post-eradication era are developed and deployed, how effective is surveillance to pick the covert WPV transmission, how quickly does

immunity wane from various types of exposure to polioviruses, and the ability of IPV to interrupt transmission in the event of an outbreak.

NEED OF THE HOUR

IAP feels that if immediate remedial steps are not taken, the program may be adversely affected. Time is fast running out. We cannot afford to push the deadline beyond a reasonable limit. We must first set a fresh realistic timeline and strive hard to achieve the targets within that period. We need to give a fair trial to whatever weapons we have, but have not been used as yet.

Further, the overemphasis on SIAs is adversely affecting other public health initiatives especially in endemic states. A particular note was taken of re-emergence of large number of diphtheria cases in many districts of western UP owing to poor RI rates. The many remedial measures suggested include drastic measures to boost RI on a war footing, use of IPV in tandem with mOPV (may be of higher potency) in endemic states, annual assessment of immune status of vaccinees depending upon the seroprevalence survey results of study by Indian Council of Medical Research, and OPV challenge studies to measure gut immunity of OPV. The alternate strategies like reduced numbers of SIAs along with IPV-DTP combination in RI can also be tried if all other measures fail.

ENVIRONMENTAL SANITATION

IAP feels that the nation should wake up from its deep and long slumber over environmental sanitation. The issue cannot be allowed to be swept under the carpet any longer. It has been well established that in countries with good environmental sanitation, eradication of polio could be achieved with 2-3 doses of OPV while those with poor sanitation have not been able to achieve success even when the mean doses have exceeded ten or even fifteen(47). This evidence is so obvious that it is strange as to why we cannot see it. The amount of money spent on environmental sanitation will not only help in polio eradication but also in controlling so many other infectious diseases endemic in the country viz., enteric fever, hepatitis A, cholera, diarrhea, malaria, JE etc. IAP is hopeful that the new urban and rural renewal programs being run by the Central and State Governments would lay strong emphasis on this.

IV. RECOMMENDATIONS

1. Polio eradication is a realistic and achievable goal. However, IAP thinks that a fresh reasonably achievable 'timeline' is needed to avoid uncertainty.

2. IAP expresses satisfaction on the performance of GOI against type 1 WPV in western UP. However, at the same time; it expresses its concerns on the continued circulation of type 1 in other states particularly in Bihar. It highlights the fact that despite achieving success in UP, the tally of type 1 had already crossed the lowest reported figure of type 1 in 2005 (62 cases). The huge outbreak of type 3 in western UP that spread to many other states also should be given top priority and must be urgently curbed at the earliest by adopting appropriate strategy. Considering the experience of the past, IAP thinks that the adopted policy of targeting individual types of WPV may result in a 'see-saw' like situation in future also. It calls for an urgent need to have a multi-pronged strategy attacking both the viruses simultaneously in the first two quarters of 2008 as defined below.

3. IAP urges the GOI to give topmost priority to urgently improve the abysmally low rates of routine immunization (RI) in key states. IAP strongly recommends to GOI to take urgent measures to attain coverage of at least 90% against all UIP antigens in all the states by the end of 2008 if the goal of polio eradication is to be achieved and its benefits are to be made permanent. R1 should become a part and parcel of the development plans of the Government with participation and accountability of Gram Panchayats and municipal corporations. The coverage of 90% immunization should be sustained for ever to avert future epidemics. We should aim at elimination of the virus latest by 2012 and finally certification latest by 2015, thus making it a realistic time-bound program. Thus, the need of the hour is "intelligent use of OPV

within RI" *viz* immunizing the right beneficiaries (infants below 6 months), at right age (at birth, 6,10,14 weeks) and right coverage (near 90%).

4. Amongst the three available options to achieve elimination of both the viruses viz use of IPV, employing higher potency of OPV, and simultaneous use of both types of mOPV, IAP favors the option of using IPV in campaign mode in endemic states. It urges the GOI to urgently sort out various issues associated with implementation of IPV use in hotspot areas, like financial and logistic issues, and IEC strategies to facilitate its use at the earliest.

5. IAP advises GOI to ensure high-quality performance, uniformity and consistency in the performance of SIAs in different districts of western UP, particularly to avoid outbreak or re-establishment of circulation of WPV type 1. Help from Gram Pradhans, local corporators, community leaders should be defined and sought.

6. IAP urges the GOI and state governments to issue uniform guidelines to all states to start "Outbreak Response Immunization" (ORI) rounds as soon as possible on detecting a 'hot case' to contain dissemination of the wild virus.

7. IAP believes that AFP surveillance, particularly genetic lineage surveillance, should be strengthened further to pick incidents of cVDPV, if they occur in future. It also demands more transparency on VAPP cases (vaccinated VAPP and contact VAPP) and further improvement in stool collection rates especially in endemic areas to minimize the tally of 'compatible' cases.

8. IAP thinks it will be hazardous to stop vaccination against poliomyelitis in post-eradication phase. The best option would be to gradually switch to IPV following high-performance NIDs to ensure high immunity against polioviruses. To facilitate this process, IAP believes the time is ripe to incorporate IPV (preferably in combination form with DTP) in the states free from polio, like north-eastern and southern states of the country.

9. IAP requests the GPEI to continue simultaneous research on various aspects related to polio eradication, like reasons of vaccine failure in UP and Bihar, role of IPV in halting WPV transmission and its impact on mucosal immunity, studies on affordable IPV, safe and more potent antigen substrate for future OPV, newer polio vaccines and antiviral drugs for outbreak control and post-exposure prophylaxis, etc.

10. Social mobilization: IAP expresses its satisfaction to the good work done by UNICEF in breaking community resistance to eradication initiative to some extent. It requests social mobilization unit of UNICEF to devise and test new IEC strategies to address issues of community cooperation and participation for launch of a new intervention tool, namely IPV.

11. IAP urges GPEI to take cognizance of available data and resources from the work done in the past by national experts in the field of polio and utilize that in the best possible way.

12. Rehabilitation of polio victims, greater transparency and more urgency are also required from the GOI.

13. IAP cautions the enforcing agencies to plan schedule of SIAs in such a way that should not interfere and adversely affect the implementation of many child health related horizontal programs and schemes, particularly, in poorly performing states.

14. IAP urges the GOI and state governments to take immediate and urgent measures in sanitary engineering for improvement of environmental sanitation because this is yet another edifice which needs to be erected for the eradication of not only polio but of several other infectious diseases.

Writing Committee: *Vipin M Vashishtha, Ajay Kalra, T Jacob John, Naveen Thacker, and R.K Agarwal.*

REFERENCES

1. Shah NK, John TJ, Thacker N, Vashistha VM, Kalra A, Ugra D. Polio Eradication strategies in India: Recommendations under IAP action plan 2006. Indian Pediatr 2006; 43: 1057-1059.

2. Phadke A, Kale A. The mirage of polio eradication. Natl Med J India. 2004; 17: 282.

3. Sathyamala C, Mittal O, Dasgupta R, Priya R. Polio eradication initiative in India: deconstructing the GPEI. Int J Health Serv 2005; 35: 361-383.

4. Arita I, Nakane M, Fenner F. Public health. Is polio eradication realistic? Science 2006; 312: 852-854.

5. Roberts L. Global health. Polio eradication: is it time to give up? Science 2006; 312: 832-835.

6. Chumakov K, Ehrenfeld E, Wimmer E, Agol VI. Vaccination against polio should not be stopped. Nat Rev Microbiol 2007; 5: 952-958.

7. Global Polio Eradication Initiative:Wild Poliovirus Weekly Update. Available at: http://www.polio-eradication.org/casecount.asp. Accessed on December 18, 2007.

8. John TJ. The vicissitudes of global eradication of polio. Indian J Med Res 2004; 120: 1-3.

9. John TJ. 'Polar Spectrum' of problems in polio eradication. Indian J Med Res 2004; 120: 133-135.

10. Vashishtha VM, Thackar N. Polio eradication: How near and How far? Indian J Practical Pediatr 2006; 8: 220-231.

11. John TJ, Devarajan LV, Balasubramanyan A. Immunization in India with trivalent and monovalent oral poliovirus vaccines of enhanced potency. Bull World Health Organ 1976; 54: 115-117.

12. Ghosh S, Kumari S, Balaya S, Bhargava SK. Antibody response to oral polio vaccine in infancy. Indian Pediatr 1970; 7: 78-81.

13. John TJ. Immunisation against polioviruses in developing countries. Rev Med Virol 1993; 3: 149-160.

14. Hasan A, Malik A, Shukla I, Malik MA. Antibody levels to polioviruses in children after pulse polio immunization. Indian Pediatr 2004; 41: 1040-1044.

15. John TJ. Polio eradication and India–bringing science into public health. Indian J Med Res 2007; 126: 91-93.

16. Paul YCan polio be eradicated from India through present Polio Eradication Program? BMJ–South Asia Edition 2003; 19: 499-501.

17. Paul Y. Polio eradication in India. Indian Pediatr 2003; 40: 1100-1101.

18. Paul Y. Evaluation of OPV efficacy is required for polio eradication in India. Vaccine 2005; 23: 3097-3098.

19. Grassly NC, Fraser C, Wenger J, Deshpande JM, Sutter RW, Heymann DL, *et al*. New strategies for the elimination of polio from India. Science 2006; 314: 1150-1153.

20. Grassly NC, Wenger J, Durrani S, Bahl S, Deshpande JM, Sutter RW, *et al*. Protective efficacy of a monovalent oral type 1 poliovirus vaccine: a case-control study. Lancet 2007; 369: 1356-1362.

21. John TJ. Establish herd effect to interrupt wild polio virus transmission. Indian J Med Res 2006; 124: 1-4.

22. Grassly NC. Presentation made at the meeting on potential use of IPV in interrupting WPV transmission in Western UP, India. New Delhi: ICMR; August 27, 2007.

23. World Health Organization. Global update on vaccine-derived polioviruses. Weekly Epidemiol Rec 2007; 82: 337-344.

24. John TJ. The final stages of the global eradication of polio. N Eng J Med 2000; 343: 806-807.

25. World Health Organization. Global Polio Eradication Initiative Strategic Plan 2004-2008. Weekly Epidemiol Rec 2004; 79: 55-57.

26. Immunization surveillance, assessment and monitoring. Available at: http://www.who.int/immunization_monitoring/en/globalsummary/timeseries/tswucoveragedtp3.htm.Accessed December 17, 2007.

27. Multiple Indicator Survey–2000 (MICS-2000): India Summary Report. November 2001. Available at: http://www.childinfo.org/MICS2/newreports/india/india.pdf. Accessed on December 17, 2007.

28. National Family Health Survey (NFHS-3), 2005-06: India: Volume I., 2007. Available at: http://www.nfhsindia.org/NFHS-3%20Data/VOL-1/National%20Family%20Health%20Survey%202005-06%20India%20Report%20-%20Volume%20I%20(6823K).pdf. Accessed on December 17, 2007.

29. Srivastava RN. Make routine immunization compulsory. Indian Pediatr 2007; 44: 848-850.

30. John TJ. Will India need inactivated poliovirus vaccine (IPV) to complete polio eradication? Indian J Med Res 2005; 122: 365-367.

31. John TJ. The golden jubilee of vaccination against poliomyelitis. Indian J Med Res 2004;119: 1-17.

32. Goldblum N, Gerichter CB, Tulchinsky TH, Melnick JL. Poliomyelitis control in Israel, the West Bank and Gaza Strip: changing strategies with the goal of eradication in an endemic area. Bull World Health Organ 1994; 72: 783-796.

33. Plotkin SA, Vidor E. Poliovirus vaccine-Inactivated. *In:* Plotkin SA, Ornenstein WA, editors. Vaccines. 4th edition. Philadelphia: WB Saunders; 2004. p 625-649.

34. Faden H, Modlin JF, Thomas ML, McBean AM, Ferdon MB, Ogra PL. Comparative evaluation of immunization with live attenuated and enhanced-potency inactivated trivalent poliovirus vaccines in childhood: systemic and local immune responses. J Infect Dis 1990; 162: 1291-1297.

35. Dayan GH, Thorley M, Yamamura Y. Serologic response to inactivated poliovirus vaccine: a randomized clinical trial comparing 2 vaccination schedules in Puerto Rico. J Infect Dis 2007; 195: 12-20.

36. Cuba IPV Study Collaborative Group. Randomized, placebo-controlled trial of inactivated poliovirus vaccine in Cuba. N Engl J Med 2007; 356: 1536-1544.

37. Asturias EJ, Dueger EL, Omer SB, Melville A, Nates SV, Laassri M, *et al*. Randomized trial of inactivated and live polio vaccine schedules in Guatemalan infants. J Infect Dis 2007; 196: 692-698.

38. Hanlon P, Hanlon L, Marsh V, Byass P, Sillah H, Hayes R, *et al*. Serological comparisons of approaches to polio vaccination in the Gambia. Lancet 1987; 4: 800-801.

39. Moriniere BJ, van Loon FP, Rhodes PH, Klein-Zabban ML, Frank-Senat B, Herrington JE, *et al*. Immunogenicity of a supplemental dose of oral versus inactivated poliovirus vaccine. Lancet 1993; 341: 1545-1550.

40. Sutter RW, Suleiman AJ, Malankar P, Al-Khusaiby S, Mehta F, Clements GB, *et al*. Trial of a supplemental dose of four poliovirus vaccines. N Engl J Med 2000; 343: 767-773.

41. World Health Organization. Combined immunization of infant with oral and inactivated poliovirus vaccines: results of a randomized trial in the Gambia, Oman, and Thailand. WHO Collaborative Study Group on Oral and Inactivated Poliovirus Vaccines. Bull World Health Organ 1996; 74: 253-268.

42. Parent du Châtelet I, Merchant AT, Fisher-Hoch S, Luby SP, Plotkin SA, Moatter T, *et al*. Serological response and poliovirus excretion following different combined oral and inactivated poliovirus vaccines immunization schedules. Vaccine 2003; 21: 1710-1718.

43. El-Sayed N, Al-Jorf S, Hennessey KA, Salama M, Watkins MA, Abdelwahab JA, *et al*. Survey of poliovirus antibodies during the final stage of polio eradication in Egypt. Vaccine 2007; 25: 5062-5070.

44. Report of Expert Consultations on Potential Use of IPV in Interrupting WPV Transmission in Western UP, India. Available at: http://www3.niaid.nih.gov/news/events/meetings/polio/kant.pdf. Accessed on February 22, 2008.

45. Dasgupta R, Chaturvedi S, Adhish V, Ganguly KK, Rai S, Sushant L, *et al*. Social determinants and polio 'endgame': A qualitative study in high-risk districts of India. Indian Pediatr 2008; 45: 357-365.

46. Conclusions and Recommendations. The seventeenth Meeting of the India Expert Advisory Group for Polio Eradication, Delhi, India, 29-30 May 2007.

47. Simoes EAF. Polioviruses. *In*: Behrman RE, Kliegman RM, Jenson HB. Nelson's Textbook of Pediatrics, 17th edition. Philadelphia: Saunders, 2004. p 1037.

ACKNOWLEDGMENT

IAP acknowledges the help from UNICEF for providing scientific grant for the meeting.

Annexure I: Experts present at the meeting:

Conveners: Naveen Thacker, *President*, IAP; R K Agarwal, *President Elect*, *IAP*; and Vipin M Vashishtha, *Convener, Polio Eradication Committee, IAP.*

Chairpersons: *T Jacob John*, Past President, IAP; *Y K Amdekar*, Past President, IAP & Chairman IAP Committee on Immunization; and *A Parthasarathy*, Past President, IAP.

Participants (in alphabetical order): *Atul Agarwal*, Co-convener, Polio Eradication Committee; *Girish*

C Agarwal, IAP Bareilly; *NK Arora*, AIIMS, New Delhi; *Marzio Babille,* Chief, Health Section, UNICEF; *Sunil Bahl*, Dyp. Project Manager, NPSP; *Swati Y. Bhave,* Past President, IAP; *AJ Chitkara*, New Delhi; *Panna Choudhury*, Editor-in-Chief, IP; *Michael Galway*, In-charge Communication, UNICEF; *Ajay Gambhir*, Vice President, IAP; *Piyush Gupta,* Editor, Indian Pediatrics; *Satish Gupta,* UNICEF; *Salim Habayeb,* WHO Country Representative; *Ajay Kalra*, Co-convener, IAP Polio Eradication Committee; *Deepak Kapur*, Chairman, Rotary Polio Plus, India; *SA Krishna*, Member, Polio Eradication Committee; *Shyam Kukreja*, New Delhi; *Gyan P Lal ,* President Elect, UP State Branch IAP; *Joseph L Mathew*, PGI, Chandigarh; *Onkar Mittal,* Jan Swasthya Abhiyan, Delhi; *Yash Paul*, Member, IAP Polio Eradication Committee; *HPS Sachdev*, Past President IAP; *Nitin Shah*, Imm. Past President, IAP; *Raju C Shah*, Past President, IAP; *Tabbasum Shahab,* Prof. & Head, JNMC, AMU, Aligarh; *Utpal Kant Singh*, East Zone Coordinator, IAP Polio Eradication Committee; *Tanu Singhal*, Convener, IAP Committee on Immunization; *Rolland Sutter*, WHO HQ, Geneva; *Rajiv Tandon*, Health Advisor, USAID; and *Arun Kumar Thakur*, President, IAP Bihar State Branch.