## *Debate*

# Polio Eradication and the Indian Academy of Pediatrics

It is ironic that the IAP has chosen to accede to the request of the India Expert Advisory Group (IEAG) made during the meeting on July 28, 2006 to "make a strong statement in support of polio eradication program"(1). At the outset, it may be relevant to recall that members of IAP (individually and collectively) proposed, promoted and strived towards the eradication of poliomyelitis well before the IEAG even came into existence. On the other hand, considering that four of the eight members present at the July 28 IEAG meeting(2) are stalwarts of the IAP (three past and one current President), the request and its response are probably not surprising. Nevertheless, it is heartening that the IAP has made an appeal (to its members) to "work unitedly to achieve polio eradication"(1). Since IAP is a body of academic professionals, this means (presumably) that the IAP (represented by the authors) welcomes academic input in relation to polio eradication and is (hopefully) not merely calling on fellow members to toe the line of the IEAG or agencies which direct the latter's activities. In that spirit, despite recognizing that we are likely to have aspersions cast on our capacity to understand, interpret, analyze and apply data, as has often happened to others in the past(3,4); it is important to draw attention to the following:

1. While the statistical figures of decline in polio cases over the past 20 years are undoubtedly impressive, we have still not achieved the status of eradication nor do we appear to be near that target. Therefore, IAP members led by its leadership would do well to analyze and reason why this is happening rather than "fully support the plan of action once accepted by the Government of India and partner agencies".

2. Giving 5 doses of OPV during infancy was never advocated as a tool for polio eradication. It should be remembered that even with increased coverage using 3 doses of OPV (between 1991-1995) there was a decline in polio cases by over 90 % (from 40,000 to 4000 annually). This substantiates that it is increased coverage rather than just greater number of doses, which is important for polio elimination/ eradication.

3. Assuming that five doses of OPV during infancy would have led us closer to the goal of eradication, what is the reason that despite over five doses (three in routine plus two or more during national/ subnational immunization days), infants are still not protected and remain susceptible to polio?

4. What is the basis for the calculation that 10 doses of OPV are required to be administered prior to 9 months of age for children in western UP to be protected? If they remain unprotected even with 10 doses, will this figure need to be revised upward to 12, 15 or even greater number of doses?

5. Even if the above calculation is assumed to be correct, how is this to be achieved? Are infants in western UP (and possibly elsewhere) expected to receive OPV

vaccination every two to three weeks during the first 6-9 months of life?

6. What is the basis for the latest recommendation of the IEAG to give 2 doses of IPV in a pulse manner in the hyper-endemic areas and what if this also fails?

7. While the revelation that "health workers and families are colluding to falsify data" is appreciated, what is the solution? It is unlikely that either health workers or families will continue to cooperate indefinitely simply on the basis of frequent assurances that the 'country is on the verge of polio eradication' and 'this is the final push'.

8. Likewise, how is the community to be empowered to fulfill the "national pledge" to eradicate polio? Does the IAP expect that the community should voluntarily 'demand' indefinite more 'pulse polio rounds' as a sign of "education, encourage-ment and empowerment" provided by its members?

9. It is heartening that the IAP appears to have taken cognizance of the need for introducing eIPV in India, a fact that has been emphasized several times starting from the year 2000(5-7). However, it has chosen to leave the decision of the modalities involved (when to start, how many doses, who will administer, regional or national coverage, who will provide the required number of doses, what will be the cost) to the Government, rather than guiding it towards a correct decision.

10. It will be informative to know the constitution of the "National Consensus Meeting" that is round the corner and the "wider participation" that is planned.

11. In light of the IEAG's request to the IAP to "make a strong statement in support", it will be relevant to know what proportion of the IEAG is comprised of IAP members and also what proportion of IAP's Polio Eradication Committee is on the IEAG.

12. Since the Government is the ultimate decision making authority, although it seems to "accept plans of action" what is the official forum for IAP members to bring important issues to the notice of the Government?

    Finally, although the IAP cannot be held responsible for the proceedings at IEAG meetings, the following clarifications are required, on the conclusions and recommendations drawn at the July 28 IEAG meeting since 50% of the membership comprised of IAP leaders.

13. The meeting noted that the rapid rise in cases in Western UP was due to "factors favouring virus circulation, lower vaccine efficacy and deterioration of SIA quality". The first two of the three reasons need to be elaborated and explained to IAP members

14. The IEAG noted "the results of the analysis of pre-release titres for tOPV and mOPV" and was thereby apparently satisfied with the quality of OPV used(2). However, if the aim of the analysis was to allay anxiety regarding potency of OPV(1), despite the VVM being intact, it is puzzling why the IEAG was content to accept the results of pre-release potency testing rather than insisting on testing of samples from the field.

15. "A full twelve months of high quality activity" has been deemed necessary for wild poliovirus transmission to cease(2). While nothing specific has been mentioned about this new terminology

(high quality activity), presumably it refers to another twelve months of the repetitive exercise of administering OPV drops.

16. Although the IAP statement (1) suggests that the modalities of using eIPV in our country are still under consideration and debate, the proceedings of the IEAG meeting (2) are quite clear that two rounds of IPV are to be used eight weeks apart in two districts of UP and has even set a timeline for this exercise (first round in December 2006). Once again, considering the composition of the IEAG meeting in question, this disparity is puzzling.

**S. K. Mittal**
*Head, Department of Pediatrics,*
*Max Hospital,*
*Pitampura, New Delhi, India*
*E-mail: skmittal44@yahoo.com*,

**Joseph L. Mathew,***
*Assistant Professor,*
*Advanced Pediatrics Center,*
*PGIMER, Chandigarh 160 016, India.*
*E-mail: jlmathew@rediffmail.com*

**Corresponding author*

**REFERENCES**

1. John TJ, Shah NK, Thacker N. Indian Academy of Pediatrics and Polio Eradication in India. Indian Pediatr 2006; 43: 765-768.
2. Special interim meeting of the India Expert Advisory Group for Polio Eradication. Delhi, India, 28 July 2006. Conclusions and recommendations.
3. John TJ. Polio Eradication: Future strategies (Reply). Indian Pediatr 2003; 40: 1102-1104
4. John TJ, Shah NK, Thacker N. Set back in Polio Eradication in Indian in 2002: Reasons and Remedies(Reply). Indian Pediatr 2004; 41:203-204.
5. Mathew JL, Gera T, Mittal SK. Eradication of Poliomyelitis in India- Future Perspectives. Paediatrics Today 2000;10: 647-660.
6. Mathew JL, Mittal SK. Polio Eradication and After: Does IPV have a Role? Indian J Pediatr 2001; 68 SS1: S15-S22.
7. Mittal SK, Mathew JL. Vaccine associated paralytic poliomyelitis. Indian J Pediatr 2003; 70: 573-577.

## Polio Eradication and the Indian Academy of Pediatrics (Reply)

We thank Drs. S.K. Mittal and J.L. Mathew for raising several issues related to polio eradication and IAP. It is important that all issues are identified and discussed. New ideas and constructive suggestions will be useful but discussion just for the sake of discussion will not help. Unfortunately, their letter contains many misconceptions and some internal contradictions. We will point out the misconceptions first and proceed to answer the questions they have posed. The contradictions need not be enumerated as readers can easily spot them. We ignore the obloquy. The main misconceptions are listed below.

- Ironic means "happening in the opposite way to what is expected". Acceding to India Expert Advisory Group (IEAG) request by Indian Academy of Pediatrics (IAP) is what should be expected under the specific situation. It is not ironic.
- Drs. Mittal and Mathew claim to “recall that members of the IAP (individually and collectively) proposed, promoted and strived towards the eradication of poliomyelitis well before the IEAG even came into existence”. This tall claim is contrary to facts. Eradication is a global agenda. It was the Rotary International that first (in 1985) proposed and promoted “a polio-free world by 2005”. The 1988

World Health Assembly resolved to eradicate polio globally and as a signatory the Government of India (GoI) became involved. IAP was not in the picture then. Later IEAG was created to advise the GoI on eradication activities in India and IAP was represented on it from its early days.

- IAP is not the implementing agency of the eradication program in India, but it plays an important supportive role to the efforts of GoI. The differences of opinions of IAP with the GoI and the WHO are known to the concerned officers and to IAP members through our many conferences and publications. IAP maintains its dignity and decorum even when we disagree on specific issues. We have strived for change and succeeded in many instances through persuasion. Cynicism and acrimony are always avoided.
- IAP is a body of qualified pediatricians, not exclusively of "academic professionals". Academic professionals should not belittle the membership of non-academic colleagues, who outnumber academic professionals.
- Reduction of incidence by 90% and eradication are not mere quantitative variants of epidemiological achievement through routine immunization. India has achieved 99.9% reduction in incidence but eradication has not been achieved in spite of extremely high vaccine coverage. To interrupt wild poliovirus transmission 3 doses of OPV are grossly insufficient even if 100% coverage is achieved. Both high vaccine efficacy (which requires many more doses) and high vaccine coverage (virtually 100%) are needed. They are needed prior to the age at which infants get wild virus infection. These are the problems of the exclusive use of OPV for eradication.
- Five doses of OPV induce immunity in only about 80% infants against types 1 and 3 according to studies conducted in south India. The unprotected remnants in large communities will sustain the circulation of these types, even after very high coverage is achieved, as is evident in UP.
- On the other hand, 5 doses are sufficient for near-100% immunity against type 2. The higher efficacy was the reason why India could eliminate it even in UP by October 1999, when sufficiently high coverage had been reached. The same coverage was inadequate to interrupt transmission of the types 1 and 3, as vaccine efficacy was insufficient.
- Drs. Mittal and Mathew advise that: "IAP members led by its leadership would do well to analyze and reason why this is happening rather than fully support the plan of action once accepted by the Govt. of India and partner agencies". The assumption that the two processes are mutually incompatible arises out of the lack of understanding of facts. The reasons for delay in achieving eradication are analyzed and reviewed periodically by IAP independently and also together with IEAG. In one such IAP analysis early this year Dr. Mittal was an active participant. IAP is not in the "opposition" mode.
- Polio eradication is a complex process, led by the GoI MoH with many functionaries—the health workers, supervisors, volunteers, NGOs, State Governments, partner agencies and donors—who have to work in harmony. Without their efforts IAP alone cannot achieve elimination of polio.
- The need for IPV in India was identified long before 2000, by which time (belatedly) some academic professionals also began grasping its potential in India.

Independent scientists had moved the Immunization Mission (under Technology Mission) under the Rajiv Gandhi Government, in 1987, to establish IPV manufacture in India. A unit was established in 1988 in Gurgaon with support from the GoI Ministry of Science and Technology. However, the Ministry of Health (MoH) opposed the move and apparently declared that it would not license IPV and the unit was closed in 1994. Our own academic professionals did not raise their voices in protest.

- In the past the National Regulatory Authority (NRA) of the GoI (under MoH) had persistently refused to register IPV in India. It was licensed for the first time only in June 2006. It came about after the National Technical Advisory Group on Immunization (NTAGI) and the IEAG so recommended it to the GoI. IAP is represented on both committees and played a crucial role. The NRA (Drugs Controller General) decides which vaccine is to be registered in India. IAP could not have persuaded GoI to use IPV prior to this first step of licensure.
- The innuendo in the statement "IAP appears to have taken cognizance of the need for introducing eIPV in India" is another misconception. Our colleagues confuse between our taking cognizance of the opportunity for introduction of IPV (due to its licensing) and its need for introduction. IAP's long-held view that IPV has a role has been vindicated by the licensing of IPV, thus opening the door for its future use in India. The next crucial step is for the GoI to make it available in sufficient quantities. IPV will have a role for concluding eradication activities also.
- The use of IPV is no longer under debate but under active consideration. The GoI has to procure it and its use will be guided by the IAP/IEAG recommendations. While IAP and the IEAG wish its introduction as early as December 2006, the needed quantities may not necessarily be available by then, or the health care delivery system may not be adequately prepared to introduce it in December. In case of delay there is no disparity to be puzzled about.

**We will now answer the questions.**

- "Why do infants remain unprotected in spite of 5 doses of OPV?" While 5 doses are sufficient to protect against type 2 in near-100% infants, they are not equally effective against types 1 and 3. This is due to low immunogenicity of OPV especially to types 1 and 3, which in turn is due to low infectivity of these vaccine viruses.
- Why did we accept pre-release potency as sufficient evidence for the quality of OPV in use? The fact that VVM is a reliable marker of the time-temperature course taken by vaccine vials has been validated in the past. However, if water is put in and the VVM is good, that does not mean the vial contained good vaccine. Therefore, the pre-release potency is what is relevant to ensure the quality of vaccine. Thereafter it is the VVM that helps in maintaining quality and acts as the visible marker of potency.
- "What is the basis for the calculation that 10 doses of OPV are required to be administered prior to 9 months of age for children in western UP to be protected? If they remain unprotected even with 10 doses, will this figure need to be revised upward to 12, 15 or even greater number of doses?" Primary immunization in India would require 10 doses to match up with the level of protection achieved by 3 doses of OPV in the United States. Most

"academic professionals" had disagreed with these research findings of the 1970s and 1980s. Each additional dose raises seroconversion by the principle of arithmetic proportional increment, instead of prime-boost principle as in the case of IPV. In UP and Bihar, the need for a minimum of 10 doses has now (belatedly) become obvious even to the skeptics - as a result of analysis of local data. The median age of polio is around 18 months and over a third of cases occur in infancy. Thus, the speed and force of transmission of wild viruses (particularly type 1) are extraordinarily high. Protection by vaccination should reach before wild virus infection reaches children, ideally by 3-4 months of age, for which reason the EPI schedule of 6-10-14 weeks was established. Since giving so many doses is difficult if not impossible, how far can we stretch the age? Are 12 months too risky? Are 6 months too difficult? To suggest that so many doses are needed by 12 or 9 months is already a compromise on what is ideal.

- "Even if the above calculation is assumed to be correct, how is this to be achieved?" How can so many doses be given at so young an age? Had routine doses been 5, topping up would have been relatively easy. If 4 or even 3 doses were given in routine immunization, some 6 pulses could have succeeded in giving 10 or nearly 10 doses during infancy. Where routine doses are delayed or not given, most doses must come through pulse campaigns, and giving 10 doses during infancy is virtually impossible. The reason to highlight this was two-fold. One, to identify one of the main causes of delay in eradication. Second, this technical remedy does not appear to be feasible and a fresh solution seems necessary, which is given under the next point.

- "What is the basis of recommendation to give 2 doses of IPV in campaign mode?" When 10 doses before 9-12 months of age are required, either routine immunization must be built up or an alternative method of rapid immunization should be identified to circumvent the problem. That is how the alternative of IPV becomes realistic. Three doses of IPV will protect near-100% and that is achievable below 6 months of age. Under the eradication mode the priority age group should be addressed simultaneously, instead of gradually building up high immunity coverage. As the quantity of IPV will be limited, the most efficient way to distribute it will be to give 2 doses to the most vulnerable age group, namely infants and toddlers. Two doses, given at or after 8 weeks of age and with 8 weeks interval have already been shown to result in >95% seroconversion to types 1 and 3, in Indian studies in the 1980s.

- "What if this also fails?" If India fails in spite of this additional intervention, IAP, IEAG, GoI MoH, global partners and WHO will have to design more effective interventions which the GoI must implement.

- "What is the official forum for IAP members to bring important issues to the notice of the Government?" Any citizen can bring issues to the notice of the Government, but that is not "official". When IAP has to officially inform something to the Government, its officers must do so. IAP members may bring matters through appropriate committees of IAP to make formal IAP policies or recommendations. Matters related to immunization can be brought up to NTAGI

via the IAP Immunization Committee and those related to polio eradication, to IEAG via the IAP Polio Eradication Committee.

- What is meant by "factors favoring virus circulation" and by "lower vaccine efficacy?" The factors favoring virus circulation are high density of infant and child population, crowded living conditions and low vaccination coverage in the very young with high number of doses. Lower vaccine efficacy refers to the estimate of efficacy by number of doses of OPV in western UP - the estimated efficacy of 10 doses of OPV is lower than what was documented in the past in southern India and what is currently estimated for the rest of India

May we conclude by stating that the IAP consensus building meeting (referred to in the letter) took place in New Delhi on October 1 and Dr. S.K. Mittal had personally got most of the above issues clarified. The draft of the consensus statement has been sent to all participants for finalization. Obviously this letter was written by Drs. Mittal and Mathew prior to 1 October. We thank the Indian pediatrics for the opportunity to clarify many issues.

**T. Jacob John*,**
*Co-Chair, NTAGI and Co-chair,*
*IAP Committee on Polio Eradication,*
*439 Civil Supplies Godown Lane,*
*Kamalakshipuram,*
*Vellore,*
*Tamil Nadu 632 002.*
*Email: vlr_tjjohn@sancharnet.in*

**Nitin K. Shah,**
*President, IAP 2006 and Chairperson,*
*IAP Committee on Polio Eradication,*
*186/A-3, Vaswani Villa,*
*Sion (West), Mumbai 400 022.*
*Email: drnitinshah@gmail.com*

**Naveen Thacker,**
*President-Elect IAP 2006 and Convener,*
*IAP Committee on Polio Eradication,*
*D-70 Shaktinagar,*
*Gandhidham, Kutch,*
*Gujarat 370201.*
*Email: drnaveenthacker@gmail.com*

**Corresponding author*

**Editor's Note:**
Recommendations for Polio Eradication Strategies in India under IAP Action Plan 2006 appears in this issue on pages 1057 to 1063.