

Recommendations

Polio Eradication Strategies in India: Recommendations under IAP Action Plan 2006

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Indian Academy of Pediatrics (IAP) held a National Consensus Meeting on 1st October 2006 for formulating recommendations on Polio Eradication strategies in India under IAP Action Plan 2006. List of experts present at the meeting are given in *Annexure I*.

Polio eradication goals: IAP strongly believes that polio will be eradicated from India and that it will happen sooner or later, sooner the better. IAP also has full faith in the current polio eradication goals. IAP firmly believes that the 4 pronged strategy of polio eradication consisting of effective routine immunization, Supplementary Immunization Activity (SIA), AFP surveillance and mop-up immunization has worked in rest of the country where polio is well contained and will also work in the remaining areas of the country where polio still remains to be contained. IAP feels that it is the

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failure to implement all the 4 prongs effectively that has led to failure in UP and Bihar and not the failure of the strategies *per se*. The most neglected prong is routine immunization coverage and that needs to be strengthened for long term success.

Potency of OPV that is used: IAP recognizes that there is enough data available, both for the unused vials as well as vials used in the field during the NIDs and SNIDs, to suggest that the potency of the tOPV as well as mOPV1 of all the manufacturers whose vaccines are used in India is well above the minimum requirements of vaccine titers of > 6.0 CCID₅₀/dose. Hence, it is very reassuring to note that the Oral Polio Vaccine (OPV) used in the country is adequately potent.

Need, effectiveness of safety of mOPV1: Some doubts have been raised in the contemporary medical circle about the need, efficacy and safety of mOPV1 introduced in areas with wild polio virus transmission.

IAP believes that as P2 wild polio virus is eradicated from world since October 1999, it is unnecessary to continue to use this strain in the vaccine in areas where P1 wild polio virus transmission is still not interrupted. P3 wild polio virus is almost on the verge of eradication and at present is restricted to limited areas of Moradabad in UP. Theoretically one dose of mOPV1 will be 3 times more successful in leading to seroconversion than one dose of tOPV as there is interference within the 3 different strains of OPV vaccine viruses when one uses tOPV. The available data shows that mOPV1 is at least 2 times more successful than one dose of tOPV used as birth dose in leading to seroconversion in Egypt. Hence,

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mOPV1 is equal, if not better, than tOPV in UP and Bihar. Accordingly, IAP recommends that mOPV1 be used for birth dose and SIAs in areas where wild polio transmission continues. Additional one round of mOPV3 SIA will be necessary in the areas where P3 wild polio virus transmission is known to occur. However there is a need to carry out the impact study of use of mOPV1 in areas where it is currently used. As said before, mOPV1 used in India is satisfactory in its potency from the data available. In rest of the country tOPV should be used for SIA. Routine immunization of course should be always with tOPV in all the areas until further discussions are held among the Partners regarding the removal of type 2 virus in the vaccine.

Some doubts are raised as to whether the recent steep rise in the number of AFP cases reported from UP and Bihar is any way related to mOPV1 being introduced or increased Vaccine Associated Paralytic Poliomyelitis (VAPP) due to monovalent OPV1 (mOPV1)? While it is true that the rate of non-polio AFP rates have risen steeply, but it is only due to over-enthusiastic reporting of AFP rather than any other reason. It is also true that the number of cases where vaccine virus is grown from the stools of AFP patients has increased in absolute numbers of late, however the proportion of cases growing vaccine virus from stools of AFP patients has actually gone down, which proves that increase in the absolute number of such cases is due to increase in the absolute number of AFP cases reported. The number of VAPP cases has not increased since last 2 years. This proves that the mOPV1 is as safe as tOPV.

Current scene: IAP is concerned that currently there is an outbreak of wild polio cases mainly in Moradabad district of Western UP and also in many other parts of western and central UP. It obviously means that wild polio virus

transmission is rampant in western UP. Though Bihar is doing well at present, the transmission of wild polio virus remains uninterrupted. However, the number of cases of wild polio in UP in 2006 are much lower than a similar outbreak in UP and Bihar in 2002 and the lineages of P1 virus have dropped significantly from 8 to 2 in UP and from 5 to 2 in Bihar. P3 wild polio virus cases are well contained except some parts of Moradabad district only and P2 wild polio virus has been eradicated from whole of India.

Reasons behind current scene: IAP believes that the reasons behind failure to interrupt wild polio virus transmission in country, especially UP and Bihar is both failure to vaccinate and failure of OPV, failure to vaccinate being more responsible and more amenable to improvement than failure of the vaccine. Every SIA round should reach near 100% coverage of the under-5 children, particularly infants.

Questions are raised as to why the polio eradication strategies have failed in UP and Bihar whereas same strategies have worked in most parts of the country where similar type of population and milieu exists? IAP believes that this is because of the low routine OPV coverage and also the peculiar environmental situation in UP and to some extent in Bihar.

In UP and Bihar, high birth cohort, suboptimal performance on the National Immunization Days (NIDs) and sub-National Immunization Days (SNIDs), resistance to immunization by certain minority community and most importantly poor routine immunization coverage allow accumulation of a pool of susceptible children at any given time. This along with high density of population and poor sanitation allow speedy and potent transmission of wild polio virus with chances of contact with wild polio virus very early in life. Immunization strategies will have to be

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highly effective to match this speed and force of transmission of wild polio virus. However, presence of non-polio enteroviruses and other GI pathogens prevent good uptake and effectiveness of OPV. Sub-optimal effectiveness of oral polio vaccine (OPV) adds to the problems of increased susceptibility in spite of immunization and chances of clinical polio in spite of immunization. Thus it is estimated that one needs to give 8-10 doses of OPV to reach 85% seroconversion in most parts of India and 10-15 doses of OPV to reach 75% seroconversion in UP and Bihar. It is not feasible to give so many doses of OPV in the first 6-12 months of age before the child has chances of contracting wild polio virus. Hence, speed and potent transmission of wild polio virus remains unmatched due to poor coverage and sub-optimal effectiveness of OPV. Regression model prediction based on the population density, incidence of diarrhea and low routine 3 doses of OPV coverage have shown that the risk is highest in western UP and Bihar, precisely the areas affected maximally currently.

The local population does not have easy and adequate access to many other basic health services which in some ways is reflected on the current polio scene. Hence, while deciding on the further course; one also needs to take care of these issues including improvement of local civic administrative services.

Possible solutions: As happens after every epidemic, the transmission of wild polio virus will ebb in next few months after the outbreak is over, and we need to take advantage of this situation and hit hard with multi-pronged strategies. These strategies include:

- (1) *Strengthening of routine immunization:* This is the first and the most important, yet the most neglected prong of the original 4 pronged strategy and is the weakest link in

our efforts. No program of polio eradication can succeed without paying enough and sustained attention to routine immunization. This will also help in long run. IAP realizes that it is difficult to strengthen routine immunization overnight. IAP suggests evolving mechanism for effective coverage of routine immunization. Village panchayats could be involved in ensuring that every child receives the routine immunization. National Health and Immunization card should be made available to every child which will encourage the parents to get the child immunized as per the recommendations on the card. IAP also recommends that its members indulge more in this public cause and observe Routine Immunization weeks as well as conduct free vaccination camps regularly throughout country, more so in UP and Bihar. Experience of conducting such activities by various IAP branches is so far encouraging. IAP also pledges to spread the message of routine immunization at various forums and IAP has planned for country wide Immunization Updates for its members with a stress on routine immunization.

- (2) *Birth dose of OPV:* IAP has for many years recommended birth dose of OPV to be given soon after birth (within 15 days of birth). Many of the IAP members do practice the same in their office practice. However for it to be meaningful, it has to be implemented at national level. Unfortunately, this so called 'zero' dose of OPV has received zero attention! Recent efforts of UNICEF in implementing birth dose of OPV in a pilot project in Moradabad blocks have achieved 85% coverage by providing home visits as most of the birth in such areas take place at

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home. IAP strongly recommends scale-up of the birth dose of OPV at least in the areas where wild polio virus transmission is not interrupted. It requests the health authority to make appropriate provisions in form of infrastructure and man power. In future, this will be taken care by Integrated Management of Neonatal and Child Health Illnesses (IMNCI) where home visits will be made by Accredited Social Health Activists (ASHAs). IAP recommends use of mOPV1 for birth dose in areas where wild polio P1 virus transmission continues.

- (3) *Improvement in performance of NIDs and SNIDs:* IAP recognizes that the age distribution of the cases of wild polio has not shown shift to right as still more than 70% of cases occur in children less than 2 years of age. Over 70% of cases occur in Muslim children though they form less than 40% of the susceptible children in Moradabad. It clearly means that not enough children are being vaccinated in UP and Bihar, both routinely and during the SIAs. Yet more than 50% of wild polio cases have received more than 10 doses of OPV as per the data available. The question is whether this data is reliable completely, as most of this data on number of OPV doses received by the wild polio victim is as per recall by the parent and not based on documentation. There is a need to clarify this issue further by conducting a pilot project to collect authentic data on the number of OPV doses received by the wild polio victim based on genuine documentation.

IAP recognizes that in UP, especially Moradabad district, the number of 'X' houses went up from 4% in early 2005 to 10% by mid 2005. This was coupled with some additional 5% of houses being marked wrongly as 'P' in stead of 'X' in

spite of children being not vaccinated, children spitting out the vaccine, children being vaccinated in prone position or while sleeping or marking the fingers of children without giving OPV in connivance between the local health care worker and the parents. This meant 15% less coverage of the houses that led to outbreak in next 6 months in these areas. As compared, in Bihar the proportion of 'X' houses remained at 10% through out 2005-2006 and there was no outbreak in Bihar.

There are various reasons to this deterioration of performance on the day of NIDs and SNIDs. These include program fatigue, minority resistance, too frequent NIDs and SNIDs, unfilled vacancies in concerned areas in local health infrastructure and lack of supervision by local administration. These loop-holes should be plugged by filling up the vacancies, placing the right person at right place, providing incentives for better performance to the local health care workers, independent monitoring and better social mobilization, especially of the minority population with the help of celebrities, local IAP branches and local religious leaders.

- (4) *Number, duration and timing of NIDs and SNIDs:* IAP believes that too frequent NIDs and SNIDs have led to program fatigue, both for the health care workers and the parents. Similarly, too long duration of NIDs and SNIDs (5-7 days as is the current practice) is against the principle of pulse immunization which is based on giving OPV simultaneously on the same day to all susceptible children in a given local area. IAP suggests shortening the NIDs and SNIDs to 72 hours with 1st day as booth based activity and next 48 hours as house to house activity. IAP also recommends restricting the NIDs to only 2

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during winter season and SNIDs to bare minimum as required. In absence of effective routine immunization coverage, it may be unwise to reduce the SNIDs in UP and Bihar, however once the routine immunization coverage is improved; the SNIDs in these areas should be accordingly reduced in long run.

- (5) *Need for additional tools:* IAP also believes that, though all the efforts to improve the performance of NIDs and SNIDs will help reduce the transmission of wild polio virus in UP and Bihar, at best it may bring the situation back to pre-outbreak state. Whether it will lead to interruption of transmission in these difficult areas is difficult to guess. Can we improve the performance beyond 90-95% coverage at best is difficult to answer. Even more difficult is to sustain such high performance round after round, year after year in spite of our best efforts. Hence, additional tools are required to interrupt wild polio transmission.
- (6) *Role of IPV in current epidemic:* We know that OPV has not shown herd effectiveness as it has failed to protect non-immunized children in UP and Bihar, or for that matter any where in the country (and has even failed to protect some who have received more than adequate number of OPV doses). This means that one needs to achieve near 100% coverage during routine immunization and SIAs with OPV. This is nearly impossible. In addition one needs to give a staggering 10-15 doses of OPV in UP and Bihar for individual protection with OPV, that too as early in life as possible, preferably before the age of 6-12 months to interrupt wild polio virus transmission. This is technically and operationally not feasible. Imagine all this in presence of very high force of

transmission of wild polio virus in UP and Bihar, poor routine immunization coverage and sub-optimal SIAs performance. What then is the solution?

IAP notes that many western countries have eradicated polio by using IPV alone or along with OPV. IPV has no risk of VAPP, Circulating Vaccine Derived Polio Virus (cVDPV) or Circulating Vaccine Derived Polio Virus in Immunocompromised Host (iVDPV). IPV is known to lead to 95-98% protection of the individual given 3 doses. Similar efficacy is seen with use of 3 doses of IPV in developed countries (unlike OPV where more doses are required and OPV has true vaccine failure) even when given at 6-10-14 weeks of age, early enough before wild polio virus gets to the intestines of the child in UP and Bihar. Limited data available from India on effectiveness of IPV has shown similar high effectiveness including high field efficacy, as high as 98%. The immunity following IPV is even long lasting.

IPV also has been used in campaign mode (Oman, Gaza strip) and shown to boost the immunity by way of increase in titers of antibodies induced by OPV as well as 8-14 fold increase in the chances of seroconversion in those who failed to seroconvert with 3-5 doses of OPV even by a single dose of IPV (situation similar to that present in UP and Bihar).

Based on the data available, IAP recommends that this year and early next year, 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 per the availability of the number of doses for immediate use. It could be given as 2 doses of IPV at 2 months interval to children from 2 months to 2 years of age. In the 2nd year, it should be given to children of < 1 year of age again in campaign mode. In

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the 3rd year, it should be incorporated in the routine immunization as 3 dose schedule at 6-10-14 weeks as by then the steps taken to strengthen routine immunization coverage would have shown satisfactory scale-up. OPV will be continued to be used in the remaining rounds of SIAs, as birth dose, for routine immunization and for SIAs as in other parts of the country.

Use of IPV in current situation should be done after appropriate and effective social mobilization and creating proper IEC material in regional languages. Field personnel to disseminate the IEC material should be properly created and properly trained before launching IPV. At no time IPV should be projected as the panacea of all the problems or to be better than OPV; and no false promises on its effectiveness or surety to eradicate wild polio, if at all, should be made to public by any health worker or IEC material. IAP also recommends that the impact study of use of IPV should be carried out simultaneously using the modern research methods.

AFP surveillance: IAP recognizes that the AFP surveillance system is very efficient in India. In fact there has been over enthusiastic reporting of AFP cases in UP and Bihar since last 2 years and that is the reason behind unprecedented high non-polio AFP rates from these states since last 2 years. IAP believes that it is neither due to increased cases with mOPV1 that is being used since last 1 year nor due to increased number of VAPP cases.

IAP suggests that there is a need to improve the proportion of AFP cases with adequate stools collection so that the number of 'compatible' polio cases (without virus isolation) can be minimized. It is also important to collect reliable data on the AFP cases, especially the number of OPV doses received by the AFP victim so that we can learn

about the true OPV failure, as it exists. IAP also suggests that data on VAPP and break-up of non-polio AFP cases should be provided to IAP and other scientific groups from time to time. Lastly, IAP strongly recommends evolving state sponsored rehabilitation program for all patients with childhood paralysis due to wild poliomyelitis or VAPP.

Post-polio eradication scene and immunization: IAP believes that it will be unsafe and unethical to continue to use OPV in post-polio eradication era. Following concepts should be kept in mind while deciding India specific guidelines for post-polio eradication immunization. .

- (1) It will be unethical and unsafe to continue to use OPV after zero wild polio case and zero transmission status is achieved due to risk of VAPP following OPV.
- (2) It will be unwise to discontinue use of polio immunization altogether after zero polio status is achieved due to fear of cVDPV, iVDPV. Past experience from some countries has shown that countries which have eradicated wild polio virus and have slackened in their routine polio immunization programs have experienced cVDPV outbreaks. These outbreaks of cVDPV were curtailed by strengthening routine immunization and giving 2 or more rounds of SIAs using OPV. However in post-polio eradication era, it will be unethical and unsafe to reintroduce OPV in such areas. It will force us to depend on the stocks of WHO or any such agency for OPV vaccine should out-break of wild polio or cVDPP occur. Hence India should preempt the emergence of cVDPV and has to become self sufficient in stock-piling enough polio vaccine now to meet any such unforeseen eventuality in future.

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- (3) Looking at the above problems, IAP recommends that India should switch over to IPV, preferably as IPV-DTP, in its routine immunization program gradually in post-polio eradication era. India should encourage indigenous manufacturer to produce enough IPV so that it becomes affordable so that it will be possible to switch to IPV in due course, looking at the huge requirement of the number of doses.

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Annexure I

List of experts present at the meeting:

Chairperson: Nitin K. Shah

Conveners: Shyam Kukreja
Anupam Sachdeva

Invited Members:

Naveen Thacker, T. Jacob John, Raju C. Shah, V.N. Tripathy, Vipin Vashishtha, A. Parthasarathy, R.N. Srivastava, S.K. Mittal, Yash Paul, A.K. Dutta, B.K. Dutt, Atul Agarwal, Ajay Kalra, Mahesh Goel, Vineet Saxena, M.L. Sridhar, S.A. Krishna, S.P. Srivastava

UNICEF: Marzio Babilie, Abhay Saraf, Dharmendra Dewan.