24th Meeting of the India Expert Advisory Group for Polio Eradication (IEAG)
Delhi, India, 15-16 March 2012

Conclusions and Recommendations

The twenty-fourth meeting of the India Expert Advisory Group (IEAG) was convened on 15 - 16 March 2012 in Delhi, with the following objectives:

1. To review progress on polio eradication since the twenty-third meeting of the IEAG in July 2011;
2. To make recommendations on strategies to ensure the maintenance of polio-free status in India.

The meeting was co-chaired by Mr P.K. Pradhan, Secretary (Health and Family Welfare), Ministry of Health and Family Welfare, Government of India, and Dr Jagadish Deshpande, Director, Enterovirus Research Centre (ICMR), Mumbai. A list of IEAG members that attended the meeting is annexed. The IEAG was pleased to have the participation of Ms. Anuradha Gupta, Additional Secretary & Mission Director, NRHM, Dr. Jagdish Prasad, Director General Health Services, along with other representatives from Government of India, Deputy Commissioners, Dr Ajay Khera and Dr. Pradeep Haldar, MoHFW and representatives from the States of Bihar, Uttar Pradesh (UP), Jharkhand, Delhi, West Bengal, Maharashtra, Punjab, Haryana, and Uttarakhand. In addition, core partner agencies (WHO, Rotary International, UNICEF, and CDC) were represented as were the Bill and Melinda Gates Foundation, USAID, MCHIP, CORE, JICA, World Bank and KFW.

Introduction

The IEAG met in the context of India being polio-free for more than 12 months and no longer considered as a polio-endemic country.

The IEAG was posed the following questions by the Government of India:

1. What are the challenges that India is likely to face in maintaining polio-free status until regional and global certification and beyond?
2. What lessons from other countries can be applied in India to protect the programme gains?
3. What strategies should India follow in 2012-2014 to sustain polio-free status?
4. Is isolation of VDPVs a concern for India?
5. How should India plan for the polio endgame strategy?

Findings and conclusions

India has not reported any case of confirmed polio due to wild poliovirus for more than 12 months; the last confirmed case had onset on 13 January 2011. Following the completion of a full year free of polio, with no wild poliovirus detected through surveillance for acute flaccid paralysis or environmental surveillance, the World Health Organization has announced that India has been removed from the list of polio-endemic countries. This is an extremely satisfying development for the IEAG, and reflects great credit on the Union and State governments for their strong commitment to completing polio eradication, including through the provision of substantial financial resources, thorough implementation of previous IEAG recommendations and, most importantly, successfully identifying and addressing programme weaknesses, and reaching high risk areas and populations with high quality immunization and surveillance activities.

The challenge for India now is to remain polio-free until the global eradication of all circulating wild polioviruses.

The epidemiological situation

Wild poliovirus type 1 (WPV1): No WPV1 has been reported in India from any source since January 2011. No WPV1 has been detected in UP since November 2009, and in Bihar since September 2010. The last isolations of WPV1 were two cases in West Bengal (December 2010 in district Murshidabad and January 2011 in district Howrah), and WPV1 in an environmental sample from Mumbai in November 2010.

Wild poliovirus type 3 (WPV3): The last WPV3 case reported had onset in October 2010 in district Pakur in Jharkhand and the last environmental isolate reported was from Delhi in July 2010. No case of WPV3 has been reported in Bihar since January 2010 and in Uttar Pradesh since April 2010.

Vaccine derived polioviruses (VDPVs): In 2011 a total of six vaccine derived polioviruses (VDPVs) type 2 and one VDPV type 3 were detected from AFP cases in six states. In 2012 to date, one VDPV type 2 has been detected in an AFP case in West Bengal. There is no evidence that any of these viruses were circulating. None of the detected viruses were related to each other or to cVDPVs detected in 2009 or 2010.

Risks to maintaining polio-free status in India

Currently the programme in India is maintaining high quality of surveillance and supplementary immunization activities (SIAs). Immunity levels against polio are high. Seroprevalence studies in high risk areas of UP and Bihar indicate high immunity against both polio 1 and 3 in these areas. Surveillance sensitivity and laboratory diagnosis capabilities have improved over the years. The absence of

wild poliovirus in AFP cases, their contacts and the environmental samples for more than 12 months provides increased confidence that WPV transmission has been interrupted in India.

Nonetheless there remain significant risks to India's polio-free status:

1. **International importation of wild poliovirus.** The most significant risk is the importation of wild poliovirus from countries with active circulation. Potentially any area in the world with current WPV circulation constitutes a risk for India, but the most significant risks are from the remaining endemic countries which continue to have extensive transmission. Pakistan and Afghanistan are in close geographical proximity to India, and although Nigeria is distant, it has a long history as an exporter of wild poliovirus. There remains a risk that populations associated with carrying poliovirus outside India in the past could bring the virus back from remaining active areas of circulation. Likewise, new movements of people with contacts with other polio infected countries could reintroduce WPV into India. The historic reservoir areas of Western Uttar Pradesh and Bihar and areas with recent transmission of poliovirus remain at higher risk of sustaining transmission should wild poliovirus be re-introduced. Additionally the known risk groups of migrant and mobile populations remain at significant risk of sustaining transmission and moving virus around the country should an importation occur.
2. **The development of circulating vaccine derived poliovirus (cVDPVs).** The rare situation of emergence of cVDPVs is also a risk for the programme in India. Although no cVDPVs were detected in 2011, experience from India in the past and from other countries demonstrates that cVDPVs (particularly cVDPV type 2) can develop if population immunity is very low. Type 2 cVDPVs are more likely to develop than either type 1 or type 3. While the regular use of tOPV in national campaigns in the past 3 years reduces the risk of type 2 cVDPV development in India, the risk remains.

Challenges and lessons from other polio free countries

The experience of other countries that have become polio-free is of significance for India. It is clear that importations of wild poliovirus have been and are a significant risk for polio-free countries; more than 40 countries have suffered from importations since 2000. The key lessons that can be derived from the experience of these importations are:

- It is vital to maintain high levels of population immunity
- Maintaining high surveillance and laboratory quality improves the speed of detection of importations
- Rapid SIA response reduces both the duration and intensity of outbreaks, and is in turn dependant on effective preparedness
- Flexibility of response is important to ensure that the correct strategy is used

- Regular assessment and mitigation of risks maintains preparedness and reduces the chances of importation causing significant outbreaks

IEAG Recommendations

The recommendations below outline the strategies and activities that take into consideration the need to mitigate the risks outlined above.

Maintaining immunity

The IEAG considered that both supplementary immunization and enhanced routine immunization will be necessary to maintain optimum population immunity to minimize the consequences of any WPV importation, and to ensure that cVDPVs do not develop.

OPV Supplementary Immunization Schedule (SIAs)

The IEAG recommended the following supplementary immunization schedule for the period from May 2012-2014.

Polio SIAs for the remainder of 2012:

- Three large scale SNIDs with bOPV, targeting all of UP, Bihar, Delhi, and associated high risk areas of Haryana, Rajasthan, and Uttarakhand, and migrant/high risk areas in Maharashtra, Punjab, Gujarat, Jharkhand, and West Bengal.

Polio SIAs 2013: 2 NIDs+4 SNIDs

- Two NIDs with tOPV in all areas in 1st quarter of 2013
- Four SNIDs with bOPV, one in each quarter of 2013 targeting all of UP, Bihar, Delhi, and associated high risk areas of Haryana, Rajasthan, and Uttarakhand, and migrant/high risk areas in Maharashtra, Punjab, Gujarat, Jharkhand, and West Bengal.

Polio SIAs 2014: 2 NIDs+3 SNIDs

- Two NIDs with tOPV in all areas in 1st quarter of 2014
- Three SNIDs with bOPV, one each in quarter 1, 2 and 3 of 2014 targeting all of UP, Bihar, Delhi, and associated high risk areas of Haryana, Rajasthan, and Uttarakhand, and migrant/high risk areas in Maharashtra, Punjab, Gujarat, Jharkhand, and West Bengal.

Maintaining surveillance and laboratory performance

The IEAG was well satisfied with the overall performance of the AFP surveillance system, and was particularly impressed that speed of laboratory results continues to remain high despite increasing numbers of AFP samples submitted for testing. The IEAG noted the findings and recommendations of the AFP surveillance reviews conducted in 2011, including the urgent need to improve surveillance in Andhra Pradesh. The IEAG also noted the progress made in Delhi, Maharashtra and West Bengal following the recommendations of surveillance reviews.

- An extremely high level of vigilance is necessary in the coming months to ensure that any importation or circulation of poliovirus and VDPV are reliably and rapidly detected; surveillance quality must be sustained across the whole country with special focus on identified areas and populations that are at higher risk for importation and/or poliovirus circulation including:
    - Historic poliovirus reservoir areas of Western Uttar Pradesh and Bihar
    - Areas with recent transmission
    - Areas / populations at higher risk of importation, i.e. with genetic linkages with past international movement of wild poliovirus, and areas bordering neighbouring countries with current active transmission
    - Migrant and mobile populations

- The IEAG endorsed the plan to expand environmental surveillance to Punjab and Gujarat in 2012.
- Regular field reviews of surveillance systems should continue as planned and recommendations acted upon to address surveillance gaps.
    - The issues identified by the surveillance review in Andhra Pradesh should be urgently addressed.
    - Efforts to improve surveillance sensitivity should seek to optimize the reporting network to ensure all risk populations are adequately captured by the surveillance system

- Greater involvement of district and block level government officials in all components of AFP surveillance, i.e. response to AFP case reporting, sensitization of the existing reporting network, regular review of surveillance data and its utilization to improve the system.
- Recognizing the increasing workload for the polio laboratory network, the human and financial resources should be reviewed and sufficient funds ensured in order to maintain the current level of performance.

Readiness to respond

- The IEAG re-emphasized the previous recommendations that *any circulating poliovirus detected, regardless of source, anywhere in the country should be considered a public health emergency and responded to by multiple high quality mop-up vaccination campaigns*.
- The new emergency response plans prepared by the States should be reviewed and evaluated by GOI and partners by the end of April 2012. These reviews should confirm appropriate selection of rapid response team members, thorough assessment of risks, clarity of roles and responsibilities, communications components, and response to WPV should it be reported.
- The Emergency Preparedness and Response Plans (EPRPs) should be updated at a minimum annually; the update should include a full new risk analysis to inform risk mitigation measures.
- State EPRPs must adequately address:
    - Plans to overcome staff vacancies in high risk areas;
    - Systematic inclusion of HR areas/populations for RI strengthening;
    - Timeline for harmonization of SIA and RI microplans in high risk areas;
    - Assignment of HR districts to Rapid Response Team members (RRT) for regular review of RI, SIA and emergency preparedness;
    - Assessment of communication risks and social mapping;
    - Identification of media spokespersons;
    - Plans for procurement of logistics and IEC materials for undertaking urgent mop-ups.
- Simulations of the emergency response plans at national and state levels should be conducted by the Union government on an urgent basis.
- Immunization of travellers at border crossing points should continue until there is no longer an epidemiological risk. At border crossing points with Pakistan, children should continue to be immunized. Particular attention should continue to be paid to border populations to ensure that they are effectively covered by SIAs and routine immunization.
- All detected VDPVs should continue to be thoroughly investigated to determine any risk of circulation. During the investigation, routine immunization intensification should be undertaken as appropriate. Findings should be reported to the State Secretary of Health and action taken to address any deficiencies identified with routine immunization coverage.
- If there is any evidence of circulation of a VDPV (i.e. cVDPV) or an obvious impending risk based on the investigation, then an appropriate mop-up response should be conducted to prevent expansion of circulation and reduce the risk of further VDPV emergence.

Reducing Risk

Communications and Social Mobilization

The IEAG was very impressed with the extensive programme for communications for polio eradication in India. IEAG commented that the communications network developed by a partnership of agencies is a significant asset for public health in India and the experience developed in polio eradication must be used to inform other public health programmes. At the same time, intensive communication support will continue to be necessary to ensure that the eradication effort maintains momentum and avoids complacency.

- Continued community engagement activities through the Social Mobilization Network (SMNet) and other ground-level initiatives (eg, ASHA and Anganwadi Workers) in both traditional polio reservoirs and in newly emerging high-risk areas such as West Bengal and Malegaon, must be maintained at least through 2012-13, as essential efforts to ensure mobilization of migrant, mobile and other difficult-to-reach groups.

- Media engagement must be continued with an additional focus on engaging journalists to ensure accuracy of reporting and to prevent misinformation that could affect the existing strong community support for the polio programme. EPRP media plans should build in strategies to prevent inaccurate reports, for rapid response to control misinformation, and to build community confidence. Media training must be held for all identified EPRP spokespersons, as well as identified health spokespersons in key states.

- In order to share best practices and the extensive experience gained by the programme, all aspects of the communication effort over the past decade should be carefully documented. These best practices, which include elements of the SMNet, media engagement as well as the engagement of high-risk populations, should be available not only for polio outbreak preparedness and the strengthening of routine immunization, but also for other public health programmes.

- To help develop a platform for sustaining the gains in polio eradication, communication efforts at all levels should adopt promotion of routine immunization as a primary message in all public communication. This promotion must be matched with operational initiatives to ensure that vaccine logistics and supplies are in place to meet the increasing community demand.

Continued focus on high risk areas and groups

The IEAG commended the efforts of Government and partners to ensure that areas and populations at highest risk are given special attention to ensure that every child is reached with vaccine:

- Efforts to identify migrant areas as well as urban and peri-urban high risk populations and incorporate them into SIA, surveillance, and routine immunization plans should continue as a priority activity
- Government and partner efforts to focus on the 107 high risk blocks should be maintained, with increased attention on fully implementing the plan across all blocks, and particular emphasis on improving routine immunization coverage, scaling up distribution of zinc/ORS, and water/sanitation interventions.

OPV supply

- The Union Government should take the following steps to ensure timely and sufficient supplies of OPV for polio vaccination campaigns:
    - Plan for a 24 month time frame for OPV procurement
    - Encourage all pre-qualified global OPV producers that are not yet licensed in India to complete the licensing process, to ensure that the choices for vaccine are as wide as possible and to reduce the risks of unavailability.
    - DCGI should be encouraged to fast track the licensing process for already prequalified OPVs
    - Consider the possibility of a reduction in the shelf life specification for procurement of OPV for polio vaccination campaigns from the existing stipulation of 18 months. The specifications for shelf life of OPV for polio vaccination campaigns should be within the permissible bands of the National Regulatory Authority which permit a shelf life of 14 months at the time of vaccine delivery to the programme.
    - Consider relaxing the procurement specification stipulated for labelling the primary packaging by allowing a flexibility on mentioning the sentence “Central Government Supply – Not for Sale” on the primary packaging
- The Union Government should continue to ensure a rolling emergency stock of 50 million doses of OPV (40 million bOPV and 10 million tOPV) to enable rapid response to both WPV and cVDPV detections. The composition of the stockpile should be reviewed every 6 months and adjusted as necessary in response to changes in the risk and epidemiology.

Building on Polio Eradication

Strengthening Routine immunization

The IEAG re-emphasized the importance of ensuring high levels of routine OPV coverage to help protect the success achieved and keep India polio-free.

- Convergence of polio eradication and routine immunization must continue, particularly with respect to using the lessons of polio for micro planning,

communications, and identification and inclusion of marginalized populations such as migrants, and urban/peri-urban areas in routine immunization plans.

- State EPRPs and Year of Intensification of UIP plans should be consolidated and operationalized, with a focus on monitored timelines and milestones, and include the identification and inclusion of high risk areas and populations – particularly migrants, and urban and peri-urban populations – in routine immunization microplans.
- The focus of efforts to improve routine immunization should be on the 239 low performing priority districts identified by the national programme. Priority should also be given to ensuring that Auxiliary Nurse Midwives (ANMs) and medical officers (MOs) are present in these high risk areas.
- The IEAG noted and endorsed plans to conduct Immunization Weeks in the north-eastern states, and in UP, Bihar, Madhya Pradesh, Rajasthan, Gujarat and Jharkhand.
- The IEAG again urged states to fully scale-up the monitoring of routine immunization sessions and the use of monitoring data for programme decision making at all levels.
- Surveillance for vaccine preventable diseases should be expanded commencing in 2012 based on the experience and structure of the AFP surveillance system.

Preparing for the endgame

There are significant policy and programmatic implications that follow from India becoming polio-free such as Southeast Asia Region will be able to submit Regional Polio Eradication Certification document in 2014 and confidence in success of Global Polio Eradication has increased greatly.

Programme planning for the future

- The national immunization programme should now begin incorporating into its planning:
    - tOPV to bOPV switch in routine immunization, potentially as early as 2014
    - Eventual cessation of all OPV at some point in the future (possibly 2017-18 period).
- This planning should include consideration of the introduction, in advance of a tOPV-bOPV switch, of at least one dose of IPV (e.g. at DPT3 contact), to boost population immunity and reduce the risk of a type 2 cVDPV emergence and the consequences of a potential cVDPV.
- The national programme should begin examining the programmatic need and cost implications of adding an IPV dose to the routine EPI schedule (e.g. at the DPT3 contact) in advance of a global tOPV-bOPV switch, including:

- Examination of implications of delivering IPV as a fractional (1/5th) dose intra-dermally (ID) versus a full dose intramuscularly (IM).
- Consolidating the considerable IPV study data already existing in India, including from licensing trials, to help inform policy options.
- Finalizing and starting the planned trial to verify the immunogenicity and programmatic feasibility of a 'bOPV + 1 dose of IPV (ID or IM)' routine schedule.

- GOI should convene a small consultation with IEAG members in mid-2012, following the SAGE (April 2012) and World Health Assembly (May 2012), to facilitate national deliberations on the timing and IPV policy options for a tOPV-bOPV switch.

Research Activities

- The national programme should implement the planned research agenda, giving priority to:
  - Completion of the mucosal immunity study that is currently underway
  - New seroprevalence surveys in 2012 in UP and Bihar in 5 high risk and 5 non high risk blocks in each state.
  - Assessing different bOPV products from different manufacturers and generating data on immunogenicity and safety of these additional bOPV products for potential licensing by national regulatory authority (DCGI) in India.
  - Assessing strategies for a safe tOPV-bOPV switch by comparing immunogenicity against poliovirus types 1 and 3 by bOPV & tOPV given as part of routine EPI schedule and assessing the gain in immunity (booster effect) of a full dose or fractional dose of IPV when added to tOPV or bOPV at 14 weeks (DPT3 contact) in EPI schedule.
  - Assessing the social determinants of vaccine refusals (survey for social networking analysis) in Malegaon (Maharashtra).

Annex

List of India Expert Advisory Group Members

1. Mr P K Pradhan, Secretary, (H & FW) MoHFW, Govt of India
2. Dr Jagadish Deshpande, Director, Enterovirus Research Centre, ICMR, Mumbai
3. Ms Anuradha Gupta, Additional Secretary & Mission Director, MoHFW, Govt of India
4. Mr Jagdish Prasad, DGHS, Govt of India, MoHFW
5. Prof A K Dutta, Prof & Head Dept of Pediatrics, LHMC & Kalawati Saran Hospital
6. Dr R N Srivastava, Consultant Pediatrician and Member of Expert Group on case classification for polio, New Delhi
7. Dr Harish Chellani, Consultant Pediatrician & Associate Professor, Safdarjung Hospital, New Delhi
8. Prof Sanjay Chaturvedi, Prof. Community Medicine, Dept of Community Medicine, UCMS, Delhi
9. Prof V K Srivastava, Director, Integral Institute of Medical Science, Kursi Road Lucknow,
10. Prof Ashok Mishra, Dept of PSM, Gwalior Medical College
11. Prof D K Taneja, Director, Prof of Community Medicine, MAMC, New Delhi
12. Dr Rohit C. Aggrawal, President, Indian Academy of Pediatrics,
13. Dr Shashi Khare, Additional Director, NCDC, Delhi, (on behalf of Dr L S Chauhan, Director, NCDC, Delhi)
14. Mr Deepak Kapur, Chairman, INPPC, Rotary International
15. Mr Carl Tinstman, Public Health Consultant, former Principal Advisor Polio Eradication, UNICEF/WHO, Geneva
16. Dr Bruce Aylward, Assistant Director General, WHO-Geneva
17. Dr Steve Cochi, Senior Advisor, Global Immunization Division, CDC, Atlanta
18. Dr Jeffery Bates, UNICEF Health, Communications Specialist, Polio Unit Health Section, UNICEF-New York (represented UNICEF-New York)
19. Dr Ajay Khera, Deputy Commissioner (CH & I), MoHFW, Govt of India