Conclusions and Recommendations of the Advisory Committee on Poliomyelitis Eradication (ACPE) 
Geneva, 18-19 November 2008

The 5th Meeting of the ACPE was convened at the World Health Organization in Geneva, Switzerland to provide the Global Polio Eradication Initiative (GPEI) with expert advice on:

- interrupting wild poliovirus (WPV) transmission worldwide;
- optimizing the use of tools for polio eradication;
- limiting the international spread of polioviruses.

The ACPE provides guidance on broad strategic issues, while advisory bodies in each endemic country and some re-infected countries provide detailed technical and operational guidance specific to the context of those countries.

1 Key findings and conclusions

After careful review of the intensified eradication effort in the four countries that have never stopped transmission of indigenous polioviruses, the ACPE concluded that:

(a) India has a very high performing eradication programme which, if current efforts are sustained and contingency plans rapidly implemented to enhance programme efficacy, will interrupt poliovirus transmission;

(b) Afghanistan has an eradication programme which demonstrates top political commitment and engagement, community determination, and ongoing innovation which, with modest improvements in access in security-compromised areas and campaign oversight and quality in accessible areas, should interrupt poliovirus transmission;

(c) Pakistan has an eradication programme which is sound, but which, because of very efficient virus transmission, gaps in campaign quality, and a deterioration in security in a key transmission zone, requires further improvements in campaign quality and continued innovation to interrupt poliovirus transmission; particularly important will be to achieve an appropriate balance among monovalent and trivalent OPVs in each infected area;

(d) Nigeria will continue to pose a high risk to international health until the new, top political commitment is translated into field level improvements in campaign quality. More than 30% of children are still unvaccinated in Kano, for example. This has resulted in the ongoing co-circulation and international exportation of WPV1, WPV3, and cVDPV type 2. The international risks posed by Nigeria are compounded by the current economic climate which severely compromises the capacity of the international community to respond to any new international spread from the large areas of uncontrolled poliovirus transmission in the north of this country.

Recommendations

- In Nigeria, polio campaign performance must be improved markedly by end-March 2009, with independent, objective evidence that the proportion of zero dose children has been reduced to <10% in all polio-infected states.
In Pakistan, province-specific eradication plans, which include the mix of polio vaccines to be used in each area, should be established by end-2008, fully implemented, and reported back to ACPE by end-March 2009. Objective data (e.g. finger-marking) should be provided to the ACPE in April 2009 to demonstrate that all children are being reached in campaigns.

The ACPE should, together with SAGE, assess this progress by April 2009, and report to the Director-General such that the international risks to global polio eradication and public health can be effectively conveyed to all WHO Member States during the World Health Assembly in May 2009, to facilitate appropriate risk management by polio-free countries.

The ACPE highlights the importance of all endemic countries having completed and reported on the major studies and/or programme initiatives they are planning between now and end-March 2009, including:

- the launch of the Presidential Initiative in Kano, Nigeria to reach all children with vaccines,
- the trials of bivalent OPV and IPV in India,
- the serosurveys in Pakistan to better assess programme effectiveness and vaccine efficacy,
- the Government of Afghanistan directive to all health NGOs operating in southern Afghanistan to make polio eradication a priority.

2 Current status and major developments

As of 12 November 2008, 1473 polio cases due to wild poliovirus (WPV) were reported from 16 countries compared to 707 cases in 11 countries for the same period in 2007. The four countries that have not yet interrupted indigenous transmission of WPV (India, Nigeria, Pakistan, Afghanistan) accounted for 93% of all cases, with Nigeria and India reporting 51% and 34%, respectively. Two endemic countries, Nigeria and Pakistan, have considerably higher numbers of cases than in 2007 due to type 1 outbreaks.

The remaining 97 cases were from 12 re-infected countries: Angola, Benin, Burkina Faso, Central African Republic, Chad, the Democratic Republic of the Congo (DRC), Ethiopia, Ghana, Mali, Nepal, Niger, and Sudan. Eleven of these suffered new importations in 2008, and five (Sudan, Chad, DRC, Angola, Niger) have had prolonged transmission (more than 12 months) following importations.

Consequently, only one of the milestones established at the commencement of the Intensified Eradication Effort in early 2007 has been fully achieved; the others are at best partly achieved. The milestones were not fully achieved due to:

- Sub-optimal OPV efficacy in key areas of northern India, where despite multiple campaigns achieving high immunization coverage, WPV1 transmission has not yet been completely stopped.
- Sub-optimal campaign quality in Nigeria, parts of Pakistan, the Southern Region of Afghanistan and the 5 countries with prolonged transmission of importations, where coverage has not achieved the levels necessary to interrupt transmission of a WPV and, in the case of Nigeria, a type 2 cVDPV.
- Insecurity which is limiting access to communities during immunization campaigns in parts of Afghanistan and Pakistan.
Despite the difficulties faced in 2008 a number of important developments have occurred which place the programme on a stronger footing going into 2009:

- The May 2008 World Health Assembly Resolution on polio eradication was adopted, highlighting a renewed international commitment to the goal.
- Reaffirmation of the technical feasibility of polio eradication was provided by the cessation of transmission of indigenous WPV1 in western Uttar Pradesh, previously the most endemic area for WPV1 in the world.
- The Heads of Government and State in all of the endemic countries have now publicly committed to polio eradication. In Nigeria and Pakistan there has been improved engagement of some state/provincial governments.
- New importations of wild poliovirus into polio-free areas have in general been met with a quick response on an appropriate scale, with the result that, unlike previous years, outbreaks have been limited in size.
- The speed of detection of wild poliovirus has improved markedly following the introduction of new laboratory procedures (average time to WPV confirmation 42 days in 2007 vs 21 in 2008).
- The commitment of new, multi-year funds by major partners including Rotary International, the Bill and Melinda Gates Foundation, the World Bank, and a number of G8 countries has substantially improved programme financing.
- The programme is pursuing an active research agenda, through its reconstituted Polio Research Committee, and employing new strategies to overcome obstacles to eradication, including the use of mOPVs.

Thus, while the milestones have not been fully met, the ACPE considers that the GPEI strategies are valid and can succeed even though grave risks remain, including those posed by the recent global economic downturn which threatens funding.

**Recommendations**

- The ACPE believes that the milestones adopted following the Stakeholder Consultation in February 2007 remain valid, though additional milestones should be developed to:
  - provide specific goals for each of the four polio endemic countries, and for re-infected countries as a group, and
  - closely monitor the performance of selected programme processes, especially for SIAs, to more rapidly and effectively guide midcourse corrections.

These milestones should be incorporated into the Strategic Plan 2009-2013.

- The ACPE welcomes the Director-General’s commissioning of an independent review of the intensified eradication effort and suggests that it focus on polio campaign quality in the countries that have never stopped transmission, taking into account the recommendations of the ACPE and national technical advisory groups.

- Noting the current global economic situation, the GPEI should develop contingency plans to ensure that key, critical activities and programme components can be supported.
• Stopping WPV transmission within 12 months of an importation into a polio-free area should be considered a key milestone for both 2009 and 2010 and appropriate measures undertaken to ensure that this milestone can be met (see below).

• To continue progress towards the more rapid detection of WPV and cVDPVs, the implementation of the laboratory testing algorithm and incorporation of new diagnostic tools (e.g. real-time PCR) should be carried through to completion.

3 Interrupting transmission in countries with indigenous wild poliovirus

3.1 General principles

The overriding priority for the GPEI is to interrupt transmission in India, Nigeria, Pakistan, and Afghanistan. The ACPE has previously pointed out that these countries face different challenges. India has to overcome the problem of sub-optimal vaccine efficacy in the remaining endemic areas, especially in western Uttar Pradesh. Nigeria, Pakistan, and Afghanistan must all achieve consistent immunization of all children during supplementary immunization activities.

Recommendations

India, Nigeria, Pakistan, and Afghanistan should:

• Conduct a minimum of 6-10 high quality SIAs per year in infected and high risk areas until WPV transmission has been interrupted.

• Use a mix of mOPV1, mOPV3 and tOPV to interrupt the WPVs and maintain immunity against poliovirus type 2; the optimum mix is likely to vary among countries and areas based on the epidemiological situation, but should include at least 2 rounds of tOPV.

• Seek recommendations on the vaccine of choice for specific SIAs from their national polio eradication advisory body, based on the epidemiology and population immunity data.

• Continue to prioritize eradication of type 1 poliovirus, particularly in India and Nigeria, given its higher paralytic rate and propensity for spread to polio-free areas.

• Maintain Head of State engagement to monitor activities until at least 12 months have passed with no reported cases in the presence of sensitive surveillance.

3.2 Dealing with sub-optimal OPV efficacy in northern India

At present, the ACPE considers northern India, and particularly areas of western Uttar Pradesh (UP), as the only location in the world where sub-optimal efficacy of OPV is the major limiting factor for eradication. The main concern in terms of sub-optimal efficacy is immunity against WPV1. The likelihood of further large outbreaks of WPV3 in the immediate future is small.

The programme has taken a number of steps to address the issue of sub-optimal OPV efficacy in northern India including introducing monovalent OPVs, conducting multiple mOPVs rounds with short intervals between them to rapidly build population
immunity in very young children, and conducting clinical trials to evaluate a higher potency mOPV1.

Recommendations

- The highest priority must be to interrupt WPV1 in western UP and central Bihar. The current strategy of multiple, short interval rounds with mOPV1 is of demonstrated effectiveness, though resource intensive. Subsequent to WPV1 interruption, a mix of tOPV and mOPV3 should be used until WPV3 is interrupted.

- The ACPE endorses the IEAG recommendation on assessing the efficacy of higher-titre mOPV1 in western UP, as a part of already planned studies, to determine if there is a benefit in such settings.

- The ACPE believes that there are potential benefits to adding IPV to the mOPV strategy in northern India to further reduce the risk of ongoing transmission. The ACPE concurs with the IEAG recommendation to assess the utility of a supplementary dose of IPV in the highest risk districts of western UP beginning in the first half of 2009. The ACPE further recommends:
  - An operational and communications plan should be developed as soon as possible to ensure that the planned mOPV SIAs are not jeopardized. Consideration should be given to phasing the IPV campaign.
  - The activity must be carefully evaluated to understand the epidemiological impact and the operational and communications issues. An evaluation framework should be developed as soon as possible.
  - Recognizing the IEAG's recommendation to introduce IPV, and though understanding the Government of India's desire to use an IPV-containing combination vaccine, as the enquiries by BMGF, WHO and UNICEF have confirmed that only standalone IPV can be available in sufficient quantity in 2009, this vaccine should be secured as soon as possible.
  - The existing AFP surveillance system should provide adequate data to gauge the impact of this strategy on poliovirus circulation, however this could be supplemented by targeted studies including environmental sampling.

- The Government of India should ensure close monitoring of all studies on mOPV1, bivalent OPV (see below) and IPV, and on population immunity levels, to ensure data are available by end-March 2009 to guide the programme at this critical time.

3.3 Dealing with sub-optimal OPV delivery in Nigeria, Pakistan, and Afghanistan

In Afghanistan, Pakistan, and Nigeria the key issue remains reaching all children consistently with OPV during campaigns by addressing:
- the quality of the campaigns (i.e. the effectiveness of service delivery)
- the attitude and practice of the population in accepting or seeking out the service
- access to all target populations for the service (compromised in areas of uncertain security).

The relative weights of these elements vary by country. The ACPE notes the conduct of knowledge, attitude and practice (KAP) research in all three countries has provided valuable information for developing strategies to help close some of these gaps.
**Afghanistan:** Southern Region has dominated transmission for the last 3 years and there is a clear differential in the immunization status of children in that region compared with other parts of Afghanistan. The security situation significantly affects the capacity to reach all children in the region, and also the capacity to ensure good quality SIAs even in accessible areas due to the limited movement of independent monitoring and supervisory staff. The ACPE notes the tremendous efforts and courage of those working on polio, who regularly face risks in their day to day work, exemplified by the sad loss of two colleagues and their driver in September 2008 to a violent attack.

**Pakistan:** in addition to indigenous poliovirus transmission in 3 provinces, there is a large WPV1 outbreak in Punjab, illustrating the continued risks to polio-free areas. Different factors clearly affect WPV transmission in each province, though the immunization status of polio cases, coupled with SIA monitoring data based on finger marking, indicates that many children remain under-immunized. The movement of people related to the recent security problems in NWFP/FATA appears to be a major factor in the spread of WPV1 and the WPV3 outbreak in NWFP. In these areas efforts are being made to negotiate access to security compromised areas and an opportunistic approach is being taken to immunize. In Sindh SIA quality appears to be improving by engaging the provincial and district governments.

**Nigeria:** The major WPV1 outbreak in the northern states is due to the continuing failure to reach and vaccinate children in these states. Despite all the activities carried out to date, for example, Kano state still has over 30% of children under 5 years of age who have never had a dose of OPV. Encouragingly, progress has recently been made in key northern states such as Kebbi and Jigawa, due to increasing ownership and engagement of the State Governments. However, the ACPE emphasizes that the continuing WPV transmission in northern Nigeria remains the main threat to eradication in Africa and globally.

**Recommendations:**

*All countries*

- The independent review proposed by the Director-General should give attention to SIA operations in all three countries using established best practices to identify and rectify root causes for ongoing coverage gaps in key areas.
- Finger-marking should be systematically used to independently monitor SIA performance; all areas with less than 90% coverage must be re-covered.
- High population immunity should be maintained in polio-free areas through routine immunization and periodic SIAs.
- Community knowledge, attitudes and practices should be systematically re-assessed every 6 months to evaluate interventions and to further tailor social mobilization and communications strategies.
- Communications teams from these countries should meet in early 2009 to review available data and develop or adapt appropriate communications and social mobilization models based on a common framework.
- For security compromised areas, quarterly reviews should be implemented to quantify and prioritize problems and their implications, based on the evolving security situation, population size and movements, and the estimated number of missed children during each SIA.
Nigeria

- Given the ongoing exportation of WPV to polio-free areas, the situation in Nigeria should be monitored on a quarterly basis by the Director-General of WHO to determine whether current measures to reduce the risk of WPV spread to other areas are being effectively applied and if additional measures are needed.
- The highest priority must be to reduce the proportion of 0-dose children to less than 10% in every state and to achieve an average of at least 4 OPV doses per child.
- The ACPE emphasizes need for state and local government ownership, with the formation of a Task Force for Polio Eradication in all high risk states to ensure that real actions are taken to improve SIA quality and coverage.

Pakistan

- A systematic, province by province analysis of the factors involved in ongoing WPV transmission should be undertaken to inform decisions on the number and timing of SIAs, and the vaccine of choice for each round in each province.
- In areas of discordant programmatic and epidemiological data, seroprevalence surveys should be rapidly conducted to verify programme performance and vaccine efficacy, and to guide strategy.
- Efforts must be enhanced at provincial and district level, particularly in Sindh and Baluchistan, to ensure accountability of all government officials for improving SIA quality.

Afghanistan

- Focus should be on those districts of Southern Region which are responsible for the bulk of WPV cases in recent years, with area-specific tactics developed for each based on experience in other conflict-affected areas.
- The Government of Afghanistan is urged to ensure that government-contracted NGOs operating in the high risk Regions, in particular Southern Region, be given the responsibility for supporting SIAs.
- The global polio partners should continue to explore the possibility of formal Days of Tranquillity through negotiation with all parties.

4 Optimizing the use of eradication tools

4.1 monovalent and trivalent OPV

The ACPE reviewed mathematical models of population immunity based on the immunization status of non-polio AFP cases and case control studies on the per dose efficacy of monovalent and trivalent vaccines. These data were found to correlate very well with the epidemiological situation. In India such work has also been used to help guide recommendations on SIAs and the vaccines of choice; in Nigeria it has been used to assess the impact of mOPV1 introduction. This tool, although still requiring caution in interpretation, is improving as a guide for decisions in all country programmes.

The correct mix of mOPV1, mOPV3, and tOPV for SIAs was discussed using an illustration from the Pakistan programme. While recognizing that the optimal mix of vaccines may be difficult to predict, the ACPE remains convinced that monovalent OPVs, both type 1 and type 3, offer significant advantages in increasing population immunity rapidly. How these vaccines are used, together with tOPV, will be key to
interrupting the remaining WPVs. Based on programme experience, it is now possible for national advisory bodies to more systematically recommend the vaccine(s) of choice.

**Recommendations:**

- Mathematical models of population immunity should be developed and reviewed each quarter for Nigeria, Pakistan, Afghanistan and India, based on the immunization status of non-polio AFP cases and the estimated per dose efficacy for each vaccine.

- National advisory groups should consider this mathematical modeling data in their recommendations on the vaccines of choice for specific SIAs. Where necessary, models should be constructed to project population immunity based on different SIA scenarios.

- Factors such as maternal antibody protection and immunity induced by infection with WPV should be assessed as possible elements to be included in modeling.

- Modeling should also be considered to guide outbreak response activities in key re-infected countries.

**4.2 bivalent OPV**

The ACPE has previously discussed the potential role of a bOPV (Sabin poliovirus types 1 and 3), given that there is co-circulation of WPV1 and WPV3 in some infected areas. To provide real programmatic advantage, a bOPV would need to achieve similar per dose seroconversion to each serotype as the respective mOPV. The status of the bOPV clinical trial was reviewed, as well as a proposed framework for its use, depending on the trial results. The ACPE realizes that the potential role of bOPV will vary depending on the epidemiological situation and the outcomes, due at end-March 2009, of the clinical trial.

**Recommendations:**

- To help OPV manufacturers gauge decisions on the development and licensing of additional bivalent OPVs, WHO and UNICEF should rapidly generate and share potential demand scenarios for bOPV based on the main possible clinical trial outcomes, and WHO should establish and share the regulatory pathway for bOPV.

- The ACPE should be rapidly consulted to review the results of the bOPV trial and assess its potential role. It is already understood that bOPV would not replace the role of tOPV in maintaining population immunity in polio-free areas. It is also understood that the main potential role for bOPV would be in areas with co-circulation of serotypes 1 and 3 and where suboptimal OPV delivery is the major problem. The ACPE does not anticipate that bOPV would have a substantial role in areas of suboptimal OPV efficacy.

**5 International Spread of Wild Poliovirus**

As at 14 November, a total of 93 polio cases have been reported from 12 non-endemic countries following WPV importations. Of note, in 2008 multiple importations of WPV3 occurred, in Nepal, Chad, and Angola, with the latter two having multi-case outbreaks which was previously a rare occurrence. While long distance importations continued to occur in 2008, most notably the WPV3 importation into Angola from India, the risk of an importation remains greatest for those countries that immediately neighbour an endemic or re-infected area.
The risk of importations remains significant as in 2008 the number of individual importation events is at the same level as in 2007 while more countries have experienced importations. However the number of multi-case outbreaks following an importation has further declined in 2008, suggesting that response activities have become more effective.

Despite the overall improvements in responding to importations, five countries (Angola, Chad, the Democratic Republic of the Congo, Niger, Sudan) are experiencing persistent transmission of an imported poliovirus (i.e. continued cases for more than 12 months). The ACPE is concerned that despite conducting multiple SIAs using mOPV, the quality of response activities in these countries has been inadequate to stop transmission.

The recommendations on polio immunization laid out in WHO's *International Travel and Health* are of value to countries in deciding steps to reduce the risk of importations. Most notably, Saudi Arabia has now for 3 years included polio immunization as part of the health requirements for pilgrims travelling for Hajj. The ACPE discussed and endorsed language that was proposed to update these recommendations in response to requests to WHO for further guidance from polio-free countries.

**Recommendations:**

- To reduce the risk of international spread of polioviruses, and to provide countries with updated technical advice in this regard, WHO should amend its recommendations on immunization against polio in *International Travel and Health* to reflect current knowledge on risk reduction, particularly with respect to vaccination of travellers who are resident in endemic areas.

- Countries at particular risk of WPV importations, especially those neighbouring infected areas, should consider steps to ensure the immunization of travellers arriving from infected areas, ideally prior to arrival but also at the point of entry.

- The Director-General of WHO should consider the potential value of a WHA resolution on the immunization against polio of travellers from endemic areas.

- All polio-free countries should maintain the highest possible routine immunization coverage to reduce the risk of WPV spread should it be imported.

- All re-infected countries should fully implement existing ACPE outbreak response recommendations to stop transmission of WPV as rapidly as possible and to prevent further international spread.

- Countries in which an imported WPV has continued to circulate for greater than 12 months should conduct an immediate assessment by an international team, which includes ACPE members, to verify whether all necessary steps are being taken to stop transmission.

- Countries bordering the endemic areas of Nigeria and India should continue to conduct annual SIAs on an appropriate scale until transmission in the relevant reservoir is interrupted.