Report of the South-East Asia Regional Consultation on the Polio Endgame Strategy

14 December 2012, Bangkok, Thailand

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Contents

1. Introduction

A consultation on the Polio Endgame Strategy in the South-East Asia Region was held in Bangkok, Thailand on 14 December 2012. It followed a consultation on new and underutilized vaccine introduction (NUVI), which included a discussion on inactivated polio vaccine (IPV). Participants from 10 out of 11 Member States representing their ministries of health and national programmes of immunization attended the regional consultation. In addition to Immunization Technical Advisory Group (ITAG) members, temporary advisers, representatives from donor and partners agencies and WHO staff from country offices involved in EPI participated in the consultation. The agenda for the consultation and a list of the participants are attached to the report as annexes I and II, respectively.

The Regional Director, Dr Samlee Plianbangchang inaugurated the regional consultation. In his speech, he mentioned that as long as there was circulation of wild poliovirus, all countries in the Region remained susceptible to importation of wild poliovirus.

The Regional Director highlighted that continued use of oral polio vaccine (OPV) after interruption of wild poliovirus transmission was considered inconsistent with the idea of eradication, as OPV may cause, in rare instances, vaccine-associated paralytic polio (VAPP) and may lead to outbreaks of circulating vaccine-derived poliovirus (cVDPV). The Polio Endgame Strategy has focused on differential risk management strategies for post-OPV surveillance, choice of vaccine, vaccine supply, management, financial support and sustainability.

Dr Piyanit Thamaphonpilas, Medical Officer, Advisory Level, Bureau of General Communicable Diseases, Department of Disease Control, Ministry of Public Health, Thailand chaired the meeting with Mr Sonam Dorji, Drug Controller, Drug Regulatory Authority, while NCIP Member, Bhutan acted as the rapporteur.

2. Objectives of the consultation

Dr Sangay Thinley, Director, Family Health and Research, WHO-SEARO presented the objectives of the workshop.

2.1 General objective of the consultation:

The general objective of the consultation was to review and discuss proposed strategies for maintaining the polio-free status in the South-East Asia Region following global certification.

2.2 Specific objectives of the consultation

The specific objectives of the consultation were to review the current status and progress of polio eradication and certification in the Region; to review the global polio endgame strategy; and to develop a road map for the Regional Polio Endgame Strategy.

3. Update on polio eradication in the South-East Asia Region

Updates on regional polio eradication and polio-free certification, recommendations and conclusions from the meeting on the transition from OPV to IPV in Bali, Indonesia, 29–30 April 2008, and the summary of the IPV discussion from the NUVI meeting held in Bangkok, Thailand from 11–13 December 2012 were presented. It was mentioned that on 25 May 2012, the Sixty-fifth World Health Assembly declared polio eradication an emergency for global public health and requested DG to rapidly finalize a comprehensive polio endgame plan.

3.1 Recommendations and conclusions from the meeting on the transition from OPV to IPV in Bali, Indonesia, 29–30 April 2008

The first meeting in the Region on the transition from OPV to IPV and the use of IPV was held in 2008 and the conclusions and recommendations

formed the basis for further discussion in the NUVI Meeting on 13 December 2012.

OPV is inconsistent in a post eradication era. Although eradication is not complete, countries should consider and plan for long-term risk management. All countries should consider conducting a risk assessment prior to any policy decision on the possible use of IPV. Additional studies may be needed for countries to understand the VDPV and VAPP risks. There are significant managerial, logistic, and operational challenges to be considered for the addition of another injectable vaccine into national EPI programmes. Both national and international risk management efforts should work to explore more affordable strategies for potential use of IPV in the post-eradication era. The Global Polio Eradication Initiative (GPEI) should explore financing mechanisms to facilitate IPV use. The GPEI should continue to work with partners in the vaccine industry and research institutions to explore IPV schedules, fractional dosing, programme optimization and financing options. A significant investment will be needed to enhance laboratory bio-safety management (containment) for countries that need to retain polioviruses.

3.2 Summary of IPV discussion from the NUVI meeting in Bangkok, Thailand 11–13 December 2012

On the last day of the meeting, the discussion focused on issues related to IPV and reviewed its role as a tool for polio eradication and specifically, the Polio Endgame Strategy. The Polio Endgame Strategy refers to the risk mitigation activities related to the withdrawal of oral polio vaccines. The current strategy involves a global switch from tOPV to bOPV with at least a single dose of IPV. The scientific basis for the use of IPV in the switch as well as the conclusion of several technical meetings and studies was discussed. The session set the stage for operational discussion and practical application of the bOPV switch plus IPV. The consultation intended to answer two questions: (1) "How should the Polio Endgame Strategy for the South-East Asia Region be operationalized?", and (2) "How should each country approach the polio endgame to include vaccine options for the switch?"

4. Polio Endgame Strategy–India perspective

The Indian perspective on the Polio Endgame Strategy was explained. There were some technical and operational issues with the introduction of IPV that India would like to consider as part of their decision-making process: (1) the age of vaccination; (2) full dose versus fractional dose; (3) intramuscular (IM) versus intradermal (ID); (4) frequency of dose, (5) service delivery issues to include management and health staff training, cold chain space, advocacy and communication materials.

Other areas of concern regarding IPV introduction were: (1) the impact on areas with low routine immunization coverage and the need for IPV SIAs; (2) the laboratory containment of type 2 vaccine-derived poliovirus (VDPV) and wild poliovirus (WPV); (3) per dose cost; and (4) the post-switch management of type 2 VDPVs.

In conclusion, it was observed that careful planning and consideration of risks will be required before implementation and that the earliest possible timing for the tOPV-bOPV switch would be 2015.

5. Economic evaluation of IPV use

The Strategic Advisory Group of Experts on Immunization (SAGE) working group on polio eradication considered that any recommendation that included the use of IPV would have to address supply guarantees and affordability. The current guaranteed volume purchase price is US$ 1.00 - US$ 1.25 per dose. The SAGE has considered or defined “affordable IPV” at around US$ 0.50 per dose.

There are four studies that have evaluated IPV costs and benefits: (1) cost effectiveness of alternative polio immunization policies in South Africa (Griffiths et al); (2) cost analysis of post-polio policy options (Sangrujee et al); (3) costs of future polio risk management policies, (Tebbens et al); and (4) risks, costs and benefits of future global policies for managing polioviruses (Thompson et al).

In summary, the current UNICEF tender price is between US$ 2.50-5.70. The breakeven price per dose is US$ 0.50; and assured volume purchases can probably reduce costs to about US$ 1.00. Potential options

for making IPV affordable includes: fractional dose, adjuvanted IPV and Sabin IPV. None of these options are currently available but could be possible in 24–36 months.

6. UNICEF support to the End Game Strategy

The Supply Division of UNICEF had a three-pronged approach for supporting the Polio Endgame Strategy: (1) procurement of OPV for WPV eradication and planned switch from tOPV to bOPV (OPV2 cessation); (2) procurement of IPV for introduction prior to the switch; and (3) management of bulk stockpile of mOPV1, 2 and 3.

The introduction of IPV into the routine immunization is a critical element of the Polio Endgame Strategy, a rapid scale-up of IPV introduction is expected to meet OPV2 cessation goal. Sufficient and sustained supply of IPV will be needed in a post-polio eradication era. Affordable pricing will be critical to meeting all objectives.

7. Western Pacific Region: country experiences with introduction of IPV in the routine immunization schedule

The experience with the introduction of IPV in the routine immunization schedule in Australia, Japan, Malaysia and New Zealand was shared with the participants.

Key aspects of IPV introduction in the Western Pacific Region were: (1) after certification and having been polio-free for many years, VAPP risk becomes increasingly unacceptable; (2) risks to public confidence in the programmes were related to VAPP cases; (3) concerns about potential problems posed by VDPV outbreaks (cVDPV) or prolonged excretion of VDPV among immuno-compromised persons (iVDPV); (4) Examples of other polio-free countries; (5) Increased costs associated with both the vaccine and administration; (6) lengthy buy-in process including NCIP/NITAG, MoH, MoF, private practitioners, vaccinators, parents; (7) opportunity to re-examine and make adjustments to the RI schedule; and (8) vaccine-producing countries are in the forefront of producing IPV from Sabin strains – sIPV (Japan and China).

In case of a polio outbreak, IPV-using countries in line with their national importation preparedness plans would initially use IPV. Countries have said that they would consider using OPV for prolonged outbreak, but that would require maintaining OPV licenses or developing special mechanisms for importing vaccines. The Western Pacific Region considers that maintaining its polio-free status is of the highest priority.

8. Discussion

After technical and operational discussions at the global and regional levels, each country's had an opportunity to present their perspective on the Polio Endgame Strategy is summarised below.

(1) Bangladesh intends to go with the global and regional Polio Endgame Strategy, but needs to have adequate consensus at the national level with technical committees and multisectoral government agencies.

(2) Bhutan intends to go with the global and regional Polio Endgame Strategy.

(3) Democratic People's Republic of Korea was unable to participate and will need to be consulted separately.

(4) India needs additional information and consultation regarding tOPV-bOPV switch and introduction of IPV. They need to consider appropriate timing, availability of bOPV and operational issues.

(5) Indonesia intends to move directly from tOPV to IPV. They have some concerns about the global timeline and their national timeline for IPV introduction.

(6) Maldives intends to move directly to IPV as part of combined vaccine and depends on pricing of penta- or hexa-valent vaccine.

(7) Myanmar intends to go with the global and regional Polio Endgame Strategy.

(8) Nepal intends to go with the global and regional Polio Endgame Strategy.

(9) Sri Lanka needs additional information and consultations to consider on tOPV-bOPV switch and the use of IPV.

(10) Thailand would be able to switch from tOPV to bOPV without any problem, but the introduction of IPV will require additional government consultation.

(11) Timor-Leste intends to follow the global and regional Polio Endgame Strategy.

9. Conclusions and recommendations

There are six global prerequisites for the tOPV-bOPV switch and these were applied to the regional situation.

Prerequisites	Applied to the South-East Asia Region
Validation of the elimination of cVDPV type 2 and eradication of wild poliovirus type 2 (persistent cVDPV2 stopped/new cVDPV2 stopped within six months)	There have not been any cVDPV type 2 since 2009 and WPV type 2 since 1999 in the Region.
Stockpile of mOPV2 and response capacity	The stockpile mOPV2 will be taken care of at the global level; so, there is currently no requirement at the regional level.
Surveillance and international notification of Sabin, Sabin-like, and cVDPV type 2	All the countries in the Region have well-established surveillance systems and countries would be able to report and response any type 2 viruses.
Licensed bOPV availability in all OPV-using countries	Not all countries in the Region have licensed bOPV.
Affordable IPV options for all OPV-using countries	Not available at the global or regional level.
Laboratory Containment phase II for cVDPV2 and wild poliovirus type 2 and phase I for Sabin type 2 [phase I: inventory and safe handling; phase II: regulatory framework, BSL3/polio, repository or destruction]	Phase -1 laboratory containment is expected to be complete by the end of 2013.

The polio endgame timelines are dependent on fulfilling the prerequisites. The Region has fulfilled the first three, but will need global support for the remaining three.

Summary of country perspectives:

- Category A: countries are comfortable in following the global endgame strategy for tOPV-bOPV switch plus IPV: Bhutan, Bangladesh, Myanmar, Nepal and Timor-Leste;
- Category B: countries that need addition information or in country consultations: India, Sri Lanka and Thailand;
- Category C: countries that want to move directly to IPV: Indonesia and Maldives;
- DPR Korea needs to be consulted separately.

All countries will need to have adequate consensus at the national level with technical committees and multisectoral government agencies.

During the course of the presentation and discussion, the following list of concerns was developed for further consideration at the global, regional and national levels:

- Cost per dose (national versus external support);
- Global supply (global availability of bOPV and IPV depending on the country's preference);
- Schedules (routine immunization, supplementary immunization activities, 1 dose or 2 doses);
- Mode of administration (single antigen: intramuscular, intradermal or in combination with penta-/hexa-valent vaccines);
- Operational research (risk assessment, immunogenicity/full dose/fractional dose);
- Licensure (ensuring mechanisms for use of bOPV, mOPV1/2/3 and IPV);
- Cold chain, health system and routine immunization capacity for IPV and additional OPV vaccines;

- Communication strategy (tOPV-bOPV switch and IPV introduction);
- High-level advocacy for IPV at the regional governing bodies;
- Inclusion of IPV in the UNICEF-middle income strategy for self-procuring countries.

Annex 1

Agenda for Polio Endgame Strategy

(1) Opening session

(2) Regional progress on polio eradication, containment and certification

(3) Polio Endgame Strategy

(4) Introduction of Inactivated Polio Vaccine (IPV)

- (a) Economic evaluation for IPV introduction
- (b) Vaccine safety, quality and supply requirement for IPV introduction
- (c) Communication strategy and social mobilization for IPV introduction
- (d) Country experiences for introduction of IPV in routine immunization schedule

(5) Presentation of summary and draft recommendations

(6) Closing session

Annex 2

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A consultation on the polio endgame strategy in the South-East Asia Region was held in Bangkok, Thailand, on 14 December 2012. The primary objective of the consultation was to develop a road map for the Region on the basis of Global Polio Endgame Strategy.

The Polio Endgame Strategy refers to the risk mitigation activities related to the withdrawal of the oral polio vaccines and to the strategy involves global switch from trivalent oral polio vaccine to bivalent oral polio vaccine. Each country has presented its perspective on how the global and regional Polio Endgame Strategy is to be operationalized.

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