

# Fourth Meeting of the South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG)

*A Report*  
*New Delhi, India, 2–3 April 2013*



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## Acronyms

AES	acute encephalitis syndrome
AFP	acute flaccid paralysis
AEFI	adverse events following immunization
AI	Appreciative Inquiry
ASHA	Accredited Social Health Activist
AVD	alternative vaccine delivery
bOPV	bivalent oral polio vaccine
CMYP	comprehensive multi-year plans
CRS	congenital rubella syndrome
cVDPV	circulating vaccine-derived polio virus
DoV	Decade of Vaccines
EPI	expanded programme on immunization
EVM	effective vaccine management
EVSM	effective vaccine store management
GAVI	Global Alliance for Vaccines and Immunization
GIVS	Global Immunization Vision and Strategy
GMP	good manufacturing practices
GVAP	Global Vaccine Action Plan
HIV	human immunodeficiency virus
HPV	human papillomavirus
IMB	Independent Monitoring Board for Polio Eradication
IMCI	integrated management of childhood illness
IPV	inactivated polio virus
IRI	intensification of routine immunization
ITAG	Immunization Technical Advisory Group
ITSU	Immunization Technical Support Unit
LJEV	live japanese encephalitis vaccine

MCV	measles-containing vaccine
MCV1	first-dose measles vaccine
MNT	Maternal and Neonatal Tetanus
mOPV	monovalent oral polio vaccine
MR	measles and rubella vaccine
MRI	Measles Rubella Initiative
NCC	National Certification Committee
NCL	National Chemical Laboratory
NIDs	national immunization days
NRA	national regulatory assessments
NTAGI	National Technical Advisory Group on Immunization
NUVI	new and underutilized vaccine introduction
OPV	oral polio vaccine
PATH	Program for Appropriate Technology in Health
PMS	post-marketing surveillance
RI	routine immunization
RC	Regional Committee
RCCPE	Regional Commission for Certification for Polio Eradication
SIA	supplementary immunization activity
SEAR	South-East Asia Region
TCG	Technical Consultative Group
tOPV	trivalent oral polio vaccine
UNICEF	United Nations Children’s Fund
VDPV	vaccine-derived polio virus
VDC	Village Development Committee
VMA	vaccine management assessment
VPD	vaccine-preventable diseases
WHO	World Health Organization
WPV	wild poliovirus

# 1. Introduction

The fourth meeting of the World Health Organization's South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG) was held from 2–3 April 2013 in New Delhi, India.

The SEAR-ITAG is composed of technical experts who provide Member States with technical and policy guidance on immunization, vaccines and related technology to reduce vaccine-preventable diseases in the Region. The terms of reference are:

- (1) To review regional and Member States policies, strategies and plans for control, elimination and eradication of vaccine-preventable diseases, especially for polio eradication, measles control and maternal and neonatal tetanus (MNT) elimination, including the setting of regional immunization priorities;
- (2) To guide Member States in strengthening routine immunization programmes;
- (3) To make recommendations on a framework for national immunization policies as well as operational aspects of the immunization strategies; guide Member States on the incorporation of new scientific knowledge and technology on vaccines, vaccine delivery and immunization practices;
- (4) To advise Member States on the appropriate choices of new vaccines, guide optimal strategies for their introduction, and provide technical guidance on monitoring the impact of new vaccines once introduced into national immunization programmes;
- (5) To promote and provide technical guidance for the implementation of high-quality vaccine-preventable disease surveillance, including laboratory networks for surveillance;

- (6) To advise Member States on regulatory requirements to ensure quality and safety of vaccines used in national immunization programmes;
- (7) To identify and advise on appropriate subject areas for operational research in the fields of immunization and vaccines and review the conduct and results of the research projects; and
- (8) To advocate and promote linkages and liaise with global policy-making bodies such as the Strategic Advisory Group of Experts (SAGE), and national committees for immunization practices at the country level.

In addition to SEAR-ITAG members, other participants included members of national committees for immunization practices of Member States, SAGE members representing the Region, WHO headquarters, Regional Office for South-East Asia and country office, Expanded Programme on Immunization (EPI) focal points.

Dr Sangay Thinley, Director, Department of Family Health and Research, opened the meeting on behalf of the Regional Director, Dr Samlee Plianbangchang. Professor Lalitha Mendis chaired the meeting with Dr Supamit Chunsuttiwat as rapporteur and Dr Patrick O'Connor as co-rapporteur.

## **2. Objectives**

The objectives of the fourth SEAR ITAG meeting were as follows:

- (1) To assess the progress made on intensification of routine immunization in the Region and assess a tool developed for monitoring progress of the intensification efforts;
- (2) To review the progress of polio eradication, and management of the remaining issues and challenges towards polio-free certification in February 2014 and the polio endgame;

- (3) To review and endorse the regional strategic plans for elimination of measles and control of rubella and congenital rubella syndrome;
- (4) To review SAGE recommendation for intussusception surveillance and to review evidence that supports a favourable risk–benefit for the relaxation of rotavirus vaccine age restrictions;
- (5) To review the current status and process of effective vaccine management (EVM) assessments of the SEA Region;
- (6) To review and discuss a newly developed decision-making algorithm for new and underutilized vaccine introduction into the Region;
- (7) To review adverse events following immunization (AEFI) monitoring, preparedness and response plans in the Region;

### **3. Background**

During the third meeting of the SEAR-ITAG in 2012, there was an extensive discussion on efforts for intensification of routine immunization coverage, measles elimination, introduction of rubella vaccine and strategies for prevention and control of Japanese encephalitis. In addition, achievement of regional polio eradication, acute flaccid paralysis (AFP) surveillance and integrated vaccine-preventable diseases (VPD) surveillance were discussed. The progress in achieving MNT elimination, status of implementation of vaccine post-marketing surveillance, seasonal influenza vaccine introduction in the South-East Asia Region, and the need for pooled procurement of vaccines in the Region were reviewed.

## 4. Implementation of recommendations from the third meeting

The implementation status of the recommendations from the third meeting of the SEAR ITAG, 2012 are listed below:

Recommendations	Status
<b>Global progress on immunization: Decade of Vaccines and Global Vaccine Action Plan</b>	
<p>Validate administrative coverage by using biomarkers, more accurate denominators and linking immunization registries with birth registries.</p>	<ol style="list-style-type: none"> <li>1. Myanmar – measles and polio sero-survey, coverage evaluation surveys and a post-introductory evaluation of pentavalent vaccine introduction are planned;</li> <li>2. Bangladesh – Hepatitis B impact sero-survey completed; implementing EPI and surveillance review recommendations; examining denominator issue in Dhaka;</li> <li>3. Nepal – attempting to validate routine immunization (RI) coverage through “Appreciative Inquiry”;</li> <li>4. Indonesia – to validate RI coverage during EPI and surveillance review in June 2013.</li> </ol>
<b>Intensification of routine immunization (IRI) in 2012: progress of implementation</b>	
<ol style="list-style-type: none"> <li>1. Existing immunization initiatives should be streamlined to financially support IRI.</li> <li>2. Establish realistic IRI targets.</li> <li>3. Provide plans to highlight main barriers and strategies.</li> <li>4. Conduct regular performance measurements; guidelines for EPI and surveillance reviews.</li> </ol>	<ol style="list-style-type: none"> <li>1. Overall, implementation of IRI has been slow, but there have been positive effects on the national level immunization coverage (i.e. high priority countries India, Indonesia and Timor-Leste);</li> <li>2. In India, an Immunization Technical Support Unit (ITSU) was established to support programme operations, supply chain, demand generation, AEFI surveillance and VPD surveillance; India is reaching the unreached through immunization weeks, resulting in coverage of ~5 million children.</li> </ol>

Recommendations	Status
<b>Measles elimination in the Region</b>	
<ol style="list-style-type: none"> <li>1. Focus on integrating measles case-based surveillance/outbreak investigation/immunity gaps/sero-surveys into IRI.</li> <li>2. Review progress in 2013.</li> </ol>	<ol style="list-style-type: none"> <li>1. Regional consultation conducted in Kathmandu, 19–22 February 2013;</li> <li>2. Measles elimination and rubella/congenital rubella syndrome (CRS) control on RC66 agenda in September 2013;</li> <li>3. Nepal – measles and rubella vaccine (MR) campaign completed;</li> <li>4. India – third phase measles catch-up campaign almost completed (Bhopal and Indore cities are expected to complete by July 2013);</li> <li>5. Bangladesh – MR campaign planned in quarter 4 of 2013;</li> <li>6. Immunization and Vaccine Development (IVD) plans to conduct a surveillance standardization workshop, 23–27 September 2013.</li> </ol>
<b>Introducing rubella vaccine (RV) into national immunization programmes</b>	
<p>Provide technical assistance for translating global recommendations, documenting regional experience; facilitating introduction of RV into remaining five countries.</p>	<ol style="list-style-type: none"> <li>1. Regional strategic plan has been drafted for measles elimination and for accelerating rubella/CRS control;</li> <li>2. India is considering RV introduction – National Technical Advisory Group on Immunization (NTAGI) sub-group to review the current situation and potential future strategies for roll-out;</li> <li>3. Regional consensus on 2020 rubella/CRS control goal.</li> </ol>
<b>Progress of introduction of new vaccines</b>	
<p>Facilitate and share experience of new vaccines introduction and learn best practices.</p>	<ol style="list-style-type: none"> <li>1. New vaccine introduction meeting held in December 2012; experience shared and a draft algorithm was developed;</li> <li>2. Post-introductory evaluation conducted in Bangladesh, and Kerala and Tamil Nadu in India.</li> </ol>

Recommendations	Status
<b>Strategies for prevention and control of Japanese encephalitis</b>	
<p>Support acute encephalitis syndrome (AES) surveillance and conduct research on:</p> <ol style="list-style-type: none"> <li>1. Adequate number of doses to achieve high immunity for SA 14-14-2 live japanese encephalitis vaccine (LJEV).</li> <li>2. Optimal age for immunization.</li> <li>3. Need for vaccinating adults.</li> <li>4. Aetiology of AES.</li> </ol>	<ol style="list-style-type: none"> <li>1. Supporting AES surveillance; exploring expansion;</li> <li>2. A situational analysis will be carried out in six Program for Appropriate Technology in Health (PATH) supported countries;</li> <li>3. Bi-regional meeting will be held in April/May 2014 for sharing experience;</li> <li>4. Research activities to better understand immunization gaps and aetiology of AES – India and Nepal.</li> </ol>
<b>Progress of polio eradication: regional certification commission recommendations</b>	
<ol style="list-style-type: none"> <li>1. National polio commissions for polio eradication (NCCPE) submit updates yearly to Regional Commission for Certification for Polio Eradication (RCCPE) for certification in February 2014.</li> <li>2. Countries with high risk of importation and immunity gaps continuing supplementary immunization activities (SIAs) until the Region is polio-free.</li> <li>3. Convening a consultation to review endgame strategies.</li> </ol>	<ol style="list-style-type: none"> <li>1. Regional consultation on polio endgame strategy conducted in December 2012;</li> <li>2. Bangladesh, India and Nepal – national immunization days (NIDs) in 2012 and 2013;</li> <li>3. Regional polio certification commission meetings in August and December 2012 and March 2013;</li> <li>4. India phase-1 laboratory containment started.</li> </ol>
<b>AFP surveillance and integrated VPD surveillance</b>	
<ol style="list-style-type: none"> <li>1. Document current practices; move towards integrating VPD surveillance with surveillance of other communicable diseases.</li> <li>2. Translate AFP surveillance to include other VPD surveillance and retain skilled personnel and well-functioning infrastructure.</li> </ol>	<ol style="list-style-type: none"> <li>1. Work in progress;</li> <li>2. EPI and surveillance reviews conducted;</li> <li>3. Integration is on the agenda.</li> </ol>

Recommendations	Status
<b>Immunization research priorities: implementation research</b>	
Develop a process for identifying immunization research priorities.	Research in the IVD area: <ol style="list-style-type: none"> <li>1. Hepatitis B impact evaluation studies in Bangladesh and Nepal completed;</li> <li>2. Burden and economic impact of varicella infections in Sri Lanka (ongoing);</li> <li>3. Human papillomavirus (HPV) demonstration project in Bangladesh (planned).</li> </ol>
<b>Progress in achieving MNT elimination</b>	
Develop timelines for completing validation and plan for sustaining elimination standards.	<ol style="list-style-type: none"> <li>1. Timor-Leste validated MNT elimination in 2012;</li> <li>2. Four states in India (Delhi, Mizoram Orissa, and Uttarakhand) are in the process of MNT elimination validation in April 2013;</li> <li>3. Validation to be completed in Indonesia in 2013. All other provinces except two (Maluku and Papua) have already validated MNT elimination.</li> </ol>
<b>Capacity building of national regulatory authority (NRA) and status of implementation of vaccine post-marketing surveillance (PMS)</b>	
<ol style="list-style-type: none"> <li>1. Continue improving capacity of NRAs.</li> <li>2. Establish functional AEFI committees with expertise in causality assessments; develop a pool of experts in the Region for assisting countries in managing AEFI issues.</li> <li>3. Rename AEFI committees as national vaccine safety committees.</li> <li>4. Invite select AEFI committees to present vaccine safety workplans.</li> </ol>	<ol style="list-style-type: none"> <li>1. NRA assessments conducted in Indonesia (June); Thailand (July); India (Dec). All three functional;</li> <li>2. Implementing NRA institutional development plan in progress:                         <ol style="list-style-type: none"> <li>a. Bangladesh: National Control Laboratory (NCL) upgrade</li> <li>b. India: NRA good manufacturing practices (GMP) training, AEFI Secretariat</li> <li>c. Indonesia: PMS pilot project</li> </ol> </li> <li>3. AEFI training: Myanmar in April 2013, Nepal in October 2013;</li> <li>4. Regional consultation on AEFI April–May 2013.</li> </ol>

Recommendations	Status
<b>Seasonal influenza vaccine introduction in the South-East Asia Region: needs and feasibility</b>	
<ol style="list-style-type: none"> <li>1. Continue updating pandemic vaccine deployment plans.</li> <li>2. Conduct burden studies.</li> <li>3. Enhance surveillance.</li> <li>4. Assess the feasibility of vaccine introduction in high-risk groups.</li> </ol>	<ol style="list-style-type: none"> <li>1. Work in progress;</li> <li>2. Regional consultation held in 2012.</li> </ol>
<b>Explore the need for pooled procurement of vaccines in the Region</b>	
Initiate a consultative process to outline the steps/requirements for pooled procurement of vaccines.	<ol style="list-style-type: none"> <li>1. The WHO South-East Asia Regional Office internal consultation convened by Regional Director in late 2012;</li> <li>2. A similar mechanism is being offered by UNICEF with GAVI Alliance support and Sri Lanka has shown interest.</li> </ol>

## 5. Global progress on immunization: Decade of Vaccines and Global Vaccine Action Plan

In May 2011, at the Sixty-fourth World Health Assembly, the vision for the Decade of Vaccines 2011–2020 (DoV) and development of a Global Vaccine Action Plan (GVAP) were discussed. At its 130th Session in January 2012, the Executive Board considered the GVAP and provided guidance. The final GVAP was endorsed at the Sixty-fifth World Health Assembly in May 2012. The Health Assembly urged Member States to apply the GVAP principles to their own national plans, commit resources and report annually to regional and global governing bodies.

### *Goals for the Decade of Vaccines*

- (1) Achieve a world free from poliomyelitis;
- (2) Meet vaccination coverage targets in every region, country and community;

- (3) Exceed the Millennium Development Goal 4 target for reducing child mortality;
- (4) Meet global and regional elimination targets;
- (5) Develop and introduce new and improved vaccines and technologies.

### ***Guiding principles of the Global Vaccine Action Plan***

- (1) **Country ownership:** Countries have primary ownership and responsibility for establishing good governance and for providing effective and quality immunization services for all.
- (2) **Shared responsibility and partnership:** Immunization is an individual, a community and a governmental responsibility that transcends borders and sectors.
- (3) **Equitable access:** Providing equitable access to immunization is a core component of the right to health.
- (4) **Integration:** Strong immunization systems that are a part of the broader health systems and closely coordinated with other primary health care delivery programmes are required.
- (5) **Sustainability:** Informed decisions and implementation strategies, appropriate levels of financial investments, and improved financial management and oversight are required.
- (6) **Innovation:** The full potential of immunization is realized only through learning, continuous improvement, and innovation across all aspects of immunization.

### ***Discussion and recommendations:***

- New guidelines are under development for updating comprehensive multi-year plans (cMYPs) so that they are in alignment with GVAP strategies. Updated cMYPs will be field tested by regional offices.
- IVD has plans to review the regional strategy for immunization and vaccine development in order to align it with GVAP.
- Immunization systems need further strengthening and national authorities should take ownership and be accountable.

- Issues related to vaccine shortages need to be addressed.
- The Global Vaccine Research Forum is revamped to include more operational research.

### ***A tool for monitoring IRI***

A draft tool for monitoring IRI progress and performance was presented to the ITAG. The purpose of the tool is to enable both the programme manager at the country level and the regional focal point to track the progress of IRI activities in carrying out the routine immunization intensification efforts by countries. The tool assumes that the country has a written and approved plan of action for the intensification efforts. The tool was also proposed to be used at least on a quarterly basis.

In the discussions, it was clear that the Members of the ITAG had different expectations of such a tool. While the tool was developed with the objective to track progress of IRI, the ITAG members felt that it should be capable of being used to capture a snapshot of the situation when a visit is made to the peripheral level, for example, a district. However, the ITAG noted that the tool as it is, still might have some use.

### ***Discussions and recommendations:***

- The ITAG recommended development of a tool that can be used to assess immunization performance at the lowest level.
- The IRI monitoring tool should check policy and governance level changes.

## **6. Implementation of “2012-Year of Intensification of Routine Immunization”**

The goal of the “2012-Year of Intensification of Routine Immunization” was for all Member States in South-East Asia Region to achieve at least 90% national immunization coverage and at least 80% district level coverage (subnational level) for the six basic antigens as measured by the coverage of third dose of DTP/pentavalent vaccine by 2013. Overall, implementation of IRI has been slow, but there have been positive effects on the national level

immunization coverage (in high priority countries including India, Indonesia and Timor-Leste).

In India, an Immunization Technical Support Unit (ITSU) was established to support programme operations, supply chain, demand generation, AEFI surveillance and VPD surveillance. Through immunization weeks resulting in coverage of ~5 million children, India had been able to reach the previously unreached. India also has worked to modernize alternative vaccine delivery (AVD) mechanisms and enhance human resources to improve access to immunization services. India's key strategies included: (1) demanding generation for routine immunization services; (2) regular programme reviews and monitoring; (3) a web-enabled mother and child tracking system; (4) strengthening of AEFI and VPD surveillance; (5) utilizing lessons learnt from the polio eradication initiative for RI to strengthen micro-planning, monitoring and accountability mechanisms at all levels; and (6) adding additional incentives for Accredited Social Health Activist (ASHA) workers for ensuring full immunization of children.

The slow progress for IRI can be attributed to many reasons. IRI was launched at a very high level that caused delay due to the non-availability of funds until the financial year began. The same team was assigned to IRI activities amidst other immunization priorities. The approach was broad-based, lost focus on subnational areas and included a large number of subnational areas without first considering resource requirements. Activities were also weakly monitored.

Countries could improve IRI efforts by focusing more on areas where coverage is comparatively low, reaching children unreached by routine services. Staff should be oriented to focus on poor performing areas. Resource requirements need to be assessed and allocated. Internal reviews should take place with monitoring of conducting immunization sessions and vaccine distribution. Immunization coverage should be evaluated at regular intervals.

***Discussion and recommendations:***

- The ITAG endorsed the recommendation from the EPI-Managers' meeting in October 2012 that the IRI 2012

components should be included in multi-year immunization plans that capture GVAP strategies.

- There is a need for community-level evaluation of immunization coverage and for validating the existing immunization coverage survey methodologies.
- There should be a mechanism to externally evaluate immunization coverage.
- There should be a plan to improve data quality and to strengthen VPD and AEFI surveillance.

## **7. Progress of polio eradication: Recommendations of the Regional Certification Commission**

### **Status of global polio eradication**

Notable gains in interrupting wild poliovirus (WPV) transmission have occurred since the Sixty-fifth World Health Assembly declared that polio eradication was an emergency for global public health on 25 May 2012. The Health Assembly also requested the Director-General to rapidly finalize a comprehensive polio endgame plan. The number of countries with WPV transmission decreased from 16 in 2011 to 5 in 2012 and by 31 December 2012, there were 223 total cases of WPV compared to 642 cases in 2011, representing a 65% decrease.

### **Status of regional polio eradication**

India was removed from the list of polio-endemic countries on 25 February 2012. India (last case 13 January 2011) and Nepal (last case 30 August 2010) have been polio-free for over two years. The remaining nine countries in the Region have been polio-free for more than five years. All countries in the Region remain susceptible to importation while there is wild poliovirus circulating anywhere in the world. With the current progress in India, the Region is on-track to be certified polio-free in February 2014.

## **Polio-Free Certification, 2013–2014**

WHO regions are certified polio-free by the Regional Certification Commission and certification is based on convincing evidence presented by National Certification Committees (NCC). The Region can be certified polio-free three years after the last reported indigenous WPV is found in any country in the Region in the presence of high quality AFP surveillance. Completion, documentation and verification of phase-1 laboratory containment is a certification requirement.

The South-East Asian Regional Certification Commission on Polio Eradication (SEA-RCCPE) during its most recent meeting held from 5–7 March 2013 in Malé, Maldives, made two recommendations for maintaining the Region's polio-free status:

- (1) All NCCs should review with their respective national health authorities the current WHO recommendations for polio vaccination requirement for travellers. Regardless of age, all travellers to countries or areas with current or recent poliovirus transmission, or who plan to attend mass gatherings with the risk of exposure to infected persons should be fully vaccinated (per International Health Regulations)\* against polio before departure;
- (2) All NCCs should advocate with their respective governments to support the Independent Monitoring Board for Polio Eradication (IMB) recommendation to use the International Health Regulations to introduce pre-travel vaccination or vaccination checks for all travellers from the last three endemic countries (Afghanistan, Pakistan and Nigeria) until national transmission is stopped. No country should allow a citizen from any polio-endemic country to cross their borders without a valid vaccination certificate. The World Health Assembly should request the Director-General to move forward with the implementation of this recommendation prior to the Sixty-sixth World Health Assembly in May 2013.

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\* International Travel and Health, 2012 Edition, World Health Organization <http://www.who.int/ith/en/>

## Polio endgame strategy

The post-eradication timeline requires vaccine-derived polio virus (VDPV) elimination and validation. From 2000 to 2011, an overwhelming majority of VDPV cases have been type-2 (type-1, 79 cases; type-2, 478 cases; type-3, 9 cases). This has driven discussions of making the switch from trivalent oral polio vaccine (tOPV) to bivalent OPV vaccine (removing the type-2 component) and eventually making the switch to inactivated polio vaccine (IPV) alone or in combination with OPV. At the South-East Asian Regional polio endgame meeting in Bangkok, Thailand on 14 December 2012, the six global prerequisites for cessation of the type-2 component of the oral polio vaccine were discussed. The regional status of the prerequisites were reviewed:

Prerequisites	Status
(1) Validation of circulating vaccine derived polio virus (cVDPV) type-2 outbreaks for at least six months	Achieved; there have not been any cVDPV type-2 in the Region since 2009
(2) Stockpile of mOPV2 and response capacity	Achieved; mOPV2 stockpiles will be maintained at the global level; and there is sufficient capacity in the Region for outbreak response
(3) Surveillance and international notification of Sabin, Sabin-like and cVDPV2	Achieved; the AFP and environmental surveillance systems in the Region are well functioning and capable of detection of the polio viruses
(4) Licensed bivalent oral polio vaccine (bOPV) must be available	Not achieved; bOPV is not licensed in all countries
(5) Affordable IPV options must be available for all OPV-using countries	Not achieved; affordable IPV is not available
(6) Completion of phase II laboratory containment for cVDPV/WPV2 and phase I for type-2 Sabin virus	Not achieved; phase-1 laboratory containment is not completed

All countries in the Region agreed to the technical feasibility of the tOPV to bOPV switch and use of IPV. However, countries and experts expressed their concerns about the polio endgame including the cost per dose and how doses will be financed (national versus external), the supply, how dose will be scheduled, the mode of administration, licensure, communication strategy and the degree of high-level advocacy. Additional consultation at the country level might be required to operationalize the evolving polio endgame strategy.

***Discussions and recommendations:***

- The ITAG endorses the SEA-RCCPE's recommendations for pre-departure polio vaccination for travellers to endemic countries and mass gatherings (endemic country participants) and the implementation of an IHR requirement for polio vaccination for travellers from the three endemic countries as means to protect the South-East Asia Region's polio-free status.
- The ITAG endorses the SEA-RCCPE's programme of work including the implementation of the recommendation to the NCCPE on a regional polio-free certification goal by February 2014.
- The ITAG recommends that the WHO Regional Office for South-East Asia support country level consultations to implement the evolving polio endgame activities.
- In shifting to IPV, there is a need to look at individual country situations.
- Introduction of IPV may not give desired results without appropriate plans for sustainable coverage.
- The vaccine manufacturers need a lead time for manufacturing vaccines.

## **8. Measles elimination and rubella/congenital rubella syndrome control in the South-East Asia Region**

From 19–22 February 2013, the South-East Asia Region convened a consultation on the elimination of measles and control of rubella/congenital rubella syndrome (CRS) in Kathmandu, Nepal. The consultation discussed the global and regional measles and rubella situations, the technical and programmatic feasibility of measles elimination and rubella/CRS control, issues and challenges, and the target year for measles elimination and rubella/CRS control.

Globally, significant achievements have been made in measles mortality reduction. The estimated global measles mortality decreased 74% from 535 300 deaths in 2000 to 139 300 in 2010. Prior to the consultation, all WHO regions except for the South-East Asia Region had measles elimination goals with established target dates between 2002 and 2020. The Region of Americas already eliminated measles in 2002 and rubella in 2010.

From 2000 to 2011, first-dose measles vaccine (MCV1) coverage increased from 61% to 79% in the South-East Asia Region. Four of the eleven countries in the Region have surpassed the  $\geq 95\%$  World Health Assembly MCV1 coverage target and nine countries introduced a second dose of measles vaccine (MCV2). Annual measles incidence decreased by 29% to 36 cases per million compared to 51 per million and estimated measles mortality decreased by 48% from 137 000 to 71 000 during this period. India has accelerated its measles efforts with SIAs in 14 states followed by inclusion of MCV2 in routine immunization. In South-East Asia Region, Bhutan, Democratic People's Republic of Korea, Maldives and Sri Lanka may have already eliminated measles.

At the consultation, the biological, technical and programmatic feasibility of measles elimination were affirmed. Programmatically, all countries in the Region have strong national EPI programmes as the foundation for measles elimination. Four countries (Bhutan, Democratic People's Republic of Korea, Maldives and Sri Lanka) are close to measles elimination. National laboratories are capable of diagnosing and genotyping

measles at fully accredited laboratories. All countries in the Region (except India) already implemented case-based measles surveillance. A major portion of measles vaccines are produced in this Region. There is strong partner support from the GAVI Alliance, Measles and Rubella Initiative (MRI) and others. The strong polio infrastructure can serve as an asset for measles elimination in the Region.

At the conclusion of the consultation, all countries of the Region came to the consensus that the target year for the Region for achieving measles elimination and rubella CRS control should be set at 2020. This proposal will be submitted to the Sixty-sixth Regional Committee in September 2013 for consideration.

***Discussion and recommendations:***

- The ITAG endorsed The Kathmandu consultation recommendation for a regional measles elimination and rubella/CRS control goal of 2020.
- It was recognized that measles elimination activities provide an opportunity for rubella/CRS elimination with the recognition that there are country-level operational issues to be addressed.
- Measles surveillance should be streamlined and there is a need to ensure that India is taking up case-based surveillance as per the international guidelines.
- The five countries not using rubella-containing vaccine should develop plans for introduction and all countries should establish CRS surveillance.
- An update of the country-level measles elimination and rubella/CRS control plans should be provided at the next meeting of the SEAR ITAG.
- SIAs will help reach targeted age groups but there is a need to identify strategies for reaching other age groups as well.
- The existing regional experience on CRS surveillance (such as in Sri Lanka) needs to be documented to share with countries that do not have CRS surveillance.
- There is a need for an integrated VPD control and prevention plan including CRS.

## 9. SAGE recommendation for intussusception surveillance and relaxation of rotavirus vaccine age restrictions

In its April 2012 meeting, the WHO Strategic Advisory Group of Experts (SAGE) recommended removal of the age restriction for rotavirus vaccines. Based on the recommendations of that SAGE meeting, WHO published a revised rotavirus vaccines position paper in January 2013 stating that immunization programmes will be able to reach children who were previously excluded from the benefits of rotavirus vaccine by allowing infants to receive rotavirus vaccine together with DTP regardless of the time of vaccination.

The SAGE recommendation was largely based on a modelling exercise that explored the risk–benefit of removing the age restriction in the belief that more children can be vaccinated. The modelling output showed that if the rotavirus vaccine were administered without age restrictions in low- and middle-income countries, 203 000 rotavirus deaths would be prevented (range 10 000–281 500) while 547 intussusception deaths (range 237–1160) potentially would have occurred. Therefore, removing age restriction would prevent an additional 47 200 rotavirus deaths (18 700–63 700), but cause an additional 294 intussusception deaths (range 161–471), for an incremental benefit–risk ratio of 154 deaths averted for every death caused by the vaccine.

The ITAG reviewed the available information and after extensive discussions it was felt that careful communication around this issue is needed for those countries that intend to introduce rotavirus vaccines in future.

### ***Discussion and recommendations:***

- It was noted that removing age restrictions can increase the number of children vaccinated against rotavirus, but also has the potential risk of increasing intussusception deaths and therefore, recommended that countries carefully examine the implications of this recommendation.
- Each country should measure its baseline level of intussusception before vaccine introduction.

- Countries should establish sentinel surveillance sites to establish background rates of intussusception and also to enable monitoring intussusception trends after rotavirus vaccine introduction.
- If AEFI occurs, parents should be advised to bring back their children either to the health facility or to the health worker for further management.

## **10. Effective vaccine management assessments in the South-East Asia Region**

A high-quality vaccine supply chain is one of the most crucial elements for a successful immunization programme. New lifesaving vaccines are readily available and most of these new vaccines are much more expensive and bulkier than traditional vaccines. The supply chain will need to handle increased volumes.

The effective vaccine management (EVM) assessment tool was introduced in 2010 and combines the strengths of two previously introduced tools, the vaccine management assessment (VMA) tool and the effective vaccine store management (EVSM) tool. Ministries of health are encouraged to carry out an assessment every three years with technical support from a consultant. The key outcome of an assessment is a list of recommendations to address weaknesses and reinforce strengths. An improvement plan is prepared and implemented by the national EPI team with financial and technical support of partners. There are nine key criteria for a satisfactory vaccine supply chain and at each level of the supply chain, each of the nine criteria is assigned a score out of 100% (target 80%). Assessment is done at national, subnational, district or lowest distribution and service delivery points.

Most countries struggle with the implementation of improvement of vaccine management. EVM assessments show where the problems are, but solutions are often complex. EVM improvement plans represent a strategic opportunity to bring about positive changes to public health logistics. Successful implementation requires strong country leadership, including strong project management, effective communication between various government agencies and commitment to change at all levels of the government structure, from health logisticians to directors. The schedule of EVM assessments is given in the following Table.

**Table:** Schedule of EVM assessments in the South-East Region

Country	Last EVM	Next EVM 2014	Next EVM 2015	Lead agency (2011–2012)
Democratic People's Republic of Korea	2011	x		UNICEF
Indonesia	2011 and 2012	x		UNICEF
Myanmar	2011	x		UNICEF
Timor-Leste	2011	x		UNICEF
Bangladesh	2011	x		WHO
Bhutan	2012		x	UNICEF
India <sup>1</sup>	2011, 2012 and 2013			UNICEF
Nepal	2011	x		UNICEF
Sri Lanka	2012		x	UNICEF
<sup>1</sup> India nationwide EVM assessment conducted March–April 2013				

**Recommendations/comments:**

- UNICEF should be requested to work with countries and partners so that countries could conduct a self-assessment prior to the EVM exercise.
- Countries should ensure implementation of the EVM assessments recommendations.
- There should be a plan to carry out EVM assessments in non-GAVI-eligible countries, not just in GAVI-eligible countries.
- NTAGI should include EVM and related issues on their agendas.

## 11. Decision-making algorithm for new and underutilized vaccine introduction (NUVI)

At the new vaccine introduction meeting held in Bangkok in December 2012, the country participants reviewed existing criteria for introducing a

new vaccine in the South-East Asia Region, added new criteria to the existing set and drafted an algorithm for NUVI in the Region. Subsequently the draft was updated and presented to the SEAR-ITAG for review during the current session. The draft algorithm takes into consideration whether the disease is of public health concern, the quantum of mortality or morbidity, the attributable risk without the vaccine, and vaccine availability, evidence for its use, safety, efficacy, acceptability, affordability and programme capacity.

***Discussion and recommendations:***

- It was recognized that the NUVI algorithm was a work in progress.
- Adding strategies that may be complementary to immunization should not be considered only as alternatives to vaccination.
- Adding quantification of vaccine efficacy, safety and acceptability should be considered.
- Adding cost-effectiveness analyses at the family and national levels should be considered.
- Adding an assessment of return on investment (e.g. productivity gained) should be considered.

## **12. AEFI monitoring, preparedness and response plans**

National Regulatory Assessments (NRAs) provide insights into the level of enforcement of regulatory functions including vaccine safety PMS and AEFI. These are mostly conducted at the central level and provide limited information on the AEFI system at the subnational level. In the vaccine producing countries of the Region, AEFI monitoring systems are in place; there are national AEFI committees and guidelines for reporting AEFI and taking regulatory actions. However, AEFI detection capacity is a limitation. In countries procuring vaccines directly, strong AEFI committees have been established and good AEFI detection capacity exists. Countries procuring vaccine through UNICEF have AEFI committees that lack expertise to be able to establish national surveillance systems and have a limited AEFI detection capacity.

Training programmes are not enough to increase AEFI detection capacity or to strengthen capacity to manage and analyse AEFI data. Constraints and barriers to AEFI reporting need to be identified to include all vaccine safety shareholders at each level to update national AEFI guidelines and standard operating procedures. Gaps need to be identified and prioritization of activities should be evidence-based. Institutional capacity building should proceed with clear roadmaps, responsibility and deadlines for completion. To these ends, national AEFI guidelines are being updated in line with new vaccines introduction. Thirteen training workshops on AEFI were conducted in seven countries of the Region and support was provided to the national AEFI Secretariat to establish pilot projects. Technical support was provided to develop operational studies to identify factors affecting AEFI reporting. An intercountry workshop on causality assessment of AEFI will be held during 28 April–2 May 2013 in Bangkok, Thailand.

At the global level, new training materials and tools for causality assessment have been updated or developed. These include an update of training materials for a five-day course with new Council for International Organizations of Medical Sciences case definitions. The WHO basic course on AEFI monitoring went online in 2012 ([http://www.who.int/vaccine\\_safety/initiative/tech\\_support/ebasic/en/index.html](http://www.who.int/vaccine_safety/initiative/tech_support/ebasic/en/index.html)). In addition, the WHO updates and maintains information sheets on observed rates of vaccine reactions which are useful to compare AEFI rates collected at the country level with what has been observed globally ([http://www.who.int/vaccine\\_safety/initiative/tools/vaccinfosheets/en/index.html](http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/index.html)).

### ***Discussion and recommendations:***

- While appreciating the efforts of the WHO Regional Office for South-East Asia towards establishing a pool of regional experts, it was recommended that WHO should accelerate building capacity at the regional and national levels.

### **13. Strengthening of maternal health and immunization through mobilization of local community resources and increased ownership using Appreciative Inquiry approach**

One of the ways of intensifying and sustaining routine immunization is through creation of community demand, community participation, building ownership and mobilization of local resources. A new approach/tool known as Appreciative Inquiry (AI) was used in Nepal for mobilization of local resources, community participation and building ownership.

AI is about the co-evolutionary search for the best in people and their organizations. In its broadest focus, it involves systematic discovery of what gives "life" to a living system when it is most alive, most effective in that socioeconomic setting. AI involves, in a central way, the art and practice of asking questions that strengthen a system's capacity to apprehend, anticipate, and heighten positive potential. In AI, the arduous task of intervention gives way to the speed of imagination and innovation. Instead of negation, criticism, and spiralling diagnosis, there is a discovery, dream, and design.

In Nepal, the AI approach was piloted initially in two districts (Achham and Rukum) bringing together Village Development Committee (VDC) secretaries, health staff, journalists, local leaders, government officers, nongovernmental organizations and supporting partners together in a three-day workshop combining both immunization and maternal health. The outcome was impressive. Several participants made the commitment to ensure all children in their villages are fully immunized and no pregnant women should die because of pregnancy-related complications. Pregnant women should have service at their level and receive timely referral. However, AI alone is not enough. There should be a strong health leadership in the district to convert commitment into action and implementation should be followed up.

The outcome of the AI workshop after six months in the areas of immunization and maternal health was impressive. Several villages are waiting for declaration as fully immunized VDCs; vaccinators have been

recruited; emergency funds have been established and funds have been allocated for establishment of birth centres, all by using local resources and community participation.

***Discussion and recommendations:***

- The potential of community mobilization to improve maternal health and immunization through innovative approaches such as AI is recognized and its utility should be further explored.

## **Annex 1**

# **Agenda**

- (1) Opening session
- (2) Implementation status of 2012 SEAR ITAG meeting recommendations
- (3) Global progress on immunization: Decade of Vaccines [DoV] and Global Vaccine Action Plan
- (4) Implementation of “2012-Year of Intensification of Routine Immunization”
- (5) Progress of polio eradication: Certification of Polio eradication and polio endgame in SEAR
- (6) Measles elimination in SEAR
- (7) Measles elimination, rubella/congenital rubella syndrome control in SEAR
- (8) SAGE recommendation for intussusception surveillance and relaxation of rotavirus vaccine age restrictions
- (9) Effective vaccine management assessments in SEAR
- (10) Decision-making algorithm for NUVI
- (11) AEFI monitoring, preparedness and response plans
- (12) Strengthening of maternal health and immunization through mobilization of local community resources and increased ownership using Appreciative Inquiry approach
- (13) Conclusions and recommendations

## Annex 2

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The WHO-SEAR Technical Consultative Group (TCG) on Polio Eradication and Vaccine-Preventable Diseases was established in 1994. The TCG was an advisory body providing guidance to WHO on immunization matters. In 2008, the terms of reference for the TCG as well as its membership were revised and it became the South-East Asia Regional Immunization Technical Advisory Group (SEAR ITAG). The members of ITAG include experts from various technical areas related to immunization and vaccine development.

This publication is the report of the Fourth Meeting of the South-East Asia Regional Advisory Group on Immunization (SEAR ITAG) held from 2 to 3 April 2013 in New Delhi, India. It includes a review of the progress made in strengthening routine immunization, polio eradication, measles control, introduction of new vaccines, and injection safety. It also provides recommendations for the consideration of the Member States of the WHO South-East Asia Region on their efforts to achieve the Global Immunization Vision and Strategy (GIVS) goals endorsed by the World Health Assembly.



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