

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

Conclusions and recommendations
New Delhi, India, 15–19 June 2015

DRAFT

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Acronyms

AES	acute encephalitis syndrome
AEFI	adverse events following immunization
AFP	acute flaccid paralysis
bOPV	bivalent oral polio vaccine
CRS	congenital rubella syndrome
cVDPV	circulating vaccine-derived poliovirus
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
HPV	Human Papilloma Virus
IBVPD	Invasive Bacterial Vaccine Preventable Diseases
IPV	inactivated polio vaccine
IRI	intensification of routine immunization
ITAG	Immunization Technical Advisory Group
LJEV	live Japanese encephalitis vaccine
MCV	measles-containing vaccine
MCV1	first-dose of measles containing vaccine
MNT	Maternal and Neonatal Tetanus
mOPV	monovalent oral polio vaccine

MR	measles and rubella vaccine
MRI	Measles Rubella Initiative
NCC	National Certification Committee
NIDs	national immunization days
NIP	National Immunization Programme
NRA	national regulatory authority
NITAG	National Immunization Technical Advisory Group
NUVI	new and underutilized vaccine introduction
OPV	oral polio vaccine
PMS	post-marketing surveillance
RI	routine immunization
RC	Regional Committee
RCCPE	Regional Certification Commission for Polio Eradication
SAGE	Strategic Advisory Group of Experts
SEAR	South-East Asia Region
SIA	supplementary immunization activity
TCG	Technical Consultative Group
tOPV	trivalent oral polio vaccine
UNICEF	United Nations Children's Fund
VDPV	vaccine-derived poliovirus
V ₃ P	vaccine product, price and procurement project
VMA	vaccine management assessment
VPD	vaccine-preventable disease
WHO	World Health Organization
WPV	wild poliovirus

1. Introduction

The Sixth Meeting of the World Health Organization's South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG) was held from 15 to 19 June 2015 in New Delhi, India.

The SEAR-ITAG is a regional technical expert group, established by the Regional Director for providing advice on all aspects of immunization, vaccines and vaccine-preventable disease (VPD) prevention, control, elimination and eradication. It comprises experts from disciplines such as programme management, communicable diseases/vaccine preventable diseases control, virology, epidemiology, and immunization. It meets annually with the participation of national expanded programme on immunization (EPI) managers and national surveillance focal points and partners to review the progress on increasing and sustaining immunization coverage, surveillance performance, programme issues, and matters related to vaccine quality assurance, and provides guidance to countries on ways to improve and sustain overall high-quality performance.

The terms of reference for the ITAG are as mentioned below.

- Review the Regional and Member State policies, strategies and plans for the control, elimination and/or eradication of VPDs, especially for polio eradication, measles elimination, rubella/congenital rubella syndrome (CRS) control, and Maternal and Neonatal Tetanus (MNT) elimination.
- Provide guidance to the setting of regional immunization priorities for immunization and vaccines.
- Make recommendations on the framework for development of national immunization policies as well as operational aspects of their implementation, and also provide framework and approaches to periodic evaluation and strengthening of routine immunization (RI) services and systems.

- Advise Member States on the appropriate choices of new vaccines and recommend optimal strategies for their introduction, including technical guidance for monitoring and impact evaluation of new vaccines once introduced into national immunization programmes.
- Promote and provide technical guidance for the implementation of high-quality VPD surveillance, including laboratory networks for surveillance.
- Advise Member States on regulatory requirements to ensure quality and safety of vaccines used in a national immunization programme.
- Provide guidance on public private partnerships.
- Identify and advise on appropriate implementation research topics in immunization and vaccines, and review the conduct and the results of such research projects.

The meeting was chaired by Professor Gagandeep Kang with Dr Robert Linkins as rapporteur on days 1 and 2, and Dr Elizabeth Jane Soepardi as rapporteur on days 3, 4 and 5. Other ITAG members in attendance were Professor Sanath Lamabadusuriya, Dr Charung Muangchana, Dr Yasho Vardhan Pradhan, Professor Mohammad Shahidullah and Professor Saw Win. In addition to SEAR-ITAG members, other participants included members of National Committees for Immunization Practices (NCIPs) of Member States, Members of the Strategic Advisory Group of Experts (SAGE) representing the South-East Asia Region, national EPI programme managers and national surveillance focal points from all 11 countries, representatives from WHO headquarters, the Regional Office for South-East Asia and WHO country offices' immunization focal points, the Regional Office for the Western Pacific, United Nations Children's Fund (UNICEF) headquarters, the South Asia and the Eastern Asia and Pacific Regional offices, country offices and a number of other local and global partners and stakeholders.

The Director of Family, Gender and Life Course, Dr Arun Bhadra Thapa, opened the meeting.

2. Objectives

Immunization-related areas are very well funded, but almost disproportionately so by private foundations and global alliances, who increasingly wield influence on policy and strategy matters at global, regional and country levels. The substantial funding available has encouraged the proliferation of multiple stakeholders beyond the traditional stakeholders. There is an increasing and constant need for ensuring coordination and coherence in the development and implementation of immunization policies. Additionally, there are time-bound immunization and disease eradication/elimination/control targets that attract intense scrutiny by stakeholders. Thus it is essential for regular oversight and monitoring of the programme by a regional advisory body and for periodic course correction. In this Region, the SEAR-ITAG meeting is the mechanism that supports this role.

The primary objectives of this meeting were as mentioned below.

- (1) To review status of performance of national EPI programmes in relation to disease eradication/elimination/control targets (including Implementation of the recommendations of the Fifth SEAR-ITAG Meeting conducted in August 2014).
- (2) To address and seek guidance on ways to effectively address the following technical areas of importance to this Region.
 - I. Progress towards achieving regional and global immunization targets, including review of the Global Vaccine Action Plan (GVAP) areas.
 - II. The status and progress of regional efforts to meet the goal of eliminating measles and controlling rubella and CRS by 2020.
 - III. The risks to the polio-free status in the Region, the strategic actions being taken, which should be taken to mitigate the risks and the five readiness criteria for the withdrawal of the type 2 component of oral polio vaccine (OPV) and the potential actions required for each criteria (including for inactivated polio vaccine (IPV) introduction), in preparation of the withdrawal for the type 2 component of OPV.

- IV. Progress made towards MNT elimination, the MNT elimination status in countries, areas already validated current maintenance strategies and present action plans to reach the goal and the MNT elimination status in countries or in subnational areas where elimination has not yet been validated and in areas already validated.
- V. Experiences and lessons learned on issues related to new and underutilized vaccines, Japanese encephalitis (JE), rotavirus gastro-enteritis (RVGE) and invasive bacterial vaccine preventable diseases (IBVPD) and Human Papilloma Virus (HPV) infections.
- VI. Currently available country level influenza surveillance information and consensus on defined criteria for decision-making to introduce seasonal influenza vaccines for high-risk groups.
- VII. The status of adverse events following immunization (AEFI), vaccine product, price and procurement project (V3P), vaccine pharmacovigilance and national regulatory authority (NRA) capacity-building initiatives.
- VIII. Issues around data quality related to VPDs.

The main outcomes are related to these areas, with advice for countries and stakeholders on the most appropriate way forward.

3. Conclusions and recommendations of the Sixth SEAR-ITAG

Progress has been made in immunization activities in SEAR since the last ITAG Meeting, held in August 2014. The countries in the Region are well positioned to take the lessons learned and apply best practices to their respective national immunization programmes.

I. Measles elimination and Rubella control

The ITAG is encouraged by countries' commitment to the regional goal of Measles Elimination and Rubella/CRS Control by 2020. The ITAG clearly recognizes that with the integrated measles and rubella strategy, and the use of a combination vaccine (measles and rubella vaccine (MR) or MMR), rubella/CRS will also be eliminated. Nevertheless, the ITAG believes that the current efforts in the Region, specifically the timing of national, wide age-range MR campaigns and introduction of measles and rubella containing vaccine into the routine schedule, are inadequate to achieving the 2020 goals. To this end, the ITAG will monitor a number of interim milestones that must be met to ensure that the Region meets the measles elimination and rubella/CRS control goal by 2020:

(1) By the end of 2015:

- (a) All countries to have a nationally approved plan to eliminate measles and control rubella/CRS by 2020 and share with SEARO.
- (b) All countries to have detailed plans with timelines to achieve, maintain and verify at least 95% population immunity against both measles and rubella in all age cohorts.
- (c) Nationwide case-based surveillance for measles and rubella to be fully operational in all countries except for **India** and **Indonesia**, which will continue to expand case-based surveillance following wide age-range campaigns.
- (d) All countries to report case-based data at least monthly to the "WHO country office and WHO SEARO" in line with reporting requirements. All countries to submit an annual report to SEARO on (i) the susceptibility profile of populations to measles and rubella; (ii) plans to cover the immunity gaps shown; and (iii) subnational risk assessments of measles.
- (e) All countries to have adequate access to a proficient national and reference laboratory, and to ensure that laboratory data are linked with case-based epidemiological data.

- (f) A Regional Verification Commission will have been established and a National Verification Committee will be established in every country.
- (g) SEARO to develop and publish Regional surveillance guidelines and surveillance indicators for measles and rubella.

(2) By the end of 2016:

- (a) All countries in the Region to have implemented an RI schedule of two-dose measles-rubella containing vaccine preferably by the end of the second year of life, but no later than the third year of life.
- (b) Those countries conducting immunization campaigns against both measles and rubella to conduct an evaluation to assess whether 95% coverage at the second administrative level was achieved and outline plans to address remaining immunity gaps.

(3) In addition, the ITAG:

- (a) Commends **Nepal** for providing MR immunization to high-risk populations affected by the tragic April 2015 earthquake and requests **Nepal** to report on the status of surveillance and immunization services post April 2015 earthquake at the 2016 ITAG.
- (b) Encourages **Myanmar** to follow the implementation of their high-quality MR campaign (which was conducted in the first quarter of 2015), with a national coverage survey and to report back results at the 2016 ITAG meeting.
- (c) Would like to review at the 2016 meeting the progress on the national MR campaign and the continued expansion of the measles/rubella laboratory-supported case-based surveillance from **India** and **Indonesia**.
- (d) Requests **Sri Lanka** to report back, at the 2016 ITAG, findings from the EPI Review with special emphasis on measles and rubella activities.

- (e) Requests a report from the Regional Verification Committee at the next ITAG meeting in 2016.
- (4) Related to the MR laboratory network, the ITAG recommends by the end of 2015:**
 - (a) **Timor-Leste** to enhance its current laboratory to “proficient” status in order to support measles/rubella case-based surveillance.
 - (b) All countries to collect adequate specimens to characterize measles and rubella genotypes and share information with WHO in a timely fashion. These data should be linked to EPI case-based data to enable identification of chains of transmission.
 - (c) WHO proficient or nationally recognized laboratories be compliant with WHO standards to support CRS surveillance.
- (5) Related to the MR laboratory network, the ITAG recommends by the end of 2016:**
 - (a) To verify interruption of indigenous transmission and identify imported and import-related cases, measles virus genotypes to be characterized in at least 80% of chains of transmission.
- (6) For countries with established CRS sentinel surveillance, the ITAG recommends by the end of 2015:**
 - (a) To have a plan in place to conduct an evaluation of the CRS surveillance system (may include retrospective review of data from the reporting sites).
 - (b) To use CRS data in conjunction with case-based rubella data to monitor the progress of the rubella control programme.
 - (c) To report rubella laboratory and epidemiological data to the WHO country and Regional offices monthly.

(7) **Monitoring progress towards rubella and CRS control:**

- (a) In addition to the laboratory-supported case-based measles rubella surveillance systems, countries to consider adopting additional surveillance mechanisms to monitor programme progress, such as age-stratified serosurveys for rubella.

II. Polio eradication

The ITAG congratulates immunization, surveillance and polio laboratory teams of Member Countries of the South-East Asia Region and their national governments for maintaining polio-free status for more than four years since the last case, due to wild poliovirus (WPV), was detected in January 2011. The ITAG takes note of and endorses the actions being taken by national governments to maintain high population immunity against polio, achieve certification standard surveillance and preparedness for outbreak response in all countries. The ITAG also recognizes the support and guidance provided by the donors and partners, and the important contributions of the National Certification Committees for Polio Eradication (NCCPE) and the South-East Asia Regional Certification Commission for Polio Eradication (SEA-RCCPE).

Despite this enormous achievement, the ITAG notes the risk of WPV spread following an importation as well as the risk of emergence of circulating vaccine derived polioviruses (cVDPV) in the Region. The ITAG is concerned with the persistently low oral polio vaccine (OPV3) coverage through RI in **India, Indonesia, Myanmar and Timor-Leste**. This has resulted in an immunity gap in children less than five years in **Indonesia, Myanmar and Timor-Leste**. The gaps in **India** have been addressed by conducting polio supplementary immunization activities (SIAs). The challenges remain in maintaining acute flaccid paralysis (AFP) surveillance indicators in **Sri Lanka and Timor-Leste**. The ITAG notes that an EPI and VPD surveillance review has been conducted in **Timor-Leste** and that a review is planned in **Sri Lanka** later this year.

The ITAG also notes the Region's progress towards achieving the objectives of 'Polio Eradication and Endgame Strategic Plan 2013-2018' including plans for IPV introduction and the preparedness for the globally synchronized withdrawal of type 2 component of OPV by switching from

trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV). The ITAG acknowledges the challenges involved with the withdrawal of type 2 component of OPV and appreciates the efforts being made in the Region to overcome these challenges, including the recent dry run exercise conducted in **India** from which numerous important lessons have been learned. The ITAG also notes the efforts being made to ensure availability of licensed bOPV for use in RI post-switch; a plan for effective management of tOPV stocks; plans for containment of all type 2 polioviruses as per Global Action Plan III (GAP III); verification of elimination of WPV type 2; and outbreak response plans to manage any type 2 poliovirus outbreaks. The ITAG notes the plans of the Region for expansion of environmental surveillance to supplement AFP surveillance in order to ensure early detection of imported WPVs and emerging vaccine-derived polioviruses (VDPVs), and as a tool to monitor Sabin virus isolation after cessation of use of type 2 component of OPV. Despite a recommendation made during the 2014 ITAG, environmental surveillance has not started in **Bangladesh** and expanded in **Indonesia**.

The ITAG supports the most recent recommendations of the SAGE, SEA-RCCPE and the Global Polio Laboratory Networks.

(8) ITAG recommends that:

- (a) All countries should continue their efforts to achieve/sustain certification-level AFP surveillance and polio immunization performance.
- (b) **India, Indonesia, Myanmar, and Timor-Leste** should urgently address the issue of persistent low polio immunization coverage through RI. These countries should also conduct one to two national/subnational polio SIAs with tOPV in 2015/early 2016 to close potential immunity gaps prior to the withdrawal of type 2 component of OPV.
- (c) Considering the significant movement of population between India, Nepal and Pakistan, subnational polio SIAs targeting high-risk populations and areas should be conducted in **Nepal** in the second half of 2015/early 2016. **India** should follow guidance from its national level expert advisory body for polio SIAs. Efforts should be made to

synchronize the polio SIAs in India, Nepal and Pakistan to the extent possible.

- (d) Consideration should be given to conducting seroprevalence studies in countries with low routine OPV3 coverage to assess seroprevalence against polioviruses as a part of risk assessment. While conducting polio seroprevalence studies, consideration should also be given to using the opportunity to assess immunity against other vaccine preventable diseases.
- (e) **Timor-Leste** should fully implement the recommendations of the EPI and VPD surveillance review that was conducted in March 2015. The findings of the upcoming EPI and VPD surveillance review in **Sri Lanka** should be shared with the ITAG when ready and **Sri Lanka** should fully implement the recommendations emerging from the review for strengthening AFP surveillance. Timor-Leste and Sri Lanka should share an implementation report one month prior to the ITAG meeting in 2016.
- (f) In view of the continued transmission of poliovirus in Pakistan and Afghanistan, and the consequent potential for poliovirus importation to the Region, all countries should conduct risk mitigation activities including cross-border vaccination activities and introduce and monitor polio vaccination for travelers to/from polio infected countries.
- (g) **Bhutan, India, Indonesia, Myanmar, Sri Lanka, Thailand and Timor-Leste** should ensure that at least one dose of IPV is introduced in their EPI schedule before the switch from tOPV to bOPV.
- (h) All countries should urgently begin planning for the withdrawal of type 2 component of OPV (tOPV to bOPV switch). The national switch plans, with timelines, should be finalized and submitted to WHO-SEARO no later than September 2015.
- (i) In preparation of the switch, all countries should begin urgent actions for an inventory and effective management of their tOPV stocks to ensure that there are no stock-outs

of tOPV before the switch and that residual tOPV stocks after the switch are small.

- (j) Mechanisms for tOPV recall at the time of the switch and the destruction and the monitoring/validation of this process after the switch should be in place in all countries as a part of the national switch plan.
- (k) Countries that self-procure OPV, namely **India, Indonesia, Nepal, Sri Lanka and Thailand** should immediately start the process of bOPV procurement to meet the needs of this vaccine after the switch.
- (l) **India** should expedite the process of licensure of label and package insert change for bOPV use in RI and complete this at the earliest.
- (m) All countries that have not yet done so, should expedite the licensure process of bOPV as soon as possible. In the absence of this process being completed before the switch date, countries should consider using bOPV based on WHO prequalification.
- (n) Countries should expedite activities towards achieving laboratory containment phases 1 and 2 required to be completed before the switch as per GAP III. As such, it is crucial that active national polio laboratory containment coordinating bodies are in place and required resources are in place.
- (o) Environmental surveillance should be expanded to additional sites in **India and Indonesia** and initiated in **Bangladesh and Myanmar** in 2015. **Nepal, Timor-Leste and Thailand** should consider initiating environmental surveillance in 2016.
- (p) The NCCPEs of all countries should remain active until global certification. Certification activities should continue as per recommendations by the SEA-RCCPE.

(9) The ITAG recommends that SEARO:

- (a) Supports countries with activities in preparation for the withdrawal of type 2 OPV including IPV introduction, development of switch plans, licensure of bOPV, containment of polioviruses as per GAP III, expansion of environmental surveillance and development of protocols for outbreak preparedness.
- (b) Continues to regularly monitor the surveillance and immunization performance of all countries, assist countries with subnational risk assessments and support country risk mitigation activities.
- (c) Continues to function as Secretariat to the SEA-RCCPE and support countries in meeting poliovirus laboratory containment requirements as per GAP III.
- (d) Conducts a workshop on “Expedited Approval of Licensure of Vaccines” before the end of 2015 to facilitate availability of a licensed bOPV before the switch.

(10) The ITAG recommends that Partners (WHO, UNICEF, Rotary, NGOs, professional bodies and other stakeholders):

- (a) Work with countries that have not yet introduced IPV to ensure that the vaccine is introduced before the tOPV to bOPV switch.
- (b) Support development of national plans for the tOPV to bOPV switch in all countries by September 2015.
- (c) Recognize that comprehensive resource and advocacy support is still required after certification, to prevent complacency and shifting priorities to other public health requirements and to meet polio endgame requirements towards global eradication and certification.

III. Maternal and neonatal tetanus elimination

The ITAG notes the global and regional progress towards MNT elimination. The ITAG congratulates **India** on its recent validation of neonatal tetanus elimination. As of April 2015, MNT elimination has not been validated in 22 countries globally including 4 provinces in **Indonesia**. If the control

measures planned in these areas in **Indonesia** are fully implemented, the ITAG is confident that the country will complete MNT elimination activities in 2015 and thus be eligible for validation in 2016.

The ITAG notes that vaccination is one of multiple strategies used to achieve MNT elimination, which also includes health facility-based deliveries, presence of skilled birth attendants, clean deliveries and safe cord care practices.

The ITAG reminds national programmes and partners that MNT elimination strategies are a means of reaching women that are usually unreached and thus offers opportunities for comprehensive health service delivery (EPI, maternal and child health, basic newborn care) to contribute to reducing maternal and neonatal mortality.

The ITAG fully realizes that sustaining MNT elimination requires vigilance and addressing risks and gaps related to access, coverage and quality of health care for all communities and welcomes the operational guidelines, developed by the global MNT Elimination Initiative.

(11) The ITAG recommends that:

- (a) **Indonesia** and relevant partners continue to place high priority on implementing necessary actions to eliminate MNT by the end of 2015 in the remaining areas.
- (b) all countries and areas that have achieved elimination should conduct annual district-level risk assessment to identify low-performing areas in terms of sustaining elimination and implement appropriate corrective actions, with WHO and UNICEF participation as appropriate.
- (c) where applicable, countries should review their plans to maintain elimination status. These should include optimizing immunization schedules to ensure full and early protection against tetanus through childhood or adolescent booster doses (e.g. through school based immunization programmes) for recommended five doses in both sexes and adding diphtheria protection through shift from Tetanus Toxoid to tetanus/diphtheria toxoid containing vaccines.

IV. Vaccine Quality and Management

NRA Strengthening

In line with 2014 WHA resolution 67/20, the ITAG recognizes that effective regulatory systems for vaccines and medicines are an essential component of health system strengthening and contribute to better public health outcomes. Furthermore, it recognizes that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access safe, effective and quality vaccine and related medical products. The ITAG reiterates that strengthening regulatory systems will promote access to affordable vaccines and related medical products with assured quality, safety and efficacy. The ITAG recognizes that India, Indonesia and Thailand are the only countries in the region which manufacture WHO prequalified vaccines and have NRAs which have been assessed by WHO as functional. .

(12) The ITAG recommends that all Member States:

- (a) Ensure that NRAs actively participate in:
 - (i) monitoring AEFI surveillance;
 - (ii) effective vaccine management (EVM) assessments to enforce Good Distribution and Good Storage Practices;
 - (iii) working with National Immunization Programmes (NIP), WHO, UNICEF and other key partners to develop capacity to implement EVM assessment recommendations.
- (b) The ITAG recommends that **Bangladesh and Myanmar, the countries that are locally manufacturing and using selected vaccines in their national programmes**, invest significantly in their NRAs in order to comply with international/WHO standards for functional NRAs, such that their vaccines are of assured quality.

(13) The ITAG recommends that SEAR:

- (a) Supports capacity-building of NRAs on accelerated licensing procedures/collaborative procedures to ensure timely introduction of vaccines (e.g. bOPV).
- (b) Continues to encourage and facilitate intercountry cooperation as an effective means of using existing capacity and building capacity at the same time.

Vaccine availability and quality

In line with the 2015 WHA resolution on the GVAP, the ITAG recognizes the importance of competition to reduce prices. The ITAG further recognizes that there is the need to expand the number of manufacturers in developing countries that produce WHO-prequalified vaccines and thus create a competitive market. The ITAG notes with concern the global shortage of BCG and combined measles-rubella vaccines.

(14) The ITAG recommends that countries:

- (a) Enhance interactions between NIP managers and vaccine producers at all appropriate levels – national, regional and global – to provide manufacturers with accurate and timely information on vaccine demands and to address current vaccine shortages especially for basic vaccines.
- (b) Explore mechanisms of cooperation that promote Regional access to an assured quantity and quality of vaccines at an affordable price, such as the ASEAN Initiative on Vaccine Security.
- (c) With limited NRA capacity, continue to use exclusively WHO prequalified vaccines for their immunization programmes.

(15) The ITAG recommends that SEAR:

- (a) Works with WHO/headquarters to facilitate dialogue with manufacturers and NRAs to explore solutions to increase local/regional production of vaccines through providing access and knowledge about specific technologies, e.g. for

pandemic influenza vaccine and delivery systems of hepatitis B birth dose.

AEFI

(16) The ITAG recommends that countries:

- (a) Prioritize strengthening quality AEFI investigation to ensure and maintain the highest level of public trust in the national immunization programme.
- (b) Share AEFI data with vaccine manufacturers through NRA and NIP to consolidate vaccine safety profile with newly introduced vaccines.

(17) The ITAG recommends that SEAR:

- (a) Finalizes the manual for field investigation of AEFI and facilitate implementation at country level.

V. New and underutilized vaccines, Japanese Encephalitis, Rotavirus gastro-enteritis, invasive bacterial vaccine-preventable diseases and human Papilloma virus infection

New and Underutilized Vaccines

The ITAG notes that SEAR countries have achieved reasonable progress in adding vaccines to their national immunization schedules in recent years. All countries have introduced Hepatitis B vaccine and **Democratic People's Republic of Korea, Indonesia, Maldives and Thailand** have achieved high coverage with timely birth dose of Hepatitis B vaccine. Ten out of 11 countries of SEAR (except **Thailand**) have introduced Hib vaccine as pentavalent vaccine since 2008. **India** has completed its Hib introduction in 20 States/Union Territories in the first quarter of 2015. Among other vaccines, **Bangladesh, Democratic People's Republic of Korea, Maldives and Nepal** have introduced a supplemental dose of IPV and all other countries are planning to introduce IPV by 2016 as per the polio endgame plan. **Bangladesh and Nepal** have introduced Pneumococcal Conjugate Vaccine. Bhutan has introduced HPV vaccine nationally.

Japanese Encephalitis

The ITAG takes note that the quality JE/ acute encephalitis syndrome (AES) surveillance data are inadequate to make evidence-based decisions for JE control and prevention in some countries. Hence, the ITAG makes the following recommendations which include a number of those previously made in 2014. Furthermore, the ITAG notes that guidance and tools to use country level data for designing policies and strategies for JE control & prevention including JE vaccine introduction are urgently required.

(18) The ITAG recommends:

- (a) Countries to integrate JE vaccination into national immunization schedules in at-risk areas in all SEAR countries (except Maldives) where JE is a public health priority. Even where the number of JE-confirmed cases is low, vaccination should be considered if there is a suitable environment for Japanese encephalitis virus transmission, i.e. presence of animal reservoirs, ecological conditions supportive of virus transmission, and proximity to other countries or regions with known JE Virus transmission.
- (b) The National Immunization Technical Advisory Groups (NITAGs) to consider the recommendation, in (a) above, from the WHO position paper on JE vaccines published in February 2015 while making decisions.
- (c) **Bangladesh, Indonesia and Myanmar** to conduct desk reviews of available national data to define the magnitude of the problem and develop comprehensive plans for JE control and prevention and report on progress to the ITAG in 2016.
- (d) **Bhutan and Timor-Leste** to define the high-risk areas for JE and strengthen laboratory-based JE surveillance.
- (e) **India** should collate more evidence on the need and justification for adult JE vaccination and share it with the ITAG, facilitating guidance for other JE endemic countries in the Region.

- (f) **Nepal, Sri Lanka and Thailand** NITAGs/NCIPs should further collect data to determine the need and rationale for booster doses of JE following primary immunization and share with the ITAG for further refining the recommendation in this area.

(19) The ITAG recommends that SEARO:

- (a) Continues to support Member States to improve the surveillance data quality by:
 - (i) Assisting with reviewing their JE/AES surveillance data quality and the use of the data for determining the disease burden.
 - (ii) Supporting Global Alliance for Vaccines and Immunization (GAVI)-eligible countries in the Region that are interested in introducing JE vaccines to prepare applications, develop and implement robust vaccine introduction plans.
 - (iii) Systematically reviewing the needs of Member States and finalizing a comprehensive action plan for effective JE control in the Region for presentation to the ITAG in 2017.

Rotavirus Gastroenteritis, Invasive Bacterial Vaccine-Preventable Diseases (IBVPD)

The ITAG congratulates Member States for establishing sentinel site surveillance for IBVPD and Rotavirus gastroenteritis with and without the support of WHO. The ITAG takes note of the plans to expand this surveillance platform to include other VPDs such as typhoid. The ITAG also underscores the fact that the sentinel site assessments for performance have revealed deficiencies in the quality of surveillance.

(20) The ITAG recommends that:

- (a) All countries that are conducting IBVPD and rotavirus surveillance take steps to improve the quality of surveillance. Countries that receive WHO support and have had sentinel surveillance site assessments should

improve quality of surveillance as per the indicators of the performance management framework.

- (b) All countries that are conducting IBVPD and rotavirus surveillance with WHO support report case-based data to the WHO country office in a timely manner.
- (c) The **Indian** surveillance network of IBVPD and rotavirus gastroenteritis surveillance which is not supported by WHO is also encouraged to provide data to WHO country office and WHO SEARO is requested to facilitate the participation of the **Indian** surveillance network in all activities of the Regional network.

HPV Infection

HPV vaccine has not been introduced widely in the SEAR. The ITAG recommends that country NITAGS review the importance of the HPV in their countries. **Bhutan** introduced HPV vaccine nationwide for 9–13 year-old adolescent girls and **Sri Lanka** will be introducing HPV in 2017. **Bangladesh** and **Nepal** are planning to conduct HPV vaccination demonstration programmes in preparation for nationwide introduction.

(21) The ITAG recommends that:

- (a) **Bangladesh** and **Nepal** utilize planned HPV vaccination demonstration programmes as pilots to launch comprehensive cancer control activities and coordinate or integrate, as appropriate, with adolescent and reproductive health programmes. The two countries are requested to share lessons learned in the ITAG by 2017.
- (b) Other countries in SEAR considering introduction of HPV vaccine, as appropriate, consider a coordinated strategy that includes education about risk reduction behaviours for HPV infection, establish and/or strengthen screening programmes and treatment for cervical cancer in order to achieve comprehensive cervical cancer control and plan, where possible, to deliver HPV vaccination in close collaboration with other adolescent health programmes.

- (c) For countries that have not planned either HPV demonstration programmes or national introduction programmes, develop plans to collate evidence on disease burden and cost-effectiveness studies and present the evidence to their national NITAGs to make an informed decision on vaccine introduction.

VI. Seasonal influenza

The ITAG recognizes that there has been progress made on seasonal influenza activities since the ITAG meeting in 2014. The ITAG notes that influenza surveillance and seasonal influenza vaccination is a key component of pandemic preparedness and response. The ITAG also notes that opportunities exist for the Regional Office and Member States to strengthen influenza surveillance, determine the burden of disease and enhance regulatory capacity-building in relation to influenza vaccines. The ITAG congratulates the Regional Office for identification of Member States for targeted support and capacity enhancement in influenza laboratory diagnosis, provision of technical assistance to improve laboratory assisted surveillance and taking the leading role in collating existing evidences and planning burden of disease studies and economic analyses of seasonal influenza vaccines. The ITAG also underscores the importance of efforts of Member States in SEAR in the identification and implementation of specific activities to improve influenza surveillance and also starting to plan for collating and reviewing existing evidence for identification of information gaps for establishing policies and strategies for influenza vaccination.

(22) The ITAG recommends that countries:

- (a) Regularly assess the performance of the laboratory-supported surveillance networks to determine risk groups, seasonality of the disease and the annually circulating influenza strains. Regular review of data by NITAGs/NCIPs will contribute to the improvement of surveillance quality and use of data for decision-making.

- (b) Through NITAGs consider seasonal influenza vaccination as well as pandemic preparedness in their national immunization strategies.
- (c) Report the progress of influenza surveillance and immunization activities to the 2016 ITAG.

(23) The ITAG recommends that SEARO:

- (a) Coordinates global pandemic preparedness with the other WHO Regions.
- (b) Supports seasonal influenza surveillance activities and assessment of impact of vaccination with other partners.

VII. Data quality

The ITAG notes that the lack of quality immunization data is an impediment to monitoring and improving immunization programme performance. The ITAG notes the use of the available subnational data and not just data from national surveys can result in better national coverage estimates. Hence, it makes the following recommendations which include several made in 2014:

(24) The ITAG recommends that countries:

- (a) Namely, **Indonesia, Myanmar and Timor-Leste** conduct in-depth data quality assessments to validate immunization coverage estimates and report on progress to the ITAG in 2016.
- (b) All countries that are currently doing so, should continue to share subnational data with SEARO. The ITAG encourages **India** and **Thailand** to develop mechanisms to receive and share subnational data with SEARO.
- (c) Engage the NITAGs/NCIPs in monitoring data quality and the implementation of the data quality improvement plans.
- (d) That apply for GAVI health system strengthening grants to utilize the opportunity to include support to strengthen their immunization information systems, including coverage monitoring, VPD surveillance, and AEFI monitoring, in their proposals.

(25) The ITAG recommends that SEARO supports countries to:

- (a) Disseminate all the new data quality assessment guidelines, tools, and mobilize resources to assess and improve data quality.
- (b) Meet the GAVI data quality requirements (in relevant GAVI-eligible countries).
- (c) Continue to review the quality of the immunization data provided to SEARO and provide feedback to Member States.

Way forward

The ITAG requests WHO SEARO to provide an annual report on the progress towards reaching the recommendations. The report will be provided to all ITAG members at least one month prior to the annual ITAG meeting that includes the following:

- (1) Country-specific reports that include:
 - (a) table of MR related timelines and activities, the susceptibility profile of populations to measles and rubella, including plans to cover the immunity gaps shown, subnational risk assessments of measles, performance indicators, SIA schedule and coverage data;
 - (b) updates on the implementation of the tOPV to bOPV switch, environmental surveillance activities in relevant countries and review of serosurveys.

The ITAG requests that the ITAG 2016 agenda includes sessions on: typhoid, cholera, hepatitis B, Hib and school based immunization.

4. Conclusions

The Sixth Meeting of the SEARO-ITAG launched the tenure of the newly appointed ITAG. In addition to the ITAG members, respective MoH EPI Managers, VPD surveillance focal points and WHO country Focal Points contributed to the meeting. The other participants in this meeting included

members of NCIP of Member States, SAGE members representing the Region, WHO headquarters, Regional Office for South-East Asia and representatives from WHO country offices, UNICEF regional and country offices and a number of other local and global partners and stakeholders. The inclusion of the larger partnership allowed for more transparency and identification of challenges and synergies across the partnership. The general consensus was that this inclusion of all stakeholders was both productive and efficient and so the Secretariat has concluded that this format would be followed next year as well.

Annex 1

Agenda

1. Opening session
2. Immunization and surveillance, including:
 - (a) Measles elimination and rubella and CRS control
 - (b) Polio endgame and IPV introduction
 - (c) Maternal and Neonatal Elimination
 - (d) Vaccine Quality and management
 - (e) New and Underutilized Vaccines, Japanese Encephalitis, Rotavirus Gastro-Enteritis, Invasive Bacterial Vaccine-Preventable Diseases and HPV Infection
 - (f) Seasonal Influenza
 - (g) Data Quality
3. Thematic Group Work Sessions:
 - (a) Role of national verification committees and how to establish
 - (b) How to set up CRS Surveillance
 - (c) Preparing national plans for the tOPV-bOPV switch
 - (d) Maintaining MNTE at the country level and shifting to the life-cycle approach for tetanus protection
 - (e) Seasonal influenza vaccines for the selected high-risk groups
4. Closing

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