

WHO South East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG)

Report of the Seventh Meeting SEAR-ITAG
New Delhi, India, 7–10 June 2016



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WHO South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG)

*Report of the Seventh Meeting of SEAR-ITAG
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Acronyms

AEFI	adverse events following immunization
AFP	acute flaccid paralysis
AI	appreciative inquiry
ATAP	access to affordable pricing
CTC	controlled temperature chain
CYD-TDV	chimeric dengue vaccine, tetravalent
FDA	Food and Drug Administration
GAP	Global Action Plan
GHSS	Global Health Sector Strategy
GPEI	Global Polio Eradication Initiative
GRISP	global routine immunization strategies and practices
GVAP	Global Vaccine Action Plan
HBR	home-based records
IEC	information, education and communication
IPV	inactivated polio virus
ITAG	Immunization Technical Advisory Group
JRF	joint reporting form
LB	live births
MNCH	maternal, newborn and child health
MNTE	maternal and neonatal tetanus elimination
MOV	missed opportunities for vaccination

MCV1	first dose measles containing vaccine
MCV2	second dose measles containing vaccine
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
NT	neonatal tetanus
NUVI	new and underutilized vaccines
PCV	pneumococcal conjugate vaccine
PQ	pre-qualified
RCCPE	Regional Commission for the Certification of Poliomyelitis Eradication
RI	routine immunization
RVAP	Regional Vaccine Action Plan
RVC	South-East Asia Regional Verification Commission for Measles Elimination and Rubella/CRS Control
SAGE	Strategic Advisory Group of Experts on Immunization
SDG	Sustainable Development Goals
SEAR	South-East Asia Region
SFI	sustainable immunization financing
SIA	supplementary immunization activity
SOP	standard operating procedures
VAP	Vaccine Action Plan
VDPV	vaccine derived polio virus
VPD	vaccine-preventable disease
WPV	wild polio virus

1. Introduction

The Seventh Meeting of the World Health Organization's South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG) was held from 7 to 10 June 2016 in New Delhi, India.

The SEAR-ITAG is a regional technical expert group, established by the Regional Director of the WHO South-East Asia Region, for providing advice on all aspects of prevention, control, elimination and eradication of vaccine-preventable diseases (VPDs). It comprises experts from disciplines such as programme management, communicable disease/vaccine-preventable disease 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 progress on increasing and sustaining immunization coverage, surveillance performance, programme issues, and matters related to vaccine quality and safety. It provides guidance to Member States on ways to improve and sustain overall high-quality performance in implementing immunization programmes.

The terms of reference of ITAG are as follows:

- Review Regional and Member State policies, strategies and plans for the control, elimination and/or eradication of vaccine-preventable diseases, especially for polio eradication, measles elimination, rubella/congenital rubella syndrome (CRS) control, and maternal and neonatal tetanus elimination (MNTE).
- Provide guidance on setting regional 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 provide a framework and approaches to periodic evaluation and strengthening of routine immunization services and systems.

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

The Meeting was chaired by Professor Gagandeep Kang. Other ITAG members present were Dr Robert Linkins, Professor Sanath Lamabadusuriya, Dr Charung Muangchana, Dr Yasho Vardhan Pradhan, Professor Mohammed Shahidullah and Professor Saw Win.

Other participants included:

- representatives from National Immunization Technical Advisory Groups (NITAGs) of Member States;
- members of the Strategic Advisory Group of Experts (SAGE) representing the Region;
- national EPI managers and surveillance focal points from 11 countries;
- immunization focal points from the South-East Asia Regional Office (SEARO) and WHO country offices;
- representatives from WHO headquarters;
- representatives from the United Nations Children's Fund (UNICEF); and
- local and global partners and stakeholders.

2. Objectives

Immunization activities involve multiple stakeholders at global, regional and country levels. There is an increasing and constant need for ensuring coordination, communication and coherence between all agencies involved in the funding, implementing, regulating and developing of immunization programmes and policies. Additionally, there are time-bound immunization and disease eradication/elimination/control targets, which attract intense scrutiny of stakeholders. Thus it is essential to have regular oversight and monitoring by a regional advisory body, and to have periodic course correction. In this Region, the annual SEAR-ITAG Meeting is the mechanism that supports this role.

The primary objectives of this meeting were as follows:

- (1) To review the performance status of national expanded programmes on immunization (EPI) in relation to disease eradication/elimination/control targets; and review the implementation of recommendations of the Sixth SEAR-ITAG Meeting of 2015.
- (2) To seek the guidance of SEAR-ITAG in effectively addressing the following priority areas:
 - implementation of the Global Vaccine Action Plan (GVAP);
 - mid-term review of the regional flagship programme of measles elimination and rubella/CRS control by 2020;
 - implementation of the Polio Eradication and Endgame Strategic Plan 2013–2018 (outbreak response preparedness, validation of the switch from trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV), inactivated polio vaccine (IPV) introduction, containment of polioviruses as per Global Action Plan III and legacy planning in SEA Region);
 - validation of MNTE during 2016;
 - vaccine quality and management;
 - introduction of new and underutilized vaccines and health system strengthening for immunization outcomes.

3. Conclusions and recommendations

3.1 National Immunization Technical Advisory Groups (NITAGs)

While emphasizing that NITAGs are independent committees whose mandate is to advise their governments towards making evidence-based immunization policy decisions, ITAG commends Member States of the SEA Region for integrating NITAGs into the immunization-related policy-making systems in their respective countries. ITAG also congratulates Member States on establishing NITAGs in all 11 Member States.

ITAG is of the opinion that the establishment of the SEAR-NITAG voluntary network in April 2016 is a significant step towards enhancing the capacity of NITAGs in the Region. ITAG in particular notes the remarkable contribution of NITAGs in reviewing implementation of the GVAP in their respective countries through the national immunization programmes.

ITAG recommended that:

- (1) The capacity of NITAGs to provide guidance on evidence-based approaches to strengthen immunization systems and services should be further enhanced by sharing country experiences, best practices and resources, as well as by peer-to-peer technical assistance through the 'SEAR-NITAG Network'. The technical agencies and development partners should ensure sufficient support for a functional secretariat for the Network.
- (2) NITAGs now provide an annual report on their functioning to SEARO through their respective governments and WHO country offices. The annual reports, made in accordance with the standardized reporting format, should be reviewed at the annual SEAR-ITAG meetings. Further, individual NITAGs may consider using the WHO Collaborating Centre tool for periodic evaluation of functionality.
- (3) NITAGs should consider inviting representatives from their respective countries, who serve on the strategic advisory group of experts on immunization (SAGE), SEAR-ITAG or other regional TAGs [e.g. Regional Commission for the Certification of Poliomyelitis Eradication (RCCPE) and South-East Asia Regional

Verification Commission for Measles Elimination and Rubella/CRS Control (RVC)] to participate in their meetings.

- (4) The role of NITAGs should not be limited to the consideration of recommendations for the introduction of new vaccines, but should extend to devising strategies for optimizing the use of existing vaccines and strengthening national immunization programmes.

3.2 South-East Asia Regional Vaccine Action Plan (SEAR-VAP)

ITAG congratulated WHO-SEARO on drafting the South-East Asia regional vaccine action plan (SEAR-VAP) (2016–2020) in alignment with the goals of the GVAP (2011–2020) to reflect the joint commitment of Member States and other stakeholders towards achieving long-term collective goals in immunization in the SEA Region. ITAG recognizes the importance of defining goals, targets and priority areas for action in the SEAR-VAP, in the context of specific needs and challenges of Member States. ITAG opines that NITAGs should annually monitor and evaluate the achievement of set targets in accordance with the indicators defined by the SEAR-VAP framework.

ITAG recommended that all Member States:

- (1) develop annual plans for immunization consistent with the GVAP/SEAR-VAP, and
- (2) establish a process to annually monitor the progress of SEAR-VAP implementation by an independent body such as their NITAG, and submit an annual progress report to the SEAR-ITAG through SEARO.

3.3 Equity

ITAG reiterated that equity in immunization is vital to ensuring benefits to all. ITAG believes that it is important to have country and region-specific policies/strategies in place to achieve equity in immunization. It notes the importance of improving access to marginalized populations where disease burdens tend to be disproportionately concentrated. ITAG invites Member States to focus on reaching these communities to achieve a higher degree of

equity in immunization in the Region. As a means of operationalizing the outreach to these communities, ITAG recognizes the value of disaggregating data by geography, wealth and gender, generating such data where not available, and streamlining specific strategies for prioritization of high-risk populations for interventions.

ITAG recommended that all Member States:

- (1) Endorse lessons learnt from country experiences and promote equity in its different forms, including gender, sociocultural situation and geography.
- (2) Must address the problem of under-immunized/unreached children and missed opportunities for vaccination (MOV) in order to achieve the GVAP goals.
- (3) Should prioritize targeted interventions to administrative areas with high numbers of under-immunized/un-immunized children for increasing and sustaining population immunity most efficiently.

3.4 Immunization legislation

ITAG is of the opinion that immunization legislation is an important milestone for Member States in protecting children's rights to quality immunization, and that it reflects a country's political commitment to the programmatic and financial sustenance of its National Immunization Programme.

ITAG recommended that all Member States:

- (1) recognize that the benefits of legislation, such as the Immunization Act of Nepal 2016, are core to achieving public health goals, and
- (2) consider how such legislation may be advantageous to strengthening their immunization programmes.

3.5 Immunization financing

ITAG is encouraged to note that Member States continuously strive to introduce new and underutilized vaccines and new technologies, while at the same time working towards achieving high and equitable immunization coverage by intensifying routine immunization and strengthening health systems. ITAG acknowledges that these efforts often increase the costs of national immunization programmes beyond the currently available allocations for immunization in their national budgets. It also notes the challenges posed by the differing wealth status of Member States (as reflected in the World Bank income categorization), and also by the different phases of transition from Gavi support. Therefore, ITAG considers that addressing emerging needs for sustainable and predictable funding for national immunization programmes is a priority for the SEA Region.

ITAG recommended that all Member States:

- (1) Develop a comprehensive and sustainable immunization financing plan as part of their national immunization or any equivalent plan. These plans should be updated periodically to ensure predictable financing for:
 - routine immunization to increase and sustain equitable immunization coverage;
 - introducing new and under-utilized vaccines (NUV) based on available evidence;
 - use of innovative technologies and strategies to promote immunization; and
 - strengthening health systems for immunization outcomes.

3.6 Polio eradication

ITAG congratulated Member States on maintaining the polio-free status of the Region for more than five years since the last case due to wild poliovirus (WPV) was detected in January 2011. However, it notes with concern the detection of vaccine-derived polioviruses (VDPV) from stool specimens of acute flaccid paralysis (AFP) cases, as well as from sewage samples in India during the last 18 months; along with an outbreak of

circulating vaccine-derived poliovirus type 2 (cVDPV2) in Myanmar in 2015.

ITAG congratulated Myanmar on strong measures taken by the Ministry of Health in response to the outbreak, but remains concerned at gaps in AFP surveillance, especially in the outbreak area. It notes that the outbreak response assessment team could not conclude with certainty whether transmission of the cVDPV2 had been interrupted. It recommends urgent measures to improve the quality of AFP surveillance and to initiate environmental surveillance.

ITAG recognizes the support and guidance of donors and partners in implementing the polio eradication and endgame strategy in the Region. It acknowledges the active oversight of the National Certification Committees for Polio Eradication (NCCPE) and the Regional Certification Commission in maintaining surveillance standards, immunization and outbreak response preparedness.

ITAG notes the continued risk of wild polio virus (WPV) spread following an importation, as well as the ongoing risk of circulating VDPV due to oral polio vaccine use. ITAG is concerned about the persistently low third dose of OPV (OPV3) coverage through routine immunization (RI) in India, Indonesia, Myanmar and Timor-Leste, and notes that supplementary immunization activity with tOPV had been conducted in each of these Member States prior to the switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), to mitigate the risks of VDPV2 emergence.

ITAG is also concerned about suboptimal AFP surveillance indicators in Democratic People's Republic of Korea, Indonesia, Myanmar, Sri Lanka, Thailand and Timor-Leste. ITAG noted the progress in expanding environmental surveillance in the Region, with the addition of sites in India and initiation of sites in Bangladesh and Indonesia. ITAG appreciated the performance of the laboratory network in support of AFP and environmental surveillance, but expressed concern about performance issues in the Democratic People's Republic of Korea laboratory.

ITAG noted the Region's progress towards achieving the objectives of the 'Polio Eradication and Endgame Strategic Plan 2013–2018', including plans for IPV introduction. ITAG congratulated the ministries of health in all 11 member countries for undertaking and validating the switch from tOPV

to bOPV in April–May 2016 with support from WHO, UNICEF and other stakeholders. ITAG noted the challenges related to availability of sufficient IPV in the Region and measures taken to mitigate risks associated with short supply of IPV, such as the prioritization of IPV supplies to tier 1 and 2 countries. ITAG congratulates India for introducing off-label fractional dose IPV in eight states to stretch available IPV supplies. ITAG notes the progress in containment of all type 2 polioviruses as per the Global Action Plan III (GAP III) in the Region despite the complexities involved in this area of work.

ITAG noted the efforts being made to ensure outbreak response preparedness in the Region, with special emphasis on preparedness for any type 2 poliovirus circulation in the post-switch period. It commended the authorization for use of mOPV2 and fractional dose IPV if an outbreak is detected.

ITAG appreciated initiation efforts in the Region to develop transition plans for polio assets in five priority countries – Bangladesh, India, Indonesia, Myanmar and Nepal – to ensure that these assets contribute to broader public health gains while sustaining polio-free status.

ITAG recommended that:

- (1) All Member States should continue their efforts to achieve/sustain certification-level AFP surveillance.
- (2) An urgent review of AFP surveillance indicators and processes at the national and subnational levels should be undertaken in the Democratic People's Republic of Korea, Indonesia, Myanmar, Sri Lanka, Thailand and Timor-Leste. Corrective actions should be identified and immediately implemented.
- (3) Environmental surveillance should be initiated in Myanmar and in Nepal in 2016–2017. Thailand should also consider initiating environmental surveillance. Countries already conducting environmental surveillance should consider adding sites.
- (4) India, Indonesia, Myanmar and Timor-Leste should continue to strengthen their routine immunization programmes through the development and implementation of programme improvement plans to maximize effectiveness of IPV administered as a part of routine immunization.

- (5) Indonesia should ensure that IPV is introduced no later than July 2016.
- (6) Global Polio Eradication Initiative (GPEI) partners should regularly share information on IPV supply with all Member States, including those that self-procure the vaccine.
- (7) In view of the insufficient global IPV supply and the operational challenges associated with administering fractional dose of IPV, NITAGs should provide guidance to national programmes on IPV introduction strategies.
- (8) All Member States should ensure that their outbreak response plans are in line with GPEI protocols for response to detection of type 2 poliovirus in the post-switch period, including authorizing the emergency use of mOPV2 and IPV.
- (9) All Member States should ensure that containment activities are implemented as per Global Action Plan III (GAP III) within the stipulated timelines and in partnership with relevant stakeholders.
- (10) Ministries of health in Bangladesh, India, Indonesia, Myanmar and Nepal should develop and finalize their transition plans for polio assets by end-2016.
- (11) Certification activities should continue as per recommendations of the Regional Commission for Certification of Poliomyelitis Eradication (SEA-RCCPE).

3.7 Hepatitis B

ITAG noted the long history of immunization against hepatitis B in the SEA Region, and the achievements of Member States. However, it concludes that vaccination and control activities need to be accelerated in view of the estimated 100 million persons with chronic hepatitis B virus (HBV infection), resulting in an estimated 300 000 deaths a year from hepatocellular carcinoma (HCC), cirrhosis and other complications. HBV is highly transmissible, and newborn infants and children are at high risk. SAGE recommends two distinct but related public health interventions:

- (1) administering a birth dose to prevent perinatal infection of hepatitis B,
- (2) followed by 2–3 subsequent doses giving complete protection to infants and young children.

ITAG noted the challenges of several Member States in providing timely birth-dose vaccination given the low rate of health facility based deliveries or skilled birth attendance at home deliveries. However, the Region now has experience in overcoming this by successfully adopting innovative strategies, namely integration of birth dose with essential newborn care. While the birth dose is ideally administered within 24 hours, there are still protection benefits if given up to 7 days after birth.

ITAG considers the current global environment as very opportune for establishing a regional target for hepatitis B control through immunization, in keeping with the Global Health Sector Strategy (GHSS) Viral Hepatitis 2016–2021 endorsed by Sixty-ninth World Health Assembly 2016, the UN Sustainable Development Goals (SDGs), and the GVAP. The GHSS aims at a 30% reduction of new cases of chronic viral hepatitis B by 2020, which is considered equivalent to 1% prevalence of hepatitis B virus surface antigen (HBsAg) among children.

The present environment also provides new opportunities for partner support at a stage where several Member States will be graduating from Gavi support. Experiences from other WHO regions have demonstrated how setting a control goal contributes towards heightened national commitment to hepatitis B control, and also indirectly focuses attention on strengthening routine immunization services. Furthermore, with many Member States currently developing polio legacy documents, it is an opportune time to transition polio assets and legacy to the control of hepatitis B in the Region.

ITAG recommended that Member States:

- (1) Conduct a systematic review of hepatitis B vaccination coverage to identify gaps and causes of under-immunization – especially with regard to birth dose – and develop/implement strategies to bring coverage to target levels.

- (2) Ensure that activities required for achieving hepatitis B immunization coverage goals are adequately reflected in national comprehensive multiyear plans (cMYPs) or other expanded programme on immunization (EPI) plans.
- (3) As the overall control of viral hepatitis incorporates a range of strategies under the responsibility of different governmental units, it is critical that hepatitis B immunization strategies are clearly reflected in national action plans with clear delineation of responsibilities. NITAGs should advocate and oversee coordination between departments to achieve immunization goals.
- (4) Closely coordinate with WHO and other technical partners to identify and address specific programmatic, implementation and monitoring challenges.

ITAG recommended that WHO SEARO:

- (1) Establish a regional goal for control of hepatitis B as part of the Regional Vaccine Action Plan (RVAP). The control goal should be in alignment with the Global Health Sector Strategy on Viral Hepatitis and should have a target of $\leq 1\%$ HBsAg seroprevalence among children aged 5 years by the year 2020.
- (2) Develop an action plan for accelerating hepatitis B immunization towards the regional control goal. Given the diversity of epidemiological situations, the plan must be guided by a comprehensive consultation process with Member States, relevant experts and partners, and based on country needs and resource requirements.
- (3) Align hepatitis B control action plan with the RVAP, and also give consideration to the role of viral hepatitis A and E vaccination in a comprehensive hepatitis prevention strategy of national immunization programmes.

3.8 Maternal and neonatal tetanus elimination (MNTE)

ITAG congratulates Indonesia on having achieved maternal and neonatal tetanus elimination (MNTE) status as per WHO criteria in 2016, and the SEA Region on becoming the second of the six WHO regions after the

European Region to achieve MNTE. ITAG considers Regional MNTE as another public health victory, proving that even access-constrained, remote and vulnerable high-risk populations can be reached.

However, sustaining MNTE requires vigilance. Member States that relied solely on routine service delivery or have reliable neonatal tetanus (NT) surveillance may face fewer challenges in sustaining MNTE as compared with Member States that employed SIAs in selected districts or in the country as a whole. Nevertheless, for all Member States, the post-elimination scenario requires addressing gaps related to access, coverage and quality of health care, and routinely reviewing district performance data. Negligence in this regard might well result in some districts, or the country as a whole, reverting to previous high MNT risk status.

As such, ITAG welcomes the WHO and UNICEF operational guidelines on '*Sustaining Maternal and Neonatal Tetanus Elimination (MNTE) once achieved by a country*' to serve as a basis for joint action between immunization programmes, maternal and newborn child health (MNCH) and surveillance managers, to address gaps that could impact a Member State's ability to maintain MNTE.

ITAG recommended that Member States:

- (1) that have achieved MNTE status since the year 2000 should periodically review the performance of each district as a joint exercise by the EPI, MNCH Programme, surveillance managers and partner representatives. The review should follow WHO and UNICEF operational guidelines on '*sustaining maternal and neonatal tetanus elimination (MNTE) once achieved by a country*'. Member States should use the assessments to implement corrective measures, taking into account the country policy/strategy, local context and feasibility.
- (2) that have achieved MNTE status before the year 2000 should improve and sustain sensitive neonatal tetanus (NT) surveillance in every district to maintain elimination status, as districts should remain at a reported/estimated annual NT rate below 1/1000 live births (LB).
- (3) that have not yet optimized immunization schedules for tetanus toxoid vaccination should aim at optimizing them to ensure full

and early protection against tetanus with booster doses for both genders during childhood and adolescence.

ITAG recommended that SEARO:

- (1) develop an activity plan for monitoring/maintaining MNTE status in priority countries. This should include but not be limited to:
 - a standard set of data to be reported, analysed and reported back to Member States for action, and
 - establishing a standardized format for MNTE post-validation assessment.
- (2) support select countries in their district-level annual performance review.

3.9 Measles elimination and rubella/CRS control

ITAG is encouraged by Member States' commitment to the regional goal of measles elimination and rubella/CRS control by 2020. Nevertheless, ITAG believes that current efforts to close immunity gaps and strengthen case-based surveillance and reporting need to be intensified. To this end, ITAG will monitor a number of milestones to track progress of Member States towards reaching the measles elimination and rubella/CRS control goal by 2020.

ITAG commends Member States on progress made in providing MCV1 and MCV2 with high coverage through their respective routine immunization programmes. ITAG commends Member States on the formation of National Verification Committees, and SEARO on the formation of the Regional Verification Commission for Measles and Rubella. ITAG expressed concern over a resurgence of measles in Bhutan and an outbreak in Sri Lanka.

ITAG encourages exploring the option of utilizing the Region's polio infrastructure towards the control/elimination of measles and rubella/CRS as part of the polio legacy plan. ITAG acknowledges that high vaccination coverage may necessarily not indicate the case load or interruption of transmission in a population, and thus emphasized the need to look into surveillance performance as key indicators towards verification progress.

The centrality of surveillance was underlined, based on the Region's experience with polio elimination, and thus it was emphasized that the Region should put in all resources to meet global standards of surveillance.

ITAG encourages Member States to report progress on measles elimination and rubella/CRS control to the Regional Verification Commission following review by their respective National Verification Committees.

ITAG acknowledged that the SEA Region has the world's largest birth cohort, and that measles elimination and rubella/CRS control activities will have far-reaching implications beyond the Region and towards global progress.

ITAG recommended that:

- (1) All national verification committees (NVCs) should review and report progress on measles elimination and rubella/CRS control in their country to the Regional Verification Commission.
- (2) The Regional Verification Commission Secretariat in WHO SEARO should present a report on progress made towards meeting the goal of measles elimination and rubella/CRS control at the next SEAR-ITAG meeting in 2017.
- (3) For Member States that have introduced measles and rubella containing vaccine (MRCV), NITAGs should recommend that governments commit to rubella elimination by 2020 in keeping with the regional measles elimination goal. In Member States yet to introduce MRCV, namely India and Indonesia, efforts should continue to reach the regional rubella control goal. A 2020 target for regional rubella elimination should be set once all Member States have introduced MRCV.

ITAG recommendations related to closing the immunity gap:

- (1) All Member States should determine immunity profiles by birth cohort for various age groups (through desk reviews, sero-surveys or other mechanisms) and develop/implement plans to fill any gaps, including use of available opportunities for immunization,

optimization of immunization schedule or implementation of supplementary immunization activities (SIAs) where appropriate.

- (2) All Member States should monitor two-dose measles and rubella containing vaccine (MRCV) coverage at subnational levels and implement corrective actions when needed, in line with global routine immunization strategies and practices (GRISP).
- (3) India should begin to implement national wide-age range campaigns using MRCV by the end of 2016. This should be followed immediately by the introduction of MRCV in the routine immunization schedule.
- (4) Indonesia should begin to implement national wide-age range campaigns using MRCV by mid-2017. This should be followed immediately by the introduction of MRCV in the routine immunization schedule.
- (5) The Democratic People's Republic of Korea should introduce MRCV in the routine immunization schedule as soon as possible, preferably no later than 2017.
- (6) All Member States should consider verification of measles and rubella immunity status during the school and college admission process, and also among other risk groups, and plan vaccination as necessary.
- (7) All Member states should consider developing subnational measles elimination and rubella control/elimination workplans, such as those that have proved to be effective in the polio eradication programme.

ITAG recommendations related to MR surveillance:

- (1) All Member States should conduct subnational risk assessments of measles and rubella transmission and implement risk reduction activities.
- (2) All Member States should revise national measles and rubella surveillance guidelines in line with the updated regional surveillance guidelines and indicators.
- (3) All Member States should strengthen laboratory-supported case-based surveillance for measles and rubella as per the Framework

for Verification of Measles Elimination and Rubella Control/Elimination. India and Indonesia should continue to expand case-based surveillance following wide-age range campaigns.

- (4) All Member States should include linked laboratory and epidemiological case-based data in their national measles/rubella surveillance systems, and report these data to WHO on a weekly basis, in line with current reporting requirements.
- (5) SEARO should update regional measles and rubella surveillance guidelines and indicators in line with the Global Framework, tailoring guidelines to account for countries at different stages of measles elimination and rubella control.
- (6) SEARO should encourage operational research studies on alternative sample collection (for example, dried blood spots), new vaccine delivery technologies and point-of-care diagnostics, to support Member States such as Bhutan, Maldives, Myanmar and Nepal, where conditions are challenging.

ITAG recommendations related to the MR laboratory network:

- (1) All laboratories in the Regional Measles and Rubella Network to institute a quality assurance process that includes routine internal auditing, and ensures an adequate supply of kits and reagents.
- (2) All Member States to collect adequate specimens to characterize measles and rubella genotypes. Findings should be linked with epidemiological case-based data to identify chains of transmission. Findings should be regularly shared with all stakeholders.

Among Member States with established CRS surveillance, ITAG recommended that:

- (1) Bangladesh and Nepal should conduct an evaluation of their CRS surveillance systems and present their findings at the next SEAR-ITAG meeting in 2017.
- (2) All Member States conducting CRS surveillance to report their findings to WHO on core variables as per the data dictionary on

a monthly basis, as well as through the joint reporting form (JRF) on an annual basis.

3.10 Data quality

Accurate data is the cornerstone for formulating evidence-based policy, providing operational support for immunization systems and also essential for accountability at all levels.

ITAG noted that high-quality data are crucial for monitoring progress towards achieving national, regional and global goals. ITAG noted that subnational immunization coverage was not available for some Member States, nor was there a mechanism to validate such data of Member States that did provide it. ITAG noted that demographic and GIS information needed to be updated by a few Member States and that case-based data collection and reporting for other VPDs like neonatal tetanus (NT), diphtheria and pertussis is yet to be initiated.

ITAG appreciated the detailed review of data conducted by SEAR-IVD during 2015–2016 on immunization system performance and VPD surveillance performance indicators that were reported through the annual joint reporting form (JRF), and provided feedback to Member States on data quality and data analysis. ITAG notes that JRF data are an important source of information and performance indicators, which are used for the monitoring and accountability framework of GVAP and reporting to SAGE and WHA.

SEAR-ITAG noted the emphasis laid by SAGE on accurate data regarding prevalence and/or incidence of vaccine-preventable diseases (VPDs) and immunization system performance for evidence-based policy and operational support. ITAG reaffirmed the position of SAGE that the improvement of data quality should be one of the highest priorities for all stakeholders in the early part of the Decade of Vaccines. Likewise, data quality improvement is a strategic focus area in Gavi, The Vaccine Alliance's 2016–2020 strategy; thus, Gavi-eligible countries should meet this requirement.

ITAG recommended that Member States:

- (1) Conduct annual reviews to assess data quality of immunization coverage and VPD surveillance using WHO assessment tools. In-country independent resources, such as academia and professional associations, may also be used to ensure the quality of the assessments.
- (2) Develop, implement and monitor data quality improvement measures in response to the assessments, and develop surveillance data management systems to ensure that case-based data on acute flaccid paralysis (AFP), measles and rubella and other priority vaccine-preventable diseases, are collected as per WHO protocols.
- (3) Conduct periodic national and subnational surveys to validate immunization coverage data. India and Indonesia should conduct periodic estimations of immunization coverage, first at the subnational level, using the WHO/UNICEF methodology for estimation of coverage.
- (4) Ensure that subnational-level immunization coverage data are shared with SEARO.

ITAG recommended that SEARO provide technical support to Member States for:

- (1) analysing and interpreting immunization data, and using the findings to develop policies and data quality improvement measures
- (2) developing data quality improvement plans and guidelines for assessing data quality, and
- (3) reviewing, modifying and upgrading national AFP, measles-rubella and VPD surveillance and immunization information systems.

3.11 Vaccine quality and management

National Regulatory Authority strengthening

ITAG recognized that the National Regulatory Authority (NRA) of Member States is responsible for the safety, quality and efficacy of medicines/vaccines regardless of the procurement policy, that is, irrespective of whether procurement is from pre-qualified (PQ) suppliers or is locally produced.

ITAG fully realizes that some NRAs in the Region have limited resources, and therefore reminded such NRAs to use measures such as using WHO pre-qualified vaccines, learning from the experience of other NRAs and working towards regulatory convergence/harmonization under internationally accepted guidelines.

Also, ITAG encouraged promotion of synergies through reliance and networking among Member States in order to further strengthen the NRA capacity.

ITAG also noted WHO's role to regularly assess NRAs in the Region using standard WHO indicators to ensure that vaccines produced by regional manufacturers are considered for WHO pre-qualification.

ITAG reminded that the concept of functionality has now been replaced by a benchmarking approach that indicates a country NRA's "maturity levels" rather than it being adjudged "functional" or "non-functional".

Related to NRA strengthening, ITAG recommends that Member States:

- (1) ensure National Regulatory Authorities (NRAs) actively participate in addressing regulatory issues related to the vaccine life-cycle (namely manufacturing, regulation, distribution) in the newly instituted SEAR regulatory network,
- (2) ensure NRAs enforce good distribution and storage practices, and monitor AEFI surveillance, in their respective countries,

- (3) Bangladesh finalized the new drug policy and drug act to reinforce the importance of the NRA, assure adequate resources, and continue to invest significantly in the NRA, and
- (4) Myanmar reinforced the Food and Drug Administration (FDA) to become an independent NRA and continues to invest significantly in the NRA.

Related to NRA strengthening, ITAG recommended that SEARO:

- (1) Facilitate training on the new NRA assessment tool for all concerned national staff.
- (2) Support the Region and Member States in implementing recommendations of the SEAR regulatory network.
- (3) support the NRA in Bangladesh to achieve a maturity level that is required for the vaccine manufacturers of the country to be eligible for WHO pre-qualification functions as early as possible.
- (4) continue to support the Myanmar NRA in capacity-building, and
- (5) continue to encourage and facilitate inter-country cooperation as an effective means of optimizing existing capacity and building capacity at the same time.

Vaccine availability and quality

ITAG recognized that there is a global need to expand the number of pre-qualified vaccine manufacturers to create a more stable and competitive market. ITAG appreciates the actions taken by all stakeholders to minimize stock-outs resulting from the global shortage of BCG vaccines in 2015 and to ensure availability of sufficient buffer stocks of BCG vaccines in 2016. ITAG also understands the multiple challenges in expanding the cold-chain capacity for vaccine storage in Member States, and it reminded the Gavi-eligible countries to make use of Gavi's cold-chain optimization platform, where relevant to address this challenge. Furthermore, ITAG reiterated the importance of long-term cost-saving plans to help cold-chain expansion in view of planned new vaccine introductions in countries.

Related to vaccine availability and quality, ITAG recommended that Member States:

- (1) especially those with limited NRA capacity, continue to exclusively use WHO pre-qualified vaccines for their immunization programmes,
- (2) enhance interactions between NIP managers and vaccine producers at all 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, and
- (3) explore mechanisms of cooperation, such as the ASEAN Initiative on Vaccine Security, to promote regional access to an assured quantity and quality of vaccines at an affordable price.

Related to vaccine availability and quality, ITAG recommended that SEARO:

- (1) explore pathways to pre-qualify the cholera vaccine manufactured by Bangladesh.

3.12 Adverse events following immunization (AEFI)

ITAG recognized the importance of proactively engaging the media to overcome negative fallout in case of occurrence of serious AEFI. ITAG congratulates India on the initiative taken in terms of transparency and dissemination of information by publishing AEFI details on its health ministry's website and urges other Member States to take similar approaches. ITAG took note of described policies with regard to compensation/hospitalization expenses for AEFI cases. ITAG congratulated Sri Lanka on its intensified AEFI surveillance through tracking and post-mortems following reports of AEFI related to pentavalent vaccines. ITAG took note of India's experience regarding its recently revised initiatives to improve AEFI surveillance.

Related to AEFI, ITAG recommended that Member States:

- (1) work with academic institutions/partners to build capacity to conduct causality assessments for AEFI surveillance, and
- (2) share AEFI data with vaccine manufacturers through the NRA and NIP to consolidate the safety profile of newly introduced vaccines.

Related to AEFI, ITAG recommended that SEARO:

- (1) continue to support AEFI committees in AEFI investigation activities, finalizes the manual for field investigation of AEFI, and facilitates its implementation at the country level.

3.13 New and underutilized vaccines introduction (NUVI)

Dengue vaccine

The ITAG took note of the progress made in the research and development of dengue vaccines. It further noted that the new WHO position paper endorsed by SAGE on dengue vaccines would be available in July 2016. However, ITAG reminded national immunization programmes and their partners that there would be many tasks to be accomplished as per SAGE recommendations, should Member States consider introducing the new dengue vaccine CYD-TDV.

ITAG recommendations related to dengue vaccine:

- (1) Member States, considering the use of currently available dengue vaccine, should evaluate epidemiological data such as age-specific seroprevalence rates and/or age-specific incidence rates of disease.
- (2) NITAG decisions with regard to introduction of the dengue vaccine should carefully consider country-level assessment, local priorities, national and subnational dengue epidemiology, predicted impact and cost-effectiveness with country-specific hospitalization rates and costs, affordability and budgetary impact.

- (3) Dengue vaccine introduction should be part of a comprehensive dengue-control strategy that includes effective and sustained vector control, best evidence-based clinical care for patients and robust dengue surveillance.

Other NUVI

ITAG noted that Member States have achieved significant progress in introducing new vaccines in the SEA Region. ITAG especially noted that although Bangladesh introduced the inactivated polio vaccine (IPV) and pneumococcal conjugate vaccine (PCV) simultaneously, it has faced several programmatic challenges. The progress in introduction of rotavirus vaccine in the Region, where Thailand has introduced rotavirus vaccine as a pilot project in a single province, while India has introduced an indigenously manufactured rotavirus vaccine in four States, was also noted. ITAG also congratulated Indonesia and Myanmar for preparatory activities to introduce the JE vaccine in their national immunization programmes in 2017. ITAG requested all Member States to share locally generated information about immunogenicity, efficacy, the duration of protection, safety issues of new vaccines introduced and challenges encountered.

Related to other NUVI, ITAG recommended that:

- (1) Member States introducing multiple vaccines to children during a single visit should provide information, education and communication (IEC) to parents/guardians that in the event of non-availability of one (or more) vaccine(s) due to “stock-out” or any other reason, the other available vaccine(s) should be given to the child at the prescribed time in the national schedule. The vaccine(s) that is/are missed should be administered when available.
- (2) Member States educate and train health staff on the value and safety of multiple vaccines administered in a single visit.

4. The way forward

ITAG requests WHO-SEARO and all partners concerned to work towards setting goals in accordance with the recommendations set forth in this

report. It also directs them to prepare a progress report to be presented at the next annual ITAG meeting. Key actions for WHO-SEARO will be to:

- (1) provide technical assistance to Member States and facilitate implementation of ITAG recommendations in the Region,
- (2) closely monitor the status of implementation of recommendations of ITAG and support as per the needs of the Member States,
- (3) strengthen research and development in the Region to generate evidence related to progress towards vaccine-preventable diseases, and
- (4) present the implementation status and progress of the Region to the ITAG Chair and members in June 2017.

Annex 1

Agenda

- (1) Pre-meeting
 - Brief overview of ITAG and NITAG operations, and review of EPI programmes by country NITAGs
 - Polio eradication and endgame strategy
 - Measles elimination and rubella/CRS control
 - Maternal and neonatal tetanus elimination and control of hepatitis B
 - Strengthening of routine immunization services and systems, introduction of new and under-utilized vaccines and related technologies
 - NRA strengthening and vaccine production in SEAR
 - Effective vaccine management and social mobilization
 - Health system strengthening and immunization financial sustainability
 - Improving data quality
- (2) Opening session of Main Meeting
- (3) Review of progress and achievements since last ITAG
- (4) Implementing Vaccine Action Plan
- (5) Hepatitis B situation and way forward
- (6) Polio eradication and endgame strategy
 - situation update
 - outbreak response
 - transition planning

- (7) Accelerating measles elimination and rubella/CRS control
- (8) Strengthening data quality for action
- (9) Maternal and neonatal tetanus elimination
- (10) Strengthening vaccine quality and management
- (11) New and underutilized vaccine introduction

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The seventh meeting of the World Health Organization's South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG) was held from 7 to 10 June 2016 in New Delhi, India. SEAR-ITAG is a regional technical expert group comprising of experts from disciplines such as programme management, communicable diseases/vaccine preventable diseases (VPD) control, virology, epidemiology and immunization. SEAR-ITAG provides support on setting regional priorities for immunization and technical support for strengthening routine immunization services to member states. It meets annually with the participation of national Expanded Programme of Immunization (EPI) managers, VPD surveillance focal points and partners to review progress on increasing immunization coverage, VPD surveillance performance, programme issues, and matters related to vaccine safety and quality assurance. Further, it provides guidance on ways to improve and sustain overall high quality performance of EPI in member states.

This publication provides an overview of conclusions and recommendations of the annual meeting of the SEAR-ITAG held in 2016.



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