

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

A Report
New Delhi, India, 29–30 March 2012



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1. Introduction

The third meeting of the World Health Organization's South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG) was convened from 29-30 March 2011 in New Delhi, India.

The SEAR-ITAG comprises of technical experts who provide Member States technical and policy guidance on immunization and vaccine technology to reduce vaccine-preventable diseases in the Region. Its terms of reference are:

- Review regional and Member State policies, strategies and plans for control, elimination and eradication of vaccine-preventable diseases, especially for polio eradication, measles control and MNT (maternal and neonatal tetanus) elimination, including the setting of regional immunization priorities;
- Guide Member States in strengthening routine immunization programmes;
- Make recommendations on a framework for national immunization policies as well as operational aspects of the immunization strategies; guide Member States on the incorporation of new scientific knowledge and technology on vaccines, vaccine delivery and immunization practices;
- Advise Member States on the appropriate choices of new vaccines, guide optimal strategies for their introduction, and provide technical guidance on monitoring the impact of new vaccines once introduced into national immunization programmes;
- 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;

- Identify and advise on appropriate subject areas for operational research in the fields of immunization and vaccines and review the conduct and results of the research projects; and
- Advocate and promote linkages and liaise with global policy-making bodies such as the Strategic Advisory Group of Experts (SAGE), and national committees for immunization practices (NCIP) at the country level.

General objective of the third SEAR-ITAG meeting

The general objective of this meeting was to review the progress in polio eradication, measles control, and strengthening routine immunization and strategies for introducing new and underutilized vaccines in Member states of the South-East Asia Region.

Specific objectives

The specific objectives of the meeting were to:

- (1) provide an update on the situation of polio eradication and the remaining challenges, and agree on the next steps towards the achievement of the goal of polio eradication, specifically to discuss the recommendations of the Regional Certification Commission.
- (2) discuss risk management for polio, including cross-border issues and options to maintain population immunity in the post-eradication era.
- (3) review the measles control strategies and recommend on the feasibility of having a measles elimination target year for the Region.
- (4) arrive at a consensus on the strategies for achieving rubella control, and maternal and neonatal tetanus elimination.
- (5) assess the level of progress made on:
 - intensifying routine immunization in the Region and advise on strategies to increase routine immunization coverage in low-performing areas.

- introduction of new vaccines and defining future strategic directions for countries for introduction of new and underutilized vaccines into their national immunization programmes.
- (6) assess the systems available for quality assurance and safety of vaccines and provide guidance on strengthening of national regulatory authorities and national committees for immunization practices as part of systems strengthening in countries of the SEA Region.

The ITAG members present were: Professor Lalitha Mendis, Dr Jacob John, Dr Supamit Chunsuttiwat, Dr Nyoman Kandun, Dr Lalit Kant, Dr N. K. Arora, Dr Triono Soendoro, Dr Khin Pyone Kyi and Dr Bhuwaneshwaree Datt Chataut. Dr Vance Dietz and Prof. M.D. Ekhlalur Rahman were unable to attend. Other participants included the Chair or representative from national committees of immunization practices of Member States' ministries of health, SAGE members representing the Region, and WHO-HQ, WHO-SEARO and WHO country office EPI focal points.

On behalf of the Regional Director, Dr Samlee Plianbangchang, Dr Poonam Khetrapal Singh, Deputy Regional Director, opened the meeting. Professor Lalitha Mendis chaired the meeting with Dr Supamit Chunsuttiwat as rapporteur and Dr Patrick O'Connor as co-rapporteur.

2. Background

The Regional immunization activities have been broadly guided by the WHO/United Nations Children's Fund (UNICEF) Global Immunization Vision and Strategies (GIVS) framework and specifically by the Immunization and Vaccine Development (IVD) South-East Asia Regional Strategic Plan for 2010-2012. The GIVS has set immunization goals and provided general direction for the Member States and WHO regional/country offices.

During the second meeting of SEAR-ITAG in 2011, there was extensive discussion on: developing a framework for increasing and sustaining routine immunization coverage, achieving regional polio eradication, expanding vaccine-preventable disease surveillance, reviewing influenza pandemic preparedness plans and encouraging regional vaccine production. The table (page 4) shows the status of implementation of the recommendations from the meeting.

3. Status of implementation of recommendations from the second ITAG meeting, 2011

Recommendations	Status
General	
<p>Meeting on a regular basis (annually) in the month of March to review progress on implementation of ITAG recommendations</p> <p>Establish subgroups to review and make recommendations on specific issues such as health resource management and vaccine introduction (rubella, hepatitis B and typhoid) with each subgroup consisting of an ITAG member as the focal point, WHO staff as secretariat and invited experts from relevant areas.</p> <p>National EPI managers (or their representatives) to be invited to attend and participate in future ITAG meetings to enhance the discussion and for implementation of the ITAG recommendations.</p>	<p>Accomplished.</p> <p>Not accomplished. There were several administration changes in 2011: The Family Health and Research (FHR) Director was appointed Acting Immunization and Vaccine Development (IVD) Coordinator and there was high staff turnover (Surveillance, Vaccine Quality, Data Management, Immunization System Strengthening).</p> <p>Need clear guidance on how to establish and maintain subgroups.</p> <p>Accomplished. All NCIP Chairs were invited to attend the third ITAG meeting.</p>
Regional immunization policy	
<p>Focus more on programmatic issues that include the need for integration of surveillance, sustainability of new vaccines, public-private partnerships for immunization services and human resource development.</p> <p>Reframe the policy to address challenges in terms of inputs, processes and outputs.</p> <p>Vet the policy against the SAGE recommendations for the introduction of new vaccines highlighting the need for countries to ensure high public acceptance and long-term sustainability.</p>	<p>Re-drafted and submitted to the SEA-ACHR.</p>
Increasing and sustaining immunization coverage	
<p>All countries in the Region should engage in standardized, high-level advocacy with senior political leaders in order to obtain political commitment for immunization programmes so that technical interventions can be fully implemented.</p> <p>Countries in the Region with immunization coverage</p>	<p>Accomplished through declaring 2012 as the Year of Intensification of Routine Immunization.</p>

Recommendations	Status
<p>deficiencies should receive support from WHO to identify major issues preventing adequate immunization coverage. This process should be guided by district-based assessments of VPD surveillance and immunization coverage.</p> <p>Create a checklist and analytical framework for countries to conduct self-assessments that help prioritize steps for increasing immunization coverage, recognizing that the steps may be different based on high, medium or low immunization coverage.</p>	<p>Not accomplished fully but partially accomplished through EPI, VPD surveillance reviews and Hib (Pentavalent) post-introduction evaluation. A very clear set of recommendations identified for Bangladesh for its rural and urban populations.</p>
Regional Immunization Week	
<p>Developing and implementing a plan for a SEAR immunization week in 2012 ensuring that it is coordinated with regional immunization partners and other WHO regions.</p>	<p>Instead, a year of intensification of routine immunization has been declared by all Ministers of Health in the Region and endorsed by the Regional Committee. It has created a sense of “every week as a <i>immunization week</i>”.</p>
National committees on immunization practices	
<p>Create links between regional and country-level advisory bodies to ensure that their roles include both immunization policy and practices.</p> <p>Review NCIPs, composition and functions regularly. NCIPs should consider broadening their membership. The composition of these advisory bodies may include voting and non-voting members, ex-officials, observers and invitees to address specific issues. In order to ensure transparency of these bodies, the chairperson should be an independent expert.</p> <p>Support for the capacity building of NCIPs to include forums for information and experience sharing as well as developing a mechanism to follow up the NCIP recommendations.</p>	<p>A series of consultations are on for discussing these recommendations for strengthening national committees for immunization in all countries in the Region (NCIPs equivalent to NTAGIs).</p>
Achieving polio eradication	
<p>Maintaining high immunity against the poliovirus through routine immunization is important for achieving polio eradication in the Region.</p> <p>Develop a plan to address issues related to the transition from polio-endemic to polio-free status.</p> <p>The Government of India to ensure that financial</p>	<p>Being accomplished; already achieved some great results.</p>

Recommendations	Status
<p>support and political commitment remain high in order to eliminate the final chains of transmission in 2011.</p> <p>The Government of Nepal to continue its commitment to polio eradication by funding the national immunization days (NIDs).</p> <p>High commitment of the remaining Member States in the Region to polio eradication by remaining polio-free.</p> <p>Bhutan, DPR Korea, Maldives, Thailand and Timor-Leste not having achieved the minimum targets for AFP surveillance indicators should review their strategies and address any challenges.</p> <p>Consider organizing protective NIDs until the Region is polio-free, particularly in countries with large populations bordering India (Bangladesh, Myanmar and Nepal).</p>	
VPD surveillance in SEAR	
<p>Expansion of case-based measles surveillance for countries that have successfully completed catch-up and follow-up campaigns or countries that have evaluated coverage of >90% for two doses of measles-containing vaccine. Measles case-based surveillance should achieve all indicators of sensitivity at national and subnational levels and be integrated with government surveillance systems.</p> <p>Government support is needed for the SMO/SO (Surveillance Medical Officer/Surveillance Officer) networks with long-term plans for sustainability and integration of the SMO network with existing disease priorities and plan for a gradual assimilation into government health care systems.</p> <p>Continue providing technical support for expanding and integrating VPD surveillance at the country level.</p> <p>EPI programme managers' meeting should be used as an opportunity to discuss country priorities/strategies and to followup on the progress of VPD surveillance strengthening.</p> <p>Regional guidelines for AES (acute encephalitis syndrome) surveillance should be developed for</p>	<p>In the process of accomplishing. This was a major part of the EPI review in Bangladesh.</p> <p>Accomplished as a part of the "Year of Intensification of Immunization 2012". All countries have developed their plans.</p> <p>A draft available but not finalized.</p>

Recommendations	Status
<p>Japanese encephalitis as a priority.</p> <p>Mechanisms at the national level should be coordinated to merge laboratory and epidemiologic surveillance data.</p> <p>Endorse the proposed 2011 comprehensive EPI/VPD surveillance reviews planned for Bhutan and Bangladesh and the follow-up reviews planned for Myanmar and Nepal.</p>	<p>Not accomplished.</p> <p>Accomplished.</p>
Pandemic preparedness, influenza vaccine production and deployment	
<p>Encourage countries to assess disease burden, conduct risk assessments and determine cost-benefits/ effectiveness of seasonal influenza immunization and surveillance (including laboratory support).</p> <p>Document the lessons learned from the pandemic preparedness in 2009–2010 to guide future responses.</p> <p>National pandemic response plans should include vaccine deployment plans and countries should maintain active participation in the global influenza surveillance network.</p>	<p>A major part has been accomplished; funding has been secured from CDC; a regional workshop has been planned from 2–4 April 2012.</p>
Moving from measles mortality reduction to elimination in SEA Region	
<p>The Government of India (GoI) should be encouraged to complete the measles catch-up campaigns in all the remaining districts of the high- burden states and implement a plan to introduce MCV2 in the routine immunization programme of the remaining states.</p> <p>GoI to continue efforts to establish and maintain systemic laboratory-supported measles surveillance, particularly in states that are conducting measles catch-up vaccination campaigns, in order to measure the impact of the accelerated measles control activities.</p>	<p>In the process of accomplishing.</p>
Introducing rubella vaccine in national immunization programmes: options for SEA Region countries	
<p>Initiate/establish rubella and CRS burden to confirm both technical and financial sustainability of immunization introduction. Appropriate surveillance strategies should be in place including laboratory support to integrate rubella into existing disease notification systems.</p>	<p>In the process of accomplishing.</p>

Recommendations	Status
<p>Countries that have evidence of rubella transmission should consider the introduction of rubella-containing vaccine. Rubella control should be integrated into existing measles control initiatives and immunization strategies (i.e. catch-up and follow-up campaigns). The new rubella vaccine position paper is expected to facilitate the decision-making process. The Regional Office should assist GAVI-eligible Member States to take advantage of GAVI support for RCV (rubella-containing vaccine).</p>	
<p>Progress in new vaccine introduction and strategic framework for introducing new vaccines in SEA Region</p>	
<p>The ITAG appreciates the progress made in developing the strategic framework for new vaccines and will review for endorsement after further refinement.</p>	<p>The revised draft is available for comments.</p>

Recommendations/comments

- The ITAG commends the efforts made by countries in implementing the recommendations made at its second meeting.
- As a follow-up to the recommendations from 2011 on establishing subgroups to look at region-specific issues, the ITAG recommends creating the following working groups (the working group chairs will draft ToRs with the assistance from IVD-SEARO:
 - (1) Hepatitis (Dr Supamit Chunsuttiwat)
 - (2) Typhoid/paratyphoid/cholera (Dr Jacob John)
 - (3) Good immunization practice (Dr Ajay Khera)
 - (4) NCIP/NTAGI (Prof. Lalitha Mendis)
 - (5) Public awareness of immunization (Dr Nyoman Kandun)
 - (6) Disease surveillance (Dr Paba Palihawadena)

The list of members of each subgroup is given in Annex 3.

4. Global progress on immunization: decade of Vaccine and Global Vaccine Action Plan (GVAP)

In May 2011, the Sixty-fourth World Health Assembly endorsed the Decade of Vaccines (DoV) Vision and called for the development of a Global Vaccine Action Plan (GVAP). This plan will be built on the strong foundation of the Global Immunization Vision and Strategy (GIVS) launched in 2005. Developing the GVAP has already brought together multiple stakeholders to define collectively the goals and strategies for the next decade. The final draft of the GVAP will be presented to the Sixty-fifth World Health Assembly in May 2012.

Recommendations/comments

- The ITAG recognizes the role of IVD/SEARO in assisting countries in operationalizing the GVAP and advising Member States to build and submit a time-based plan for DoV, along with the plans of intensification of routine immunization¹ in the South-East Asia Region.
- The ITAG recommends that countries consider validating administrative coverage by using biomarkers, more accurate denominators, and linking immunization registries with birth registries.

5. Intensification of routine immunization in 2012: progress of implementation

Following the High-Level Ministerial Meeting on 2 August 2011, the Delhi Call for Action, and the resolution adopted by the Sixty-fourth session of the Regional Committee on the intensification of routine immunization, the Regional Director requested that progress should be directly reported to his office. The first report on implementation of activities in the Region and countries was provided during the Sixty-third meeting of the WHO Representatives with the Regional Director in November 2011.

¹ Routine immunization is defined as any immunization that is part of the national schedule with additional doses available through campaigns.

Following the Regional Committee session in September 2011, all countries developed a plan of action. IVD held a series of teleconferences during October and November. IVD focal points were identified, information on progress/challenges discussed and plans were finalized.

The following countries have submitted their plans of action and have already implemented some of the activities in addition to routine work carried out: Bangladesh, Bhutan, DPR Korea, Indonesia, India, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste.

Recommendations

The ITAG made the following recommendations:

- (1) The existing immunization initiatives should be streamlined to financially support intensification of routine immunization.
- (2) All countries should establish “year of intensification of routine immunization” targets based on their current achievement of national and district-level coverage of DTP3/pentavant3 vaccine (e.g. if the coverage at present is 80%, then the target should be 85% or 90% depending on the feasibility).
- (3) The intensification of routine immunization plans should highlight the main barriers and country plans to overcome such barriers.
- (4) All countries should develop an auditing mechanism to monitor immunization performance regularly; IVD-SEARO should develop a set of uniform guidelines for EPI and surveillance reviews.

6. Measles elimination in the South-East Asia Region

Between 2000 and 2008, the global measles mortality burden decreased by 78% (from 733 000 to 164 000) due to aggressively pursued measles mortality reduction strategies. However, this progress has not been uniform. The SEA Region achieved a mortality reduction of 46% during the same period (from 234 000 to 126 000). All countries in the Region except India

have achieved 90% mortality reduction. While this is a commendable achievement, there is still potential for the Region to do substantially better in terms of child survival by implementing WHO/UNICEF-recommended strategies for measles mortality reduction.

In 2010, the Sixty-third session of Regional Committee for South-East Asia recommended that Member States should consider adopting the interim goals towards measles elimination to be achieved by 2015 (as approved by the Sixty-third World Health Assembly).

The interim goals for 2015 are to:

- exceed 90% coverage with the first dose of measles-containing vaccine nationally, and exceed 80% vaccination coverage in every district or equivalent administrative unit;
- reduce annual measles incidence to less than five cases per million and maintain that level; and
- reduce measles mortality by 95% or more in comparison with 2000 estimates.

At the regional consultation on measles, held at WHO-SEARO in August 2009, it was agreed that measles elimination was technically, biologically and programmatically feasible for all countries in the Region by 2020.

All regions of WHO, except the South-East Asia Region, now have a measles elimination goal with target dates between 2012 and 2020. The Strategic Advisory Group of Experts (SAGE), at its meeting held in November 2010, concluded that measles could and should be eradicated and that eradication of measles represented unique disease control and developmental opportunities, and should be carried out in the context of strengthening routine immunization programmes.

Considering that regional elimination of measles in the SEA Region is a desirable and potentially feasible goal, the ITAG is encouraged by the progress towards measles control and mortality reduction in the Region, particularly the decision by India to introduce a second dose of measles vaccine (MCV2) in its national immunization programme. The ITAG congratulates the Government of India on its initiative and full financial support to introduce MCV2 in high-measles-burden states through catch-up vaccination campaigns and through routine immunization in other states.

Recommendation

- The ITAG recommends that the measles elimination activities (focusing on measles case-based surveillance/outbreak investigation/immunity gaps/sero surveys) be integrated into the IRI (intensification of routine immunization) activities, and that progress towards the interim 2015 goal be reviewed in 2013.

7. Introducing rubella vaccine in national immunization programmes

Four countries (Bhutan, Maldives, Sri Lanka and Thailand) in the Region have introduced rubella-containing vaccine (RCV) into their RI programme. Two countries (Bangladesh and Nepal) are planning to introduce rubella vaccine through routine immunization and mass campaigns in the near future.

Laboratory-supported measles surveillance is generating evidence of rubella transmission in the SEA Region and in some countries that have successfully completed mass immunization campaigns with measles vaccine, most of the fever and rash outbreaks were confirmed to be due to rubella (Bangladesh, Nepal).

However, robust data regarding burden of congenital rubella syndrome (CRS) is lacking in most countries. Some countries (Bhutan, Maldives, Sri Lanka, Thailand and Nepal) have generated evidence of CRS burden or risk of CRS through a combination of sentinel site surveillance, cause of disability surveys in subgroups of disabled population and serological surveys in females in the reproductive age group.

The ITAG is cognizant of the fact that a rubella working group under SAGE is preparing an update to the rubella vaccine position paper and would consider it prudent to await SAGE recommendations.

Recommendation

- The ITAG recommends that WHO provides technical assistance for translating the global recommendations, documenting regional experiences of rubella vaccine introduction and

gathering information on TORCH (toxoplasmosis, other infections (syphilis, hepatitis B, coxsackie virus, varicella-zoster virus and human parvovirus), rubella, cytomegalo virus, herpes simplex virus) diseases; so that the remaining five Member States in the Region that have not introduced can explore the feasibility and appropriateness of introduction of rubella-containing vaccine along with measles vaccine.

8. Progress in introduction of new vaccines

The most important challenges to the introduction of new vaccines and technology in SEAR countries are affordability and sustainability. Even for routine vaccines such as DTP and TT, most countries are still dependent on donor assistance to maintain their EPI programme; adding new vaccines will substantially increase vaccine and operational costs. One potential avenue for increasing the supply (and hopefully at lower costs) is to increase the capacity of vaccine manufacturers in the Region. Since 2009, sentinel site laboratory surveillance is being carried out in Bangladesh, India, Indonesia, Myanmar and Sri Lanka for invasive bacterial diseases and rota viruses in order to generate evidence for introducing pneumococcal and rotavirus vaccines. The ITAG noted the promise held out by many vaccine producers in the Region of providing vaccines to save more lives of children in the Region.

The programme and management issues noted above regarding improvements in routine immunization are high priorities in the introduction of new vaccines too. The existing gaps in cold chain and logistics that continue to be a major challenge in most countries will be exacerbated by the demands of new vaccines. Countries are urged to carefully consider these demands when deciding on making new additions to the EPI system.

Recommendation

- The ITAG recommends that countries should share experiences through IVD-SEARO on the introduction of new vaccines to learn best practices from other countries with the decision-making process focusing on: disease burden, programme

capacity, efficacy, safety, affordability (financial support), vaccine availability (regional/domestic production) and sustainability.

9. Strategies for prevention and control of Japanese encephalitis

Japanese encephalitis (JE) has become an important issue in the South-East Asia Region. However, the bulk of disease burden is confined to India, Nepal, Sri Lanka and Thailand. All four countries have successfully introduced JE vaccines in their high-risk areas and have been able to control the disease. Of the four countries, only India has reported seasonal outbreaks in focused geographical areas.

Recommendation

- The ITAG encourages countries to continue supporting AES surveillance and conduct further research to answer questions such as adequate number of doses of SA-14-14-2 live attenuated vaccine to sustain immunity, the optimal age for vaccination, inclusion of JE in routine immunization schedules after catch-up and follow-up campaigns, the need for vaccinating adults, and the etiology of other AES.

10. Progress in polio eradication: Regional Certification Commission recommendations

Background

India was removed from the list of polio-endemic countries on 25 February 2012. India (13 January 2011) and Nepal (30 August 2010) have been polio-free for >12 months. The remaining nine countries in the Region have been polio-free for more than five years. All countries in the Region remain susceptible to importation while there is wild poliovirus circulating anywhere in the world. With the current progress in India, the Region is on-track to be certified polio-free in January 2014.

Recent developments

- Polio as a public health emergency: On 21 January 2012, the WHO Executive Board declared polio as a public health emergency. This now needs to be translated into action. Stopping polio globally is not simply a matter of time and money but a matter of having a country-level programme that performs to finish the task ahead. An emergency response requires the broadest possible mobilization and it cannot be “business as usual”.
- Lessons from India: India has achieved a monumental milestone. The lessons from India’s success should not be lost but be available to others. There are four points that summarize this success:
 - Government ownership from local to national level: The Government of India has taken a leadership role in providing personnel and financial support. The Government of India pays for more than 90% of the polio activities. Medical officers from the government are deputized to work with the National Polio Surveillance Project (NPSP). All surveillance medical officers have been put on SSA (Special Service Agreement) contracts as a way to contain costs and provide flexibility in increasing and decreasing the workforce as needed.
 - Tight-knit partnership: The partnership between the government, agencies (WHO, UNICEF, NGOs) and local populations has become seamless. This has been particularly evident in the state of Bihar.
 - Focus on quality improvement and accountability: The programme has focused explicitly on quality and its improvement. The India programme has demonstrated the value of a logical and systematic approach to improving implementation of polio immunization activities (i.e. supervisory checklist, campaign monitoring forms, periodic surveillance reviews). In addition to the focus on the technical performance of the AFP surveillance system and immunization activities, an accountability structure for staff performance has been put in place. Clear expectations and goals are communicated with the staff on a regular basis. Under-performers are not retained.

- Demand for polio immunization: The India polio programme has shown the immense value of a well-executed communication strategy. In mobilizing the population, the programme has created an increased demand for polio vaccine.
- Learning from India: Achieving this milestone has not been easy. It was the result of relentless drive and determination. The programme has learned a great deal through innovation, trial and error. If India knew 10 years ago what it knows now, it would have been able to stop transmission more quickly. This should be a heartening lesson to other countries that could benefit from that experience. Of course, the programme cannot simply be copied from one country to another. There is no single national approach. The principles of the India experience need to be carefully reviewed and translated.

Issues/challenges

- Implement/intensify routine immunization
 - Operationalize 2012 as the year of intensification of routine immunization (IRI)
 - Promote high routine immunization coverage for the third dose of oral polio vaccine
- Reduce polio immunity gaps
 - Conduct supplementary immunization campaigns when necessary to improve immunity
- Maintain high-quality AFP surveillance
 - Conduct regular surveillance reviews (national/subnational) and risk assessments
 - Conduct induction and refresher surveillance training
- Re-energize the polio certification process
 - Re-energize the activities of regional and national certification committees
 - Focus on certification at the earliest date: January 2014.

Recommendations

The ITAG made the following recommendations:

- (1) The National Certification Commissions for Polio Eradication (NCCPE) in all 11 Member States should submit updates to the Regional Certification Commission for Polio Eradication (RCCPE) every year to ensure that the Region can be certified polio-free in January 2014.
- (2) Countries at high risk of importation or polio immunity gaps should conduct supplementary immunization activities (SIA) until the Region is certified polio-free. These activities should be country-specific, such as observance of annual national or subnational immunization days or inclusion of oral polio vaccine with measles or tetanus toxoid campaigns.
- (3) WHO-SEARO should convene a regional consultation to review the immunization implications of the polio end-game strategies (i.e. tOPV-bOPV switch and IPV).

11. AFP surveillance and integrated VPD surveillance

Background

Effective vaccine-preventable disease (VPD) surveillance is essential for guiding immunization strategies, monitoring programme performance, and allocating resources. In line with the guiding principles of the Global Immunization Vision and Strategy - GIVS (2006-2015) to pursue policies and strategies based on evidence and best practices, the SEA Region is encouraging Member States to ensure that by 2015 or earlier, all countries will have developed the capacity at all levels to conduct case-based surveillance of vaccine-preventable diseases, supported by laboratory confirmation where necessary. Since 2005 substantial progress has been made in accelerating and integrating surveillance of VPDs into the existing AFP surveillance systems in the Region. A comprehensive laboratory network supports field surveillance.

AFP surveillance

Surveillance for cases of AFP is the core strategy to detect the transmission of WPVs (wild polio virus) and cVDPV (circulating vaccine-derived polio virus), guide SIA strategy and facilitate eventual certification of WPV eradication. The polio eradication programme in the SEA Region continues to be a model for using data effectively to support AFP surveillance and control polio and other vaccine-preventable diseases. The polio Surveillance Medical Officer (SMO) network in Bangladesh, India, Myanmar and Nepal and the Surveillance Officer (SO) structure in provinces in Indonesia have proven to be essential components of effective AFP surveillance for polio eradication.

The AFP surveillance performance indicators of most countries have exceeded the global and regional targets. Subnational indicators have been used as benchmarks to identify areas of concern and priorities for surveillance reviews. In 2011, a joint national/international AFP/EPI surveillance follow-up review was conducted in Nepal and Myanmar. India conducted five internal AFP surveillance reviews during the same period. Systematic environmental sampling for polioviruses in some areas of India (Mumbai, Delhi, Patna and Kolkata) is being used to supplement the data for AFP surveillance.

Measles surveillance

Four countries in the Region, Nepal, Bangladesh, Indonesia and Myanmar are submitting measles case-based data on a monthly basis from their integrated VPD surveillance systems. With the aim to obtain information to determine the progress of countries in achieving measles elimination, since 2009, the data collection tools were modified to capture information on suspected measles cases, outbreaks and classification of outbreaks.

Laboratory network

The laboratory network in the Region consists of 17 polio, 22 measles and 14 JE laboratories supporting field surveillance. Laboratory data and field data are merged electronically to give the final “picture” of vaccine-preventable diseases in the Region.

Reporting

Member States submit weekly reports for AFP and monthly reports for measles, rubella, Japanese encephalitis (JE), neonatal tetanus (NNT), diphtheria, pertussis and AEFI. For 2010, all Member States submitted the annual WHO/UNICEF Joint Reporting Form (JRF) and the Annual EPI Reporting Form (AERF). The JRF and SEARO AERF remain the primary tools for collecting annual VPD, immunization coverage, and other EPI-related data, which are used extensively at global and regional levels for programme planning, resource mobilization, and evaluating programme activities. IVD-SEARO uses the data to develop the regional and country-specific “EPI Fact Sheets”.

Recommendations

The ITAG made the following recommendations:

- (1) Countries should document the current practices and move towards further strengthening of vaccine-preventable disease surveillance systems (AFP/measles/VPD/AES/rota and IBD) and integrating them into other communicable diseases’ surveillance.
- (2) With regional progress being made towards polio eradication, countries should explore plans for transition from AFP surveillance to include other VPD surveillance and retain skilled personnel and well-functioning infrastructure.

12. Immunization research priorities: implementation research

The South-East Asia Region is home to one quarter of the world’s population and home to the largest number of unimmunized children globally despite great efforts made by all countries of the Region. In the past decade, many countries have not only achieved and sustained high coverage for the six basic antigens in their national immunization programmes but have also added new vaccines such as hepatitis B, Hib, Japanese encephalitis, rubella and even human papillomavirus vaccines. Clearly, countries are committed to immunization as it is still the most cost-effective public health intervention.

However, in many countries there are major challenges to further improve the immunization programme, introduce new vaccines and sustain high coverage countrywide. Such challenges stem largely not from the lack of technology, but from the difficulties of enhancing efficiencies in the system due to lack of sufficient understanding of the socio-cultural and human behaviour dimensions and managerial capacities that impact immunization.

Research agenda identification and priority setting should follow a transparent and systematic process and should strive to obtain inputs from those people on the ground who face the difficulties to deal with barriers on a day-to-day basis. There are two options that the Region could pursue to identify issues:

- Setting up a small technical working group that defines the parameters or the framework, which guides the identification of research issues and setting of priorities. Once the technical group has such a working document, it can be brought to the attention of the SEAR ITAG, which will review and provide the guidance required to take it forward, or
- The ITAG itself can identify issues that it considers important and set priorities and advise WHO as well as countries to implement them. For such an exercise, it would be useful to have at least a few potential ideas developed into research themes for the ITAG members to consider.

Recommendation

- The ITAG recommends that SEARO should develop a process for identifying immunization research priorities for the Region.

13. Progress in achieving MNT elimination

Maternal and neonatal tetanus elimination (MNTE) is an exercise to validate whether or not the country has eliminated MNT as a public health problem and it is only a one-time exercise. So far no process has been established for re-validation. Countries need to have strategies to maintain their elimination status through:

- Intensifying routine immunization for DPT3 coverage in children under five years and tetanus toxoid in women of child bearing age;
- Conducting supplementary immunization activities (campaigns) depending on the surveillance information; and
- Promoting facility-based births, and ensuring clean deliveries.

Remaining countries to complete the validation exercise and priorities for 2012

- Indonesia (Phase IV)
 - Tetanus toxoid supplementary immunization activities planned for 2012
 - Validation exercise planned for 2013
- India (20 states/union territories)
 - Four states have planned for a validation exercise in 2012 (Orissa, Uttarakhand, Delhi and Mizoram)

Recommendations

The ITAG made the following recommendations:

- (1) Indonesia (phase IV) and India (20 states/UTs) should remain ontrack and develop timelines for completing the MNTE validation exercises.
- (2) All countries/areas in the Region that have already validated should have plans for sustaining their elimination status.

14. Capacity building of national regulatory authorities and status of implementation of vaccine safety post-marketing surveillance

The three vaccine-producing countries in the South-East Asia Region have been increasing their vaccine production rapidly. Accordingly, the national

regulatory authorities (NRAs) have been equally challenged with an increasing and complex regulatory process. Despite this extraordinary progress in vaccine production in low- and middle-income countries, there is a risk to global vaccine stocks of assured quality. The recent delisting of WHO pre-qualified (PQ) vaccines produced in the South-East Asia Region demonstrates the need to promote stronger government commitment to support enforcement of international/WHO standards for vaccine safety and quality. There is also a need for greater involvement of the South-East Asia Regional NRAs in the WHO PQ review process, which needs to be built into a comprehensive capacity strengthening programme that includes an institutional development plan (IDP), a roadmap for upgrading regulatory oversight capacity and independent national institutions responsible for vaccine quality. There is also the risk of losing public confidence in immunization with allegations of substandard vaccines and the anti-vaccine movements, which question the effectiveness and safety of vaccines by unsubstantiated findings and studies that have been publicly and scientifically refuted.

By strengthening AEFI monitoring systems, more AEFI cases were reported and investigated by independent vaccine safety expert groups for vaccine-causal association. Increased support from governments is needed to ensure compliance with vaccine pharmacovigilance norms and standards. In the last five years, countries in the Region have enhanced their access to international expertise on vaccine pharmacovigilance and to prominent experts on vaccine safety. The regional experts are members of several global WHO advisory committees including SAGE and GACVS.

Recommendations

The ITAG made the following recommendations:

- (1) SEARO should continue to work with countries to further improve the capacity of NRAs.
- (2) Countries in the Region should improve their AEFI surveillance systems and establish a functioning national AEFI committee with expertise to conduct causality assessments (with the ability to distinguish and document between expected and unexpected reactions). Countries may consider renaming these committees as national vaccine safety committees. Selected representatives

of these committees should be invited to present their current status and vaccine safety workplans at the 2013 ITAG meeting.

- (3) SEARO should develop a pool of AEFI experts who could assist countries in sorting out major AEFI problems in the Region.

15. Seasonal influenza vaccine introduction in the South-East Asia Region: needs and feasibility

Following the H1N1 pandemic in 2009, all countries in the Region updated their pandemic preparedness plans including the vaccine deployment component. IVD-SEARO provided direct technical assistance to several countries in the process of updating their plans. Six manufacturers in the Region increased their vaccine production capacity to produce H1N1 vaccine during the pandemic if needed. It is important, however, that these manufacturers should maintain this capacity in case there is future demand for seasonal influenza vaccine within the Region. While only Thailand has introduced seasonal influenza vaccine in their routine programme for high-risk categories, no other country in the Region has introduced seasonal influenza vaccine on a large scale.

Recommendations

- The ITAG recommends that countries should (1) continue updating pandemic preparedness plans including vaccine deployment plans; (2) conduct burden studies and enhance surveillance; and (3) assess the feasibility of introducing seasonal influenza vaccine at least in high-risk groups in order to sustain the regional vaccine manufacturing capacity as a component of the pandemic preparedness plan.

16. Exploring the need for pooled procurement of vaccines in the South-East Asia Region

In recent years, an increasing number of countries in the South-East Asia Region have started preparing to become graduating countries under the GAVI eligibility criteria. The ministries of health in Sri Lanka, Bhutan and Maldives have initiated dialogue and requested IVD to explore options for

cost-effective mechanisms to procure vaccines post-GAVI support. Of the 11 Member States, four have significant manufacturing capacity or are in the process of developing it: Bangladesh, India, Indonesia and Thailand. Other regions have experienced similar issues and have used a variety of pooled mechanisms to address issues of long-term sustainability to procure vaccines.

There are two United Nations pooled vaccine procurement systems:

- The United Nations Children’s Fund (UNICEF) Supply Division
 - Procured vaccines on behalf of 80-100 countries in 2010, reaching 55% of the world’s children
 - Implemented a tiered pricing policy based on country GNI and/or GAVI eligibility for low- and middle-income countries
- The Pan American Health Organization (PAHO) Revolving Fund
 - Procured 28 antigens for 40 Member States in 2012.
 - Guarantees a single contractual price for all.

Beyond the United Nations, countries in other regions have established separate pooled mechanisms:

- The Gulf Cooperation Council (Saudi Arabia, Qatar, Oman, Bahrain, the United Arab Emirates (UAE), Kuwait)
 - Pool volumes and issue combined tenders/awards but individual contracts for each country with suppliers for delivery.
 - Large country volumes benefit smaller countries
 - Limited to six countries due to products and presentations used.
- The WHO Eastern Mediterranean Region is working with Member States to develop a regional system to support middle-income countries
 - Member States requested the WHO Regional Office to explore the feasibility of pooled procurement to overcome pricing obstacle for middle-income countries to introduce new vaccines

- Established a steering committee of partners/stakeholders and a working team to explore options and research needs
- The Pacific Island Vaccine Independent Initiative (VII) through UNICEF Supply Division
 - 13 countries combine vaccine forecasts, deliveries and inter-related payments
- Subregions of Africa
 - WHO offices are considering options for mechanisms within their group of countries, but no concrete mechanism has been developed yet
- The Scandinavian Country Pooled Activities including vaccines and other products.

The overall lessons from these global experiences with pooled vaccine procurement are:

- Demand from countries needs to be evidence-based and formally recorded
- Political and technical commitment from each country involved needs to be an absolute certainty (including possible funding)
- Sharing of information is necessary for the success of any pooled procurement activity (countries sharing prices and information)
- Establishing the right mechanism for the Region will depend on preparatory steps and appropriate research (i.e. legislative issues, product harmonizing and mapping market needs)
- As a possible long-term sustainable solution, the process will require time and effort, not short-cuts and quick fixes.

Recommendation

- The ITAG recommends that SEARO should initiate a consultative process to outline the steps/requirements for pooled procurement of vaccines for countries in the Region that would ensure self-reliance.

Annex 1
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Annex 2

Agenda

Status of Implementation of the 2011 SEAR ITAG meeting recommendations

– Dr Nihal Abeysinghe

Global progress on immunization: Decade of Vaccines (DoV) and global vaccine action plan

– Dr Thomas Cherian

Intensification of routine immunization in 2012: Progress of implementation

– Dr Nihal Abeysinghe

Measles elimination in SEAR – Dr Jayantha Liyanage

Introducing rubella vaccine in the national immunization programmes

– Dr Jayantha Liyanage

Progress in new and underutilized vaccine introduction in SEAR – Dr Nihal Abeysinghe

Strategies for prevention and control of Japanese encephalitis

– Dr Nihal Abeysinghe

Progress of polio eradication: Regional Certification Commission recommendations

– Dr Patrick O'Connor

AFP surveillance and integrated VPD surveillance – Dr Mainul Hassan

Immunization research priorities: implementation research

Progress in achieving MNT elimination – Dr Patrick O'Connor

NRA capacity building and status of implementing vaccine safety post-marketing surveillance – Mr Stephane Guichard

Seasonal influenza vaccine introduction in SEAR: needs and feasibility

– Dr Ranjan Wijesinghe

Exploring the need for pooled procurement of vaccines in SEAR – Mr Homero Hernandez

Annex 3

Subcommittees

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

This publication is the report of the Third Meeting of the South-East Asia Regional Advisory Group on Immunization (SEAR ITAG) held from 29 to 30 March 2012 in New Delhi, India. This report includes a review of the progress made in strengthening routine immunization, polio eradication, measles control, introduction of new vaccines, and injection safety, etc. It provides recommendations for the consideration of Member States of the WHO South-East Asia Region on their efforts to achieve the World Health Assembly – endorsed Global Immunization Vision and Strategy (GIVS) goals.



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