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 memberships, were revised and became the South-East Asia Regional 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 First Meeting of the South-East Asia Regional Technical Advisory Group on Immunization held on 14-15 July 2008 in Bangkok, Thailand. This report includes a review of the progress made in strengthening routine immunization, polio eradication, measles control, introduction of new vaccines, injection safety etc. It provides recommendations for the consideration of Member countries of the WHO South-East Asia Region in their efforts to achieve the World Health Assembly endorsed Global Immunization Vision and Strategy (GIVS) goals.
First South-East Asia Regional Technical Advisory Group on Immunization (SEAR ITAG) Meeting

A Brief Report
14–15 July 2008, Bangkok, Thailand
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1. **Introduction**

The first meeting of the World Health Organization’s South-East Asia Regional Technical Advisory Group on Immunization (SEAR ITAG) was convened on 14-15 July 2008 in Bangkok, Thailand. The terms of reference for the meeting were:

(1) To provide policy guidance on issues relevant to immunization programmes in the South-East Asia Region;

(2) To provide a forum for discussion on immunization goals and strategies for the Region and ways to accelerate efforts to achieve immunization-related Millennium Development Goals (MDGs).

This was the first meeting of the newly constituted SEAR ITAG which replaced the South-East Asia Regional Technical Consultative Group on Polio Eradication and Vaccine Preventable Diseases. The ITAG members present were: Professor Lalitha Mendis, Dr Jacob John, Dr Supamit Chunsuttiwat, Dr Nyoman Kandun, Dr A.M. Zakir Hussain, Dr Brent Burkholder, Dr M.H. Maskey, Dr N.K. Arora and Dr Triono Soendoro. Dr Lalit Kant and Dr Khin Pyone Kyi regretted. Other attendees included representatives from the WHO headquarters (WHO HQ), the WHO Regional Office for South-East Asia (SEARO) and WHO country-level staff.

The meeting was opened by Dr Dini Latief, Director, Family and Community Health Division, on behalf of the Regional Director, Dr Samlee Plianbangchang. Professor Lalitha Mendis was appointed as Chair and Dr Brent Burkholder as Rapporteur.

2. **Background**

Under the broad framework of the WHO/UNICEF Global Immunization Vision and Strategies (GIVS), the South-East Asia (SEA) Region is currently guided by the Immunization and Vaccine Development (IVD) Strategic Plan for 2006-2009. The Plan has set specific regional immunization goals and provides general strategic direction for the Regional Office and Member States.
At its first meeting, ITAG was given the task of making specific technical recommendations on key policy and strategic issues regarding polio elimination, measles control, routine immunization, surveillance, safety of vaccine and introduction of new vaccines. Managerial issues were to be discussed separately at the regional Extended Programme on Immunization (EPI) Managers' Meeting. In 2007 the Region was able to fulfill, or partially meet, 33 out of 41 recommendations of the Technical Consultative Group (TCG), 2007. ITAG also discussed the means to ensure that future recommendations productively address regional priorities.

**Recommendations**

1. In order to ensure that recommendations from ITAG remain practical and useful to the Regional Office and Member States, ITAG requests that national programme managers, at least from the key countries, are included in future ITAG meetings. All national EPI managers are requested to provide biannual written feedback through the Regional Office on the status of implementation of ITAG recommendations.

2. Policy and strategic issues requiring more in-depth technical discussion beyond the time available at the annual ITAG meeting should be referred to separate ad hoc ITAG subgroups composed of one or more core ITAG member(s) as well as other technical experts as required. With IVD serving as a secretariat, such subgroups will report back to the full ITAG at its next meeting.

**3. Achieving regional polio elimination**

**Status**

While most of the South-East Asian region remains polio-free through July 2008, transmission continues to be endemic in northern India and sporadic importation into Nepal. The intensified strategy of preferentially targeting elimination of poliovirus type 1 (P1) coupled with the use of monovalent vaccine has resulted in a dramatic decline in P1 cases. As of 11 July 2008, India has reported only five P1 cases, with no more than one case per infected district, a record low for this time of the year. The outbreak of
poliovirus type 3 (P3) which began in the second quarter of 2007 in Uttar Pradesh, peaked and began declining in the third quarter. P3 was introduced into (until then P3-free) Bihar in the third quarter and spread extensively there, resulting in a large outbreak which peaked and began declining by the end of 2007. These outbreaks have continued into 2008 and also spread sporadically to other states. Till date, there have been 293 P3 cases in India. Nepal has also reported four P3 cases this year, three along the border with India and the most recent case in May 2008 in a western mountainous district. The last known long-distance exportation of wild poliovirus outside the region was a P3 virus transmitted to Angola from India, most likely in late 2007.

ITAG appreciates the extraordinary efforts made by the Government of India and its partners to eradicate polio but notes that the traditional high transmission season had not yet been reached for the year. ITAG concurs with the recommendations of the India Expert Advisory Group (IEAG) made at its May 2008 meeting and the assessment of risks to eradication noted by it, and cautions against any complacency. Myanmar and Bangladesh are congratulated for effectively responding to importations of poliovirus in 2006 and 2007 but are reminded that continued transmission in India still puts their children at the risk of poliomyelitis. ITAG is seriously concerned by the apparent ongoing importations into Nepal, particularly in remote areas, and urges a prompt and adequate response to this and any wild poliovirus detections in previously polio-free areas according to previous WHO guidelines.

**Acute flaccid paralysis surveillance**

The success of regional polio elimination programmes continues to hinge on maintaining certification-level acute flaccid paralysis (AFP) surveillance linked closely to a network of qualified laboratories. ITAG notes that only Bangladesh, India, Indonesia and Nepal have consistently met both primary region-specific AFP surveillance targets; however, even these countries may have underperforming and even ‘silent’ sub-national areas. While all countries except Maldives have reported at least one AFP case in 2007 and

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1 Primary surveillance indicators in the SEA Region include: 1) a non-polio AFP rate of 2/100,000 children under age 15 years; and 2) two stools collected 24 hours apart and within 14 days of onset of paralysis.
2008, those with smaller populations continue to have difficulty in detecting/reporting the actual number of AFP cases meeting surveillance targets. Of immediate concern, ITAG notes, is that Myanmar, Sri Lanka and Thailand have been able to barely meet the non-polio AFP target, particularly in high-risk areas.

The 16 polio laboratories in the regional network continue to provide high-quality and timely diagnostic support in spite of a massive increase in workload over the last two years. In order to maintain this level of support, ITAG notes the importance of institutionalizing additional laboratories in the region with the capacity to perform intra-typic differentiation (ITD). All the laboratories have fully implemented the new cell culture algorithm and continue to meet performance targets.

**Strategies**

In recognition of the 2008 WHA Resolution 61.1 and the Director-General’s recent declaration making “polio eradication WHO’s top operational priority on an urgent basis”, ITAG strongly encourages the Regional Office and Member States to accord an equally high priority to implement this goal through well-proven and appropriately modified/designed strategies to overcome obstacles. Routine immunization remains a key cornerstone to polio eradication and ITAG draws particular attention to the continuing decline in routine immunization coverage by 3 doses of oral polio vaccine (OPV3) in Nepal since 2005. There are additional concerns regarding the gaps in sub-national areas in Bangladesh, Indonesia and Myanmar as evidenced both in reported OPV3 coverage data as well as increase in the percentage of under-immunized children in non-polio AFP cases. Low-coverage areas remain susceptible to wild virus importations as well as the emergence of vaccine-derived polioviruses (VDPVs) as seen in Myanmar. Instances of intensive efforts which have proved successful in improving both coverage and surveillance in high-risk areas, such as the Kosi riverine area in Bihar, may provide guidance for other countries.

**Recommendations**

1. ITAG endorses the IEAG recommendations from May 2008, including the supplementary immunization activity (SIA)
schedule and action plans for mop ups predicated on eradicating P1 from India by the end of 2008.

(2) Countries adjoining wild virus-endemic India should continue to conduct responsive or protective SIAs in accordance with current guidelines from the Advisory Committee on Polio Eradication (ACPE).

(3) While cognizant of the implications of the wide range of population sizes in Member States, ITAG recommends continuing the current operational target of a national non-polio AFP rate of 2/100,000 children under the age of 15 years.

(4) After close consultation with national programme managers, IVD should conduct AFP surveillance reviews in Bangladesh and Indonesia in 2009. Ideally, these reviews should include a comprehensive evaluation of all VPD surveillance. All countries are advised to make special efforts to conduct targeted surveillance reviews in “high risk” or silent areas for AFP cases.

4. Accelerating measles and rubella control

Status

Remarkable progress has been achieved in global measles control, as evidenced by the overall decline of 67% in the estimated measles mortality from 2000 to 2006. During this period, mortality declined by 26% in the SEA Region – demonstrating a commendable achievement but indicating that there is still potential for the region to make substantial gains in child survival by implementing WHO/UNICEF (United Nations Children Fund) recommended strategies for measles mortality reduction. In 2007, the SEA Regional Office endorsed the regional goal of reducing estimated measles mortality by 90% as compared to 2000. WHO estimates that there were approximately 178,000 measles deaths in the region in 2006; with over 150,000 of these deaths occurring in India alone. Thus the focus of regional measles control efforts in the region is India. ITAG further notes that efforts to successfully reach global measles mortality goals will likewise depend on the progress made in India. ITAG was informed of the recent India National Technical Advisory Group on Immunization (NTAGI) recommendations to provide a second opportunity for measles vaccine through a second dose in the immunization schedule or by supplementary campaigns.
Measles/rubella surveillance

All countries except India continue to conduct case-based surveillance during outbreaks. In India, such surveillance has started in six states with plans for gradual expansion. Health facility reporting continues to provide only aggregated data in India, Myanmar and Timor-Leste. Earlier recommendations on measles and rubella surveillance have yet to be fully implemented and will need to be strengthened as control efforts in the region expand. ITAG was made aware that IVD developed a comprehensive draft Measles and Rubella Surveillance Guidelines in June 2008 which could provide further direction for surveillance in the region.

Since the last TCGs, three new measles laboratories have been set up in the region. All the laboratories are regularly reporting both measles and rubella data, and, to date, 18 of the 19 laboratories have been fully accredited.

Strategies

Four countries (Bhutan, Democratic People’s Republic of Korea (DPR Korea), Maldives and Sri Lanka) are currently implementing measles elimination strategies. Five countries (Bangladesh, Indonesia, Myanmar, Nepal and Timor-Leste) have implemented plans for sustainable measles mortality reduction. All countries except India and Thailand have conducted SIAs that have reached a total of 116 million additional children during 2000-2007. A substantial decline in the incidence of measles due to these catch-up campaigns has been observed in Bangladesh and Nepal. Nepal plans a follow-up SIA in the latter part of 2008 and Bangladesh in 2010.

However, ITAG is concerned that routine measles-containing vaccine 1 (MCV1) coverage in the SEA Region has only increased from 63% to 65% between 2004 and 2006. According to 2007 estimates, MCV1 coverage remained well below the 90% target in India, Indonesia, Myanmar, Nepal and Timor-Leste. Stagnant routine immunization is one of the main barriers to achieving and maintaining the 2010 goal of 90% mortality reduction in the region.
Second opportunity for measles immunization

Bhutan, DPR Korea, Maldives, Sri Lanka and Thailand are providing a measles second dose through routine immunization. All these countries have MCV1 of $\geq 95\%$. Since 2007, Myanmar has introduced MCV2 at 18 months of age and Indonesia is providing a second routine dose on entry at school.

Recommendations

(1) ITAG endorses the Indian NTAGI recommendations on accelerating measles mortality reduction and urges prompt implementation. Most important, the 10 states of India that account for 90\% of measles mortality should conduct high-quality measles catch-up SIAs as soon as possible.

(2) Measles surveillance data in Indonesia do not indicate a marked impact of the phased national measles catch-up campaign. Province-specific measles disease trends as well as the age-wise vaccination status of measles cases should be reviewed to better document the impact of immunization strategies and determine the most appropriate strategy for conducting follow-up SIAs.

(3) ITAG recommends that a technical subgroup be tasked with providing a comprehensive review of a South-East Asia regional rubella control policy and more comprehensive guidance on the implementation of measles control and surveillance. Specific terms of reference are to be determined by the Chair and IVD.

(4) Given the ongoing gaps in measles surveillance, ITAG reiterates the recommendation of the last TCG that all countries (and states/provinces of large countries) that have completed catch-up campaigns should initiate measles case-based surveillance with laboratory confirmation and fully investigate all detected/reported cases.

(5) ITAG reiterates the need for all countries to introduce and maintain a second opportunity for measles immunization in order to achieve effective measles mortality reduction. The second opportunity for measles immunization can be delivered either through routine services or regular SIAs, depending on which approach is best able to achieve high coverage ($\geq 90\%$). If
a second routine dose is utilized, measles follow-up SIAs should continue until coverage with both MCV1 and MCV2 is at least 90% and should be implemented before the number of non-immunized children is equal to the size of a birth cohort.

**Introduction of rubella vaccine**

Four countries—Bhutan, Maldives, Sri Lanka and Thailand—include rubella containing vaccines (RCV) in their childhood immunization programmes. With the introduction of case-based measles surveillance following successful measles catch-up campaigns, countries that have not yet introduced RCV (e.g., Bangladesh, DPR Korea, states of southern India, Indonesia and Nepal) are detecting outbreaks of rubella. In Bangladesh for example, 10–20% of rubella cases are being detected among persons in the age group of 15 years and above, indicating a risk of congenital rubella syndrome.

**Recommendations**

(1) Countries that have not yet introduced RCV into their national programmes need to strengthen surveillance for rubella and congenital rubella syndrome (CRS) by initially conducting investigation regarding rubella outbreaks (and follow-up of rubella infections in pregnancy) and establishing CRS surveillance in sentinel sites.

(2) Countries need to review the importance of the burden of rubella and CRS disease on public health, build the necessary political and financial commitment for introduction of RCV and, where appropriate, introduce RCV into their routine programmes according to WHO guidelines (see WHO Rubella Vaccines Position Paper).

5. **Integrating vaccine preventable disease surveillance and programme monitoring**

The Global Framework for Immunization Monitoring and Surveillance (GFIMS), which was adopted by WHO in 2007, provides the vision and
guiding principles to bring together all VPD surveillance and essential components of programme monitoring. Countries are encouraged to fully utilize this model to effectively measure immunization coverage and the impact of vaccines on diseases.

All Member States have submitted their annual Joint Reporting Form for 2007. While providing the best available source of data on immunization coverage and other EPI performance indicators, the overall completeness and quality of the data remain suboptimal. Sub-national coverage data is now available for all countries except Thailand (which is planning a national coverage evaluation survey in 2008/09).

ITAG is encouraged to note that timeliness and completeness of monthly reporting of aggregated vaccine preventable diseases (VPDs) continues to improve from all countries with the exception of India. Ongoing national-level analysis of laboratory-supported surveillance of basic VPDs remains essential for monitoring the impact of immunization programmes and detecting outbreaks. Sentinel site surveillance for Acute Encephalitis Syndrome (AES) has also recently started to provide regular data on the incidence of Japanese encephalitis and other causes of meningo-encephalitis in India and Bangladesh. In addition to the ongoing AES surveillance in Nepal, Sri Lanka and Thailand, the AES regional surveillance network has expanded to 11 laboratories.

While the AES network is a promising development, the SEA Region must continue to expand the surveillance and laboratory capacity in member countries in order to provide the necessary data to guide the introduction of new vaccines. This expansion can take advantage of existing networks, but it is not financially and operationally feasible to expect all sites to conduct all surveillance activities. WHO has proposed a three-tier “layered approach” which includes hospital sentinel sites for bacterial meningitis and rotavirus, enhanced sites for sepsis surveillance and population-based sites to generate incidence estimates.

**Recommendations**

(1) In order to monitor the progress in their immunization programmes, Member States are encouraged to collect, analyse and report coverage data both nationally and subnationally (state/province and district, or its equivalent). While taking into
account individual country monitoring structures and available human resources, this requirement has special relevance for large countries such as Bangladesh, India and Indonesia. Given the persistent challenges in determining accurate numerators and denominators, countries are encouraged to carefully analyse data to maximize validity.

(2) The ITAG underscores that VPD surveillance is integral to well-functioning immunization programmes and requests IVD to prepare a background paper outlining regional and national requirements and models for surveillance of routine EPI diseases as well as those covered by new vaccines. In collaboration with WHO HQ, this document should include a strategy for implementation of the “layered approach” for global surveillance of new VPDs.

6. Progress and challenges in strengthening routine immunization

Status

The SEA Region faces major challenges in striving to attain the GIVS goal for every country to reach at least 90% national diphtheria, tetanus and pertussis 3 (DTP3) coverage and at least 80% coverage in every district by 2010 and sustained through 2015. According to the 2007 WHO/Unicef estimates, six countries in the Region (Bangladesh, Bhutan, DPR Korea, Maldives, Sri Lanka and Thailand) have already achieved at least 90% national DTP3 coverage. However, three countries (India, Indonesia and Timor-Leste) have not yet achieved even 80% coverage. Of particular concern is the absolute number of unimmunized children implicit in this lower coverage in the larger countries. It is estimated that in 2006, over 26.3 million children worldwide were not fully vaccinated and of these, 11.5 million under-immunized children were in India and 1.3 million in Indonesia. Nevertheless, ITAG is encouraged by the slight progress India has demonstrated in improving DTP3 coverage from 55% in 2006 to 62% in 2007. Efforts to target rural children in the high-risk states of Uttar Pradesh and Bihar, in particular through the National Rural Health Mission and other initiatives based on the Reaching Every District approach, do appear to be having some impact.
ITAG continues to note that clearly both the Region and the world will not be able to reach the GIVS routine immunization goals as well as the measles control goal unless even more substantial progress is made to strengthen EPI in India and Indonesia. The recent decline, since 2005, in routine coverage in Nepal also highlights the need for countries with relatively high coverage to pay attention to sustaining the achievements of their programmes.

Strategies

Previously, Regional TAG had recommended that countries with a large number of unimmunized children should assess the reasons for this status and develop clear action plans to scale up routine immunization. ITAG commends Indonesia for recently conducting a thorough evaluation of their immunization programme and expects that the findings will prove instructive to other countries.

The reasons for persistently low coverage in some Member States vary by country. However, some common issues include poor infrastructure, inadequate number of immunization staff, complications of high staff turnover, challenges in accessing hard-to-reach children and limited availability and/or analysis of data to guide programme management. Many of these issues are compounded by a critical lack of training programmes for EPI managers in the Region. WHO has recently produced revised mid-level management modules; however, these do not appear to have been fully utilized yet.

ITAG notes that the Reaching Every District strategies previously developed by WHO continue to have relevance for addressing many routine immunization-related challenges in the Region. Innovative strategies to link immunization with delivery of other health services, particularly for outreach programmes, are especially encouraged. Essential to all of these efforts is high-level advocacy to ensure policy commitment and visibility of immunization programmes.

ITAG is also keenly aware that the need to incorporate new antigens and age groups into national programmes has increased the complexity of EPI schedules as well as programme management. The current Strategic Advisory Group of Experts on Immunization (SAGE) effort to consolidate routine immunization recommendations from WHO position papers into
tables is a welcome initiative. This should provide a flexible framework for countries to develop their own schedules and IVD is encouraged to share the tables widely at the upcoming EPI Managers’ Meeting.

Recommendations

(1) (a) All countries are encouraged to ensure sufficient human resource capacity at all nodal levels of national immunization programmes to maximize efficient and effective service delivery.

(b) Human resource capacity should be strengthened by the development of additional training resources at the country and regional levels. All Member States are encouraged to develop institutional linkages among centres at the country level. IVD should explore developing an EPI Programme Managers’ Training Course to help and support the Region.

(2) ITAG requests the Regional Office to take advantage of the upcoming Regional Committee meeting to strongly encourage Member States to provide political, social and programmatic support to eradicate polio, control measles and strengthen routine immunization.

7. Status and opportunities for the introduction of new vaccines

Status

With the exception of Timor-Leste, all countries in the Region have included Hepatitis B vaccine in the national immunization schedule (although India is yet to do so on a national scale). The estimated national immunization coverage for Hepatitis B vaccine ranges from 69% (in limited sites in India) to 99% (DPRK). Given the wide use of the vaccine, the question has arisen whether the Regional Office should set a Hepatitis B control target. ITAG reviewed a summary of multiple studies; however, conclusive evidence is lacking on the key question of the importance of vertical transmission in the region.
The impact of Hepatitis B vaccination cannot be monitored by disease surveillance. Therefore, the impact will have to be monitored by measuring incidence/prevalence of the infection (by core antibody) and/or chronic infection (by HBsAg); the modalities of such monitoring have to be designed by member countries.

The status of introduction of other new vaccines throughout the region demonstrates a slow but relatively steady adoption of additional antigens and formulations. In January 2008, Sri Lanka switched to the pentavalent (DTP-HepB-Hib); however, due to reports of serious adverse events, the use of the vaccine has been suspended. Nepal and Bangladesh are approved by the Global Alliance on Vaccines and Immunization (GAVI) to start introduction of the pentavalent vaccine from January 2009 and Bhutan has received a conditional approval. In April 2008, India NTAGI recommended nationwide introduction of the Hib vaccine, but an implementation date has not yet been set.

Only Indonesia and Sri Lanka have submitted letters of interest to GAVI for support of pneumococcal vaccine; to date, answers are pending. There are no firm plans to introduce Human Papilloma Virus Vaccine (HPV) or rotavirus vaccines in any of the Member States. Thailand uses seasonal influenza vaccine on a limited scale but a recent policy decision indicates that expanded use of this vaccine is likely. The intention or interest to use the seasonal influenza vaccine in other countries is unknown.

Two other vaccines of potential regional importance are Japanese encephalitis (JE) and typhoid. Sri Lanka and Thailand have used the inactivated JE vaccine for several years and both India and Nepal have introduced the live attenuated SA14-14-2 vaccine in high-risk areas. Expanded use of the vaccine in these endemic areas may depend on additional supply from regional producers. Both a polysaccharide parental vaccine and a live attenuated oral vaccine are available for typhoid; however, determining the disease burden has remained elusive due to difficulties with diagnostics. Population-based burden studies conducted by the International Vaccine Institute have found morbidity rates of culture-confirmed typhoid ranging from 80/100,000 population/year in Indonesia to over 200/100,000 population/year in India. Since resistance to antibiotics is rising and major infrastructural improvements of water and sanitation are long-term goals, vaccines may provide a viable intervention to control typhoid.
One of the major challenges to the introduction of new vaccines and technology is sustainability. Even for routine vaccines such as DTP and Tetanus Toxide (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. ITAG notes the promise that many vaccine producers in the region could provide.

The programme and management issues noted above regarding improvements in routine immunization are further highlighted in the introduction of new vaccines. The existing gaps in cold chain and logistics which 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 planning for additions to the EPI system.

Recommendations

(1) Taking note of the concerns for providing affordable new vaccines and the number of manufactures in the region, ITAG specifically endorses the WHA61.15 resolution and requests WHO to assist developing countries to establish local manufacturing capacity and strengthen vaccine research and development, including the conduct of clinical trials that meet the International Council of Harmonization Good Clinical Practice (ICH/GCP) under appropriate regulatory oversight.

(2) ITAG recommends establishing a technical subgroup to review and promote the research agenda on Hepatitis B immunization (regarding (i) the importance of vertical transmission and (ii) the criteria for monitoring the impact of immunization programmes) and to examine establishing a regional control target.

(3) Recognizing that typhoid fever may be a significant cause of morbidity and mortality in the region, ITAG encourages Member countries to identify their disease burden and at-risk populations in order to consider introduction of vaccines as part of a comprehensive disease control package.

(4) ITAG requests all countries to review their policies on the use of seasonal influenza vaccination and for IVD to provide a presentation on the regional status of the use and effect of this vaccine at the next ITAG meeting.
8. **Capacity building for immunization policy environment and promoting safe vaccines**

**Strengthening national regulatory systems and ensuring quality, safety and efficacy of vaccines**

In order to ensure access to vaccines of assured quality, national immunization programmes should procure their vaccines either from a WHO pre-qualified source or from a country that has a functional national regulatory authority (NRA). However, ITAG was concerned to note that WHO estimates that up to 15% of the total doses of vaccine administered in the SEA Region do not meet this standard.

An independent and functional NRA is essential to ensure quality, safety and efficacy of vaccines and the required regulatory functions. All SEA Region countries had their vaccine regulatory system assessed by WHO between 1999 and 2005. ITAG is encouraged to note that South-East Asia was the first WHO region where all countries have followed up their assessment with the NRA institutional development plan (IDP). However, ITAG also expressed concern that in the SEA Region countries, only two NRAs (Indonesia and Sri Lanka) are assessed as functional. Two more countries (India and Thailand) are close to becoming functional. India was functional until 2007; however this status lapsed when the WHO assessment found that four vaccine manufacturers needed to be suspended in January 2008 for failure to meet the strict enforcement of Good Manufacturing Practices (GMP). Given the critical role that Indian manufacturers play in providing national, regional and global vaccine supply, a top priority should be to restore the functional status of the NRA.

**Adverse events following immunization (AEFI)**

The recent suspension of the immunization programme in parts of Tamil Nadu (India) in response to AEFI in a small group of children highlights the significance of a sensitive AEFI surveillance system, but also the critical need for an adequate response and investigative capacity. Additional concerns have also arisen recently about AEFI related to the use of the pentavalent vaccine in Sri Lanka. As these two examples demonstrate, ITAG is concerned about the wide-ranging implications for national EPI programmes and seeks additional information on experience in the region. While AEFI surveillance systems are operational throughout the region, they
appear to vary widely in their sensitivity and in their ability to effectively address events as they occur.

**National Committee for Immunization Practices (NCIP)**

As noted in WHA61.18, ITAG recognizes the importance of strengthening national capacity for making evidence-based policy decisions. While this requirement applies to all immunization programme decisions, this capacity assumes added urgency as governments are faced with multiple options in adopting new vaccines.

In the light of this, ITAG is encouraged to note that all Member States except Timor-Leste, Maldives and Nepal have established a NCIP (or an equivalent organization) to guide national governments on immunization policies, norms and practices. While the composition of the NCIPs varies among countries, the key to the success of such groups is to maintain technical credibility and the capacity to provide independent advice to national programmes. Long-term sustainability will be maximized if governments assume ownership and agree to fund NCIP operations. ITAG appreciates the supportive role that IVD has made till date in the formation and development of NCIPs in the region and encourages continued technical assistance as required.

**Recommendations**

1. All Member States need to continue their efforts to establish, develop and sustain their vaccine regulatory systems and continue to procure all their vaccines from either a WHO pre-qualified source or from a country that has an assessed functional NRA. ITAG encourages the continued role of WHO in supporting countries to meet these goals.

2. All countries need to establish and utilize a comprehensive AEFI surveillance system, including the development of adequate response capacity to address technical, programmatic and sociopolitical-communication issues surrounding such events. ITAG further requests a review paper on regional experiences in AEFI detection and response.

3. IVD is encouraged to provide comprehensive technical support to NCIPs in Member States as necessary, especially to assist Maldives, Nepal and Timor-Leste, in organizing their NCIPs as soon as possible.
Annex 1

Programme

14 July 2008

08:30 – 09:00  Registration

09:00 – 09:20  Opening ceremony
• Welcome – (Pem Namgyal)
• Introduction of SEAR ITAG Members
• RD’s opening address (delivered by Dr Dini Latief)
• Administrative announcements

09:45 – 09:50  Appointment of Chair of SEAR ITAG and Rapporteur

09:50 – 10:00  Review of the implementation status of the 2007 TCG meeting recommendations (Pem Namgyal)

10:00 – 13:00  Global Polio Eradication Initiative
• Global progress and updates on mechanisms for management of potential risk to eradication (Chris Maher)
• Regional progress and the remaining challenges to Polio Eradication Efforts, especially in India (Sunil Bahl)
• Quick updates on country activities for polio eradication: (10 minutes each)
  – Nepal (Jeff Partridge)
  – Myanmar (Nihal Singh)
  – Indonesia (Bardan Rana)
  – Bangladesh (Serguei Diorditsa)
• Biocontainment and Global Action Plan III (Wolff)

14:00 – 14:30  AFP Surveillance, integrated disease surveillance and GFIMs—what should immunization’s role be (Karen Hymbaugh)

14:30 – 15:30  Measles mortality reduction and rubella control
• Global progress and priorities (Peter Strebel)
• Progress and challenges for the SEA Region (Jayantha Liyanage)
• Introduction of the second routine dose of measles containing vaccine and rubella for national immunization programmes (Peter Strebel)
16:00 – 16:30 Regional guidelines to integrate measles and rubella surveillance to other VPDs (Jayantha Liyanage)

16:30 – 17:30 Capacity-building for immunization policy environment and promoting safe vaccines
- National Committees for Immunization Practices; progress on the formation of such committees in countries as part of systems building for immunization (Pem Namgyal)
- National Regulatory Authorities; key to efficacious and safe vaccines in countries (Lahouari Belgharbi)

**15 July 2008**

08:30 – 09:30 GIVS and routine immunization; progress and challenges in SEA Region (Pem Namgyal)

09:30 – 10:30 New vaccines
- Introduction of new vaccines - opportunities and challenges for the SEA Region countries (Pem Namgyal)
- Hepatitis B - should we set a target for hepatitis B control in the SEA Region (Pem Namgyal)

11:00 – 12:00 Typhoid vaccines; should immunization be part of public health intervention to control typhoid? (Michael Favorov)
- Experiences on the use of typhoid vaccine in Asia-Pacific countries
- Vaccines - opportunities and challenges

14:00 – 14:30 Any other business

15:00 Wrap-up and SEAR ITAG recommendations
Annex 2

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The WHO/SEAR Technical Consultative Group (TCG) on Polio Eradication and Vaccine Preventable Diseases was established in 1994. The TCG was an advisory body providing guidance to WHO on immunization matters. In 2008 the terms of reference for the TCG, as well as memberships, were revised and became the South-East Asia Regional 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 First Meeting of the South-East Asia Regional Technical Advisory Group on Immunization held on 14-15 July 2008 in Bangkok, Thailand. This report includes a review of the progress made in strengthening routine immunization, polio eradication, measles control, introduction of new vaccines, injection safety etc. It provides recommendations for the consideration of Member countries of the WHO South-East Asia Region in their efforts to achieve the World Health Assembly endorsed Global Immunization Vision and Strategy (GIVS) goals.