The Establishment and Operation of National Immunization Technical Advisory Groups in the WHO South-East Asia Region
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Contents

Acknowledgements .............................................................................................................. v
Acronyms ............................................................................................................................ vi
Executive summary ............................................................................................................ vii
1. Introduction ....................................................................................................................... 1
2. Methods ............................................................................................................................. 3
3. NITAG establishment: timing and motivation ................................................................. 4
4. WHO-SEAR NITAG Operations .................................................................................... 7
5. NITAG Sustainability ...................................................................................................... 13
6. Challenges ........................................................................................................................ 16
7. Lessons learnt ................................................................................................................... 18
8. Support from partners ..................................................................................................... 19
9. Limitations of this report ................................................................................................. 21
10. Conclusion ....................................................................................................................... 22
11. Recommendations ......................................................................................................... 23
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### Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCD</td>
<td>Advisory Committee on Communicable Diseases</td>
</tr>
<tr>
<td>ACIP</td>
<td>Advisory Committee on Immunization Practice</td>
</tr>
<tr>
<td>AEFI</td>
<td>adverse events following immunization</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention (United States)</td>
</tr>
<tr>
<td>CoI</td>
<td>conflict of interest</td>
</tr>
<tr>
<td>CRS</td>
<td>congenital rubella syndrome</td>
</tr>
<tr>
<td>EBDM</td>
<td>evidence-based decision-making</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td>GVAP</td>
<td>Global Vaccine Action Plan</td>
</tr>
<tr>
<td>HPID</td>
<td>Health Policy and Institutional Development</td>
</tr>
<tr>
<td>IPV</td>
<td>inactivated polio virus vaccine</td>
</tr>
<tr>
<td>ITAG</td>
<td>Immunization Technical Advisory Group</td>
</tr>
<tr>
<td>ITSU</td>
<td>Immunization Technical Support Unit</td>
</tr>
<tr>
<td>IVI</td>
<td>International Vaccine Initiative</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
</tr>
<tr>
<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
</tr>
<tr>
<td>SEAR</td>
<td>South-East Asia Region</td>
</tr>
<tr>
<td>SEARO</td>
<td>South-East Asia Regional office</td>
</tr>
<tr>
<td>SIVAC</td>
<td>Supporting Immunization and Vaccine Advisory Committees</td>
</tr>
<tr>
<td>SoP</td>
<td>standard operating procedures</td>
</tr>
<tr>
<td>ToR</td>
<td>terms of reference</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Executive summary

Background: National Immunization Technical Advisory Groups (NITAGs) are independent committees that advise policy-makers on all immunization-related issues. By endorsing the Global Vaccine Action Plan (GVAP) 2011-2020 of the Decade of Vaccines at the World Health Assembly in 2012, countries have agreed to establish NITAGs by 2020 that conform to the international standards defined by WHO. In November 2015, the WHO South-East Asia Region (SEAR) became the second WHO region to have established NITAGs in all member countries. In April 2016, WHO-SEAR established a voluntary regional NITAG network, the first such network in the world. This report documents the experience to date of the WHO-SEAR countries in the establishment and operation of their NITAGs.

Methods: A questionnaire covering NITAG establishment, structure, process, function, operations, and sustainability was developed to gather information from the NITAGs on their experience of establishing and operating their committees. This questionnaire formed the basis of the report, and was augmented by a review of the published NITAG document, interviews and email follow-up on specific questions. The report is meant to provide insight into the overall experience of the NITAGs of the Region rather than formally assess the status of each committee. The lessons learnt and the contributions from external partners are also documented.

Establishment: WHO Regional Office for South-East Asia (SEARO) has played a pivotal role in facilitating the establishment of NITAGs in its Member States and in providing technical support to their functioning with the support of technical partners. Countries reported that WHO-SEARO’s support was a key factor in their motivation to establish a functional NITAG.

NITAG Operations: NITAGs have been in existence for decades in Sri Lanka and Thailand, while Timor-Leste established its committee as recently as November 2015. Therefore, there is a wide range of experience in the Region, as well as variation in the structure and policies of NITAGs. A key finding is that not all of the committees
have work plans and detailed manuals for operating procedures. For NITAGs to remain effective and fully operational, capacity building is required to standardize the processes used by NITAGs in the region to identify policy questions, evaluate and deliberate upon the evidence, and develop recommendation notes. Access to both scientific literature and external experts remain a struggle for NITAGs, which is exacerbated by the lack of local data in many of the countries in the region.

Sustainability: NITAGs in the Region are well integrated into the immunization-related policy-making systems in their respective countries. The committees and their members are valued, and the ministries of health look upon NITAGs for advice prior to making immunization-related decisions. One of WHO’s criteria for a functional committee is its independence from the Ministry of Health (MoH) and the immunization programme; however, many of the committees in the Region do not meet this criterion. This lack of independence could make the committees vulnerable to political changes and may impact the credibility of the NITAG. One of the key outcomes of a regional NITAG side meeting held during the Immunization Technical Advisory Group (ITAG) meeting in June 2015 was the recommendation to establish a network of NITAGs in WHO-SEAR. With a view to allowing countries to have a platform by which to share data and technical resources, such a network would also facilitate an exchange of experiences, and standardization of policies and procedures.

Lessons learnt: The experience of establishment of NITAGs in WHO-SEAR and their functioning could be valuable to countries in other regions that are still in the process of establishing their committees as well as for WHO and partners working to accelerate the implementation of functional NITAGs in other regions as recommended in the GVAP. The countries stressed the importance of a strong, dedicated Secretariat as a key factor for NITAG functioning. Committees’ functioning is improved by the selection of members that are interested in the committee and its work and find participation to be of value. It takes several years for the operations of the committee to run smoothly, and therefore patience is required in the initial phase of establishment.

Conclusion: Strong support from WHO-SEARO (particularly for the organization of orientation workshops), the SIVAC Initiative of the Health Policy and Institutional Development (HPID) centre and the United States Centers for Disease Control (CDC) facilitated this Region to reach its goal of establishing a NITAG in every country. Continued support will be required to strengthen their operations to meet the WHO standards for NITAG operations and to establish a fully functioning regional NITAG network to serve as a sustainable resource for the countries to support each other.
Sharing these lessons with all NITAGs will allow those still in the process of forming or strengthening their committees to benefit from the experience in the WHO-SEAR.

Key Recommendations for NITAGs:

1. Work with WHO-SEARO, SIVAC, or other appropriate partners to conduct an assessment of the status of their NITAG
2. Ensure that the nascent regional network of NITAGs meets twice a year

Key recommendation for partners: Continue, and potentially increase, support for the Region’s NITAGs to achieve adherence to the international norms for NITAG operations via capacity building, access to expertise/data, human resource support, and attendance at international meetings.
South-East Asia Region NITAG Network Consultative Workshop
7–8 APRIL 2016, Colombo, Sri Lanka

Training for the National Committee for Immunization Practices
12–14 October 2009, Kathmandu, Nepal
Introduction

With the increasing complexity in the field of Vaccine Preventable Diseases (VPDs), novel vaccine technology, higher costs of vaccines and competing health priorities, countries face challenges in decision-making with respect to the introduction of new paediatric and adult vaccines, as well as setting appropriate immunization strategies for the entire population. Immunization strategies and the decisions around them should be free from bias and based on evidence. WHO recommends that NITAGs\textsuperscript{1} be established in all countries to serve as the immunization-related advisory committees and issue evidence-informed recommendations to guide policy-makers. The presence of a NITAG is an indicator of countries’ commitment prioritization of immunization, and Member States committed themselves to establishing functional NITAGs by 2020 in the World Health Assembly resolution WHA65.17, adopted at the WHA65 in 2012.\textsuperscript{2}

WHO collects data on NITAGs and their functionality in the WHO-UNICEF joint reporting form\textsuperscript{3} and collaborates with partners, such as the United States’ CDC to facilitate their establishment and strengthening. The Health Policy and Institutional Development (HPID) centre a unit of Agence de Médecine Préventive (a WHO Collaborating Centre\textsuperscript{4}) is another partner that supports the establishment and strengthening of NITAGs through its programme, the Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative; SIVAC supports the establishment and strengthening of NITAGs\textsuperscript{5}.

\textsuperscript{1} The term NITAG will be used throughout this document, although these committees are known by other names in some countries, such as National Committee on Immunization Practice.
\textsuperscript{2} http://apps.who.int/gb/or/e/e_wha65r1.html, accessed 24 May 2016.
\textsuperscript{3} http://www.who.int/immunization/monitoring_surveillance/routine/reporting/reporting/en/, accessed [19 September 2016].
\textsuperscript{4} Headquartered in Paris, France, the HPID centre has activities and staff throughout the world. See http://amp-vaccinology.org/HPID for details, accessed [22 September 2016].
\textsuperscript{5} http://sivacinitiative.org/, accessed [19 September 2016].
A NITAG increases the credibility and transparency of the government immunization programme, leading to confidence among the population and country’s ownership of the decisions\(^6,7\). A well-functioning NITAG can be a key factor to help countries to achieve their immunization targets, as it enables a broad perspective on the entire immunization programme\(^6\). The WHO-South-East Asia Region has been declared polio free, has eliminated maternal and neonatal tetanus as per the current definition (less than one per 1000 live births in every district in every country), and is now focusing on measles elimination and rubella/congenital rubella syndrome (CRS) control by 2020, strengthening routine immunization, the introduction of new vaccines, ensuring the availability of safe and quality-assured vaccines, having effective VPD surveillance in place in all countries and strengthening the strategic planning, resource coordination.

As of November 2015, the South-East Asia Region had achieved its target of establishing a NITAG in all its member countries. The accomplishment of this goal was made possible with the support of WHO-SEARO and partners in motivating countries to establish NITAGs, communicating the value of such committees and evidence-based decision-making (EBDM), and facilitating orientation workshops to technically prepare countries to operate NITAGs.

This report documents the experience gained in the Region in the establishment and operation of NITAGs to date. The lessons learnt by these countries are valuable to share with those countries that are in the process of strengthening and refining their committees in this Region and globally. Further support from WHO and partners in the Region will enable these committees to function optimally and to begin to have lasting impact in their countries.

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Methods

The information reported in this document was gathered through a review of the published literature, interviews with the Chairs and Secretariats (and a few other key individuals in the case of India and Indonesia), based on a questionnaire, and email follow-up on specific issues. The questionnaire used the NITAG indicators defined in Blau et al. 2013\(^8\) as a starting point, and was divided into questions about NITAG establishment, NITAG structure and function (described in this report under operations), NITAG sustainability, facilitating factors and lessons learnt. In some cases, supporting documentation was provided in the form of committee charters, recommendation notes and meeting minutes.

This report was not intended to be an evaluation of each NITAG, but rather to provide an overview of the collective experience of the Region in the establishment and operation of NITAGs to date. Information collected on the indicators from individual countries should guide the conduct of future, detailed assessments of the status of NITAGs.

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NITAG establishment: timing and motivation

Sri Lanka and Thailand were the first countries in our Region to establish committees that served as NITAGs, and both did so in the 1960s. Sri Lanka’s NITAG, the Advisory Committee on Communicable Diseases (ACCD), was established in the 1960s and has the broadest mandate of NITAGs in the Region, covering vaccine-preventable as well as other communicable diseases (detailed in Wijesinghe et al., 2010\textsuperscript{9}). Thailand established its Advisory Committee on Immunization Practice (ACIP) prior to the existence of expanded programme on immunization (EPI) in the country to harmonize immunization practices (detailed in Muangchana et al., 2010\textsuperscript{10}). Since their inception, both the Sri Lankan and Thailand committees have evolved to adapt to the changing field of immunization and the local needs. India’s Ministry of Health and Family Welfare established the National Technical Advisory Group on Immunization (NTAGI) in 2001 to respond to the need of the immunization programme to have a mechanism by which to receive technical guidance (detailed in John et al., 2010\textsuperscript{11}). The majority of countries in the Region, including Bangladesh, Bhutan, DPR Korea, Indonesia, Maldives, Myanmar and Nepal established their NITAGs between 2007 and 2009. Timor-Leste’s established its NITAG in November 2015, bringing the Region to 100% of Member States with established NITAGs (see Table 1).

Table 1 indicates the year of establishment/reconstitution of NITAGs and summarizes their status with respect to indicators such as having a legislative basis, playing an advisory role only and having formal terms of reference.


\textsuperscript{11} John, T.J. India’s National Technical Advisory Group on Immunisation. Vaccine 2010;28(S):A88-A90.
Table 1: The year of NITAG establishment/ reconstitution and status with regard to playing an advisory role only, having a legislative basis and formal terms of reference

<table>
<thead>
<tr>
<th>Indicator</th>
<th>BAN</th>
<th>BHU</th>
<th>DPRK</th>
<th>IND</th>
<th>INDO</th>
<th>MAL</th>
<th>MYM</th>
<th>NEP</th>
<th>SRL</th>
<th>THA</th>
<th>TLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advisory role only</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Formal ToR</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Legislative Basis</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Availability of All expertise</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NR</td>
<td>NR</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>No. of Meetings 2015</td>
<td>1</td>
<td>NR</td>
<td>1</td>
<td>1</td>
<td>7</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Agenda &amp; documents distributed prior to meetings 2015</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Members requested to disclose CoL</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

Source: 2015 JRF EPI/MoH (Y-Yes, N-No, NR- Not reported- CoL- Conflict of Interest, ToR- Terms of Reference)
The countries that established their NITAGs from 2007 onwards were motivated to do so by global, regional and local factors. Apart from a general strengthening of decision-making, countries were motivated to establish committees to address specific issues such as the risk of polio importation (e.g. Bangladesh), anticipating that NITAG would help the country establish new vaccine policy more efficiently (e.g. the Maldives) and transparently (e.g. Sri Lanka), while mitigating the influence from external pressures (e.g. Nepal, Sri Lanka and Thailand). As mentioned above, WHO has strongly encouraged its Member States to utilize NITAGs as a means of strengthening immunization programmes and achieving the goals set out in the GVAP. These countries frequently cited encouragement from WHO-SEARO as a key motivating factor for committees’ establishment. WHO-SEARO further facilitated the establishment of NITAGs by explaining the role of the committee to MoHs, which sometimes expressed concern that their authority would be replaced by the NITAG, and orienting the members themselves to their roles on the committees.

Table 1 contains the year in which each committee in the Region was established/reconstituted and summarizes their status with respect to the following process indicators: having a legislative basis, playing an advisory role only and having formal terms of reference. The NITAGs of all countries in the WHO South-East Asia Region have formal terms of reference and they play an advisory role only and have a legislative/administrative basis. It is noteworthy that while the ToR of Bhutan’s NITAG were approved by the MoH, the Charter had not been formalized at the time of the writing of this report. Sri Lanka is the only committee in the Region to make the implementation of the committee’s recommendations legally binding. In Bangladesh, although the ToRs for the committee are defined, in practicality, the NITAG has focused solely on new vaccine introduction decisions and could broaden its scope to include monitoring of and recommendations to strengthen the immunization programme.

<table>
<thead>
<tr>
<th>Hurdle overcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thailand’s NITAG faced a hurdle to its functioning that it has found a way to overcome. It was a challenge to establish a balance in the committee between a public health perspective (which is best for most people) and an individual-centric view (which is best for individuals). To manage this situation, they carefully chose members to balance the perspectives and regularly conduct forums for exchange between different partners.</td>
</tr>
</tbody>
</table>
WHO-SEAR NITAG Operations

In order to achieve its stated objectives, a NITAG should have clearly stated policies pertaining to the procedures and operations of their committees. As elaborated below, the standard operating procedures should be formalized, and include policies on conflict of interest (CoI) and confidentiality; the use of working groups and a work plan; independence from the government; and the function of the Secretariat.

A manual on internal processes, often referred to as standard operating procedures (SoPs), and a work plan are two important tools of an effective NITAG. A comprehensive manual of the SoPs ensures transparency, consistency and adherence to international standards. The SoP manual sets out the rules and procedures for both the establishment and operation of a NITAG. It should contain an overview with the definition and ToR of the NITAG, a section outlining in detail the operations of the committee and a section describing NITAG’s budget and potential funding sources. All of the topics that should be included in the SoPs have been described in detail in Duclos et al. (2010). SIVAC recommends that countries review and revise their SoPs approximately every 5 years (as specified in the country’s SoPs) in line with the changing international or national immunization context. While many of the countries in the Region have not had their SoPs in place long enough to contemplate revising them, India has had SoPs in place since 2013, and has also recently updated them. The Thailand NITAG, despite being one of the oldest in the Region, does not yet have formal SOPs, though the committee is considering establishing them. Many of the countries (Bangladesh, Bhutan, Indonesia, Maldives, Myanmar, Nepal and Sri Lanka) have developed a combination Charter/SoP document, which has served them well in the initial phases of operation, and while each one is unique, they generally lack detail in some areas. Ideally, these countries would expand their SoPs to specify, for example, the process by which agendas and work plans will be prepared, the process by which decisions will be made (i.e. voting versus consensus), details related to

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12 This section will not include Timor-Leste due to its NITAG’s recent establishment. Great progress has been made towards the finalization of this NITAG’s operating documents (i.e. operating manual, work plan and budget), but they were not in existence at the time of the drafting of this report.
the meetings’ conduct (e.g. selecting rapporteur, declaration of interests, etc.), the guidelines for working group operations, and a plan for monitoring and evaluation of the committee’s functioning.

A conflict of interest policy is generally laid out in the SoPs. It is considered a critical component of a NITAG, as WHO has included it in the 6 basic criteria that describe a functioning NITAG. Conflicts of interest can be either personal or based on an individual’s institution, and specific to the topic of discussion or general. It is ideal if members do not have any interests that might present a conflict, but it may not be practical to exclude everyone with any interests, especially in smaller countries with limited numbers of experts. Therefore, it is critical that any potential interests be openly declared and that the CoI policy explicitly states how conflicts will be handled. The Chair and Secretariat should provide guidance as to when a member should recuse themselves from discussion and voting on a particular topic. SIVAC recommends that members declare their interests in writing at the start of each year, and verbally at the start of each committee meeting.

Several countries in the South-East Asia Region are yet to formalize a policy on CoI in their SoPs. Bhutan and Thailand consider the interests of potential NITAG members prior to their selection; however, it may be impractical to exclude all those with interests from participation in the committee, and it does not address the possibility that a member will develop an interest after joining the NITAG. In a few countries, although there is a CoI policy in place, it is not followed in practice (i.e. interests are not declared at the start of meetings as per the policy). The Maldives has a particularly strict policy that stipulates that members with interests must resign from the committee. Reassuringly, most of the countries in the WHO-South-East Asia Region reported that conflicts of interest had not posed a challenge to date in their NITAG operations; however, there are many nuances to consider in individual cases, and all members could benefit from periodic refreshers on their NITAG CoI policy.

Confidentiality is also a policy generally defined explicitly in the SoPs. To date, many of the countries in the Region (Bangladesh, Bhutan, Democratic People’s Republic of Korea, Nepal and Sri Lanka) have been relying on their members’ judgement to keep sensitive information confidential, which is a potential risk. Some

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13 SIVAC 2015 NITAG Training Catalogue: Building capacity of national immunization technical advisory groups (NITAGs).
committees, such as the US ACIP, have meetings that are open to the public and the evidence considered in recommendations is available to all, but it is important to have a clear confidentiality policy if unpublished data will be presented (e.g. by manufacturers) or if other privileged information will be discussed in the meetings.

Table 2 summarizes the 2014 status of WHO-SEAR NITAGs with respect to indicators related to membership, standard operating procedures and policies, and meetings held. As WHO recommends that NITAGs meet at least once per year, NITAGs that did so were recorded as having met this criterion. With respect to the indicator on the declaration of interests, for the purpose of this report, rather than record only whether a conflict of interest (CoI) policy is in place, a country was listed as having met the criterion if interests were declared in 2014, either at the start of the year or prior to each meeting, as per the country’s policy.

**Table 2: NITAG indicators related to structure, process and function**
(as described in section 4. WHO-SEAR NITAG Operations):
status of South-East Asia Region countries

<table>
<thead>
<tr>
<th>Indicator</th>
<th>BAN</th>
<th>BHU</th>
<th>DPRK</th>
<th>IND</th>
<th>INO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-core members</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Rules for rotation of core members</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Clearly defined SoPs</td>
<td>Lack detail</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Chair independent of MoH</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Number of meetings 2014/2013/2012</td>
<td>1/1/1</td>
<td>3/2/1</td>
<td>1/1/1</td>
<td>** 4/5/3</td>
<td></td>
</tr>
<tr>
<td>Agenda &amp; background materials distributed 1 week in advance</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Members declared interest (2014)</td>
<td>Y</td>
<td>Y</td>
<td>Y*</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Confidentiality policy</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Work plan (at least for 6 months)</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

*Reported declaring interests despite no Conflict of Interest policy
**Standing sub committee meets frequently; full committee meets once per year

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Some NITAGs use working groups to gather and analyse data and synthesize them into a format to be presented for discussion at the NITAG. Usually only a few core members serve on a working group, and subject-matter experts, either ex-officio, liaison, or external, are called upon to provide input. The use of working groups can reduce the workload of members, and also broadens the expertise consulted in a recommendation by inclusion of more individuals in the process of data analysis and synthesis. In the WHO-SEAR, Bhutan, Indonesia, Maldives, Sri Lanka and Thailand convene topic-specific working groups. Both Bangladesh and India use a distinct format, in which a subsection of the full committee serves as a standing subcommittee that addresses each topic prior to its presentation to the full committee. The Democratic People’s Republic of Korea, Myanmar and Nepal have not used working groups to date.

The process of developing a work plan increases a committee’s effectiveness by necessitating strategic planning, and facilitates a shift from NITAG being a reactive group called upon as issues arise, to a proactive body that can help the country set and define immunization policy. As a tool, a work plan supports NITAG functioning, through the inclusion not only of the scientific topics to be addressed by the committee, but also activities to strengthen the capacity of the NITAG, activities related to logistics and administrative matters, and activities to monitor

<table>
<thead>
<tr>
<th>Indicator</th>
<th>MAV</th>
<th>MMR</th>
<th>NEP</th>
<th>SRL</th>
<th>THA</th>
<th>TLS</th>
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<tr>
<td>Non-core members</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>Rules for rotation of core members</td>
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<td>Y</td>
<td>Y</td>
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<tr>
<td>Clearly defined SoPs</td>
<td>N</td>
<td>Lack detail</td>
<td>Lack detail</td>
<td>N</td>
<td>N</td>
<td>Y**</td>
</tr>
<tr>
<td>Chair independent of MoH</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
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<tr>
<td>Number of meetings 2014/2013/2012</td>
<td>2/1/1</td>
<td>1/1/1</td>
<td>2/2/2</td>
<td>4/5/4</td>
<td>1/3/2</td>
<td>N/A</td>
</tr>
<tr>
<td>Agenda &amp; background materials distributed 1 week in advance</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<td>Y</td>
</tr>
<tr>
<td>Members declared interest (2014)</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N/A</td>
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<tr>
<td>Confidentiality policy</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y**</td>
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<tr>
<td>Work plan (at least for 6 months)</td>
<td>N</td>
<td>N</td>
<td>N*</td>
<td>Y</td>
<td>Y</td>
<td>Y**</td>
</tr>
</tbody>
</table>

*Nepal has had in the past. Currently developing one
**Timor Leste documents have been finalised; awaiting for MoH’s approval
(Y-Yes, N-No, N/A Not applicable)
The NITAG’s performance and advocate for resources. A complete work plan has three parts: a narrative description of the objectives and activities, a timeline and an operating budget. Ideally, a work plan should cover at least one year, yet only half of the countries in WHO-SEAR currently have a work plan in place for at least 6 months: Bangladesh, Democratic People’s Republic of Korea, India, Indonesia, Sri Lanka and Thailand. Nepal has had a work plan in the past and both Nepal and Timor-Leste are working on theirs currently. Overall, the Region could strengthen its NITAGs by developing and utilizing work plans that go beyond the topics on which recommendations are requested.

WHO considers independence from the MoH to be another criterion that a NITAG must meet to be classified as functioning. A fundamental characteristic of a NITAG is that it is free from any influence that would bias the decision-making process; therefore, those individuals who advise the Government (NITAG members) should not be the same people responsible for the implementation of policies. A NITAG Chair that also serves as a Senior Official in the MoH could result, for example, in the topics addressed by the NITAG being limited to those that are of interest to the Government, or recommendations themselves could be biased towards an outcome favoured by the immunization programme. In the South-East Asia Region, about half of NITAGs are led by individuals with positions within the MoH and about half are chaired by individuals who do not report to the MoH. Some of the countries whose committees are not independent reported that MoH officials do not exert influence on the committees: in some committees, officials only open the meeting and, in others, the officials do not vote or participate in the drafting of recommendations. However, it was acknowledged by others that the Chair could influence the committee by virtue of his/her position in the MoH. Sri Lanka, on the other hand, consider having the NITAG led by a member of the MoH to be a facilitating factor for the implementation of the recommendations. In some countries, launching the NITAG under the supervision of the MoH may have accelerated the process; they may now consider revising the leadership structure to move away from Chairs that report to the MoH.

One function that is often provided by the MoH for the NITAG is secretarial support. The Secretariat is often led by the head of the EPI programme in the MoH, and is responsible for the administrative duties related to the NITAG meetings, as well as preparation of the background materials and managing the working groups, when applicable. Many countries recognized that support of the Secretarial was one of the most important factors for NITAG’s success; while some reported that they had sufficient support from their Secretariats, others felt that their Secretariats needed more
resources to provide support, and that their Secretariats could benefit from capacity-building. Democratic People’s Republic of Korea reported that its committee does not have a dedicated Secretariat. India’s NITAG is unique in that its Secretariat is housed outside the MoH (with reporting to the MoH), at the Immunization Technical Support Unit (ITSU), which was founded to provide technical and managerial support for the entire EPI programme, and which has an evidence-to-policy unit whose mandate is to synthesize data for evidence-based immunization policy decisions. Experts in the country noted the success of this Secretariat model, and the extent to which it has improved NITAG’s functioning.

With regard to membership, one area of struggle for some of the smaller countries in the Region is having a diversity of expertise upon which to draw. Bhutan, Maldives and Timor-Leste, for example, do not have enough experts to rotate committee members, and Maldives is sometimes unable to meet quorum for meetings. Other countries face a lack in a particular specialty: Bangladesh does not have a microbiologist on the committee, Myanmar needs an immunologist and Nepal would like to have a health economist available to serve as a member. WHO and other partners could help (as they have done in the past) by facilitating access to appropriate experts until such local expertise has been developed.

Data considered for decisions and implementation of recommendations

Data were provided by Democratic People’s Republic of Korea and Myanmar on the number of recommendations issued in 2014 that referred to peer-reviewed data were based on local data and took vaccine availability and programme capacity into account. While both were able to reference peer-reviewed data and consider vaccine availability and programme capacity, there were no local data in Democratic People’s Republic of Korea for the topic on which a recommendation was issued. The single recommendation issued by the committee in Democratic People’s Republic of Korea in 2014 was accepted by the MoH and implemented, and three of the four, issued by the NITAG in Myanmar, have been implemented (the fourth, administration of inactivated polio virus vaccine (IPV) to travellers, has not yet been recommended at the global level).

A NITAG must be fully integrated into the immunization decision-making process to be considered sustainable. Markers of integration include a legal basis for the committee’s existence and its terms of reference (addressed above under ‘establishment’), a financial provision in the MoH budget to support the committee’s operations and the MoH and other immunization stakeholders valuing the contribution of the committee.

In the WHO’s South-East Asia Region, most NITAGs are well integrated into the immunization decision-making process, and are very closely linked to the MoH. Five of the eleven (Bangladesh, India, Myanmar, Sri Lanka and Thailand) NITAGs in the Region have Chairs who are officials in the MoH. Sri Lanka and Thailand are considering changing their committee’s structure so that their respective Chairs become independent. Of the other NITAGs, some have Chairs who are also government employees and may therefore not act entirely independently. Such close ties between MoHs and NITAGs of the Region result in less autonomy and make the committees vulnerable to political change; however, the close association is a positive factor for the sustainability of these committees. The financial sustainability of each committee was not addressed in this report, but based on a broad enquiry into the financial status of each, there is a range of commitment to funding NITAGs’ activities; for example, Bhutan’s NITAG does not represent a major burden to the country, but the Maldives struggled to secure financing for the committee for 2016. India has an innovative, efficient Secretariat structure, but it is the only country in the Region to currently receive external funding to support the Secretariat, and there has not yet been a commitment to continue this support from domestic sources.

All countries in the Region reported that NITAGs were valued by the MoH and other immunization stakeholders. Such value can be demonstrated by the MoH’s requesting NITAGs to issue recommendations on particular topics, by the MoH not making immunization-related decisions without consulting the committee, and

16 This section excludes Timor-Leste, as its NITAG had just been established at the time of the drafting of this report.
by the MoH and other professional organizations implementing the committee’s recommendations (Blau et al. 2013; see Table 3 for country-specific details). Generally, the ministries of health in the Region call upon their respective NITAG whenever there is an immunization policy issue to be analysed. The NTIAGs are viewed as a resource for the often resource-strapped ministries of health whose staff have many other responsibilities. Most countries reported that the MoH has not made immunization-related decisions without consulting the NITAG. One exception was the introduction of a stock of donated Hepatitis B vaccine in the national immunization programme of Myanmar. Myanmar reported that the MoH did come to them with this issue later, and is confident that such a situation would not arise in the future. Apart from Sri Lanka (where the MoH is obligated to implement the committee’s recommendations), the other countries also reported that the ministries of health have implemented the vast majority of their recommendations, with a few exceptions in the Maldives and Thailand for financial reasons, and one recommendation in Bhutan, where further study may be requested regarding influenza vaccination for high-risk groups.

Apart from the indicators of integration that can be measured, countries described the reasons that the committees are valued, and the ways in which their existence has made the decision-making system more transparent, thereby increasing confidence in those decisions. A few examples include Bhutan, where the NITAG was valuable in finalizing the investigation and crisis response to the adverse events following immunization (AEFI) observed following the introduction of DTP-HepB-Hib (pentavalent) vaccine in 2009. Serving as a face to the public in stakeholder meetings and to justify the government’s decisions were cited by Myanmar and the Maldives as important functions of the committee members, increasing transparency of the decisions and trust of the public. In the Maldives, the NITAG provided technical advice to facilitate the introduction of new vaccines, and new vaccine introduction has been accelerated since its formation. India noted that, previously, disparate bodies for different topics existed, but the NITAG has integrated all immunization-related issues into one committee, which has strengthened the immunization programme overall. Nepal appreciates its committee because it brings together a diversity of perspectives and sources of information, and has found that conducting the process of evidence-informed decision-making has made the members better public health practitioners. When the committee members themselves feel they are valued, the sustainability of the NITAG increases. The legally binding nature of the recommendations in Sri Lanka contributes to the members feeling valued. Myanmar places much importance on the selection of members that are interested in active participation as a way of adding to the sense of value in the group.
There is a strong participation from local immunization stakeholders in the Sri Lankan NITAG meetings. In Nepal, the professional organizations approach the NITAG for guidance on immunization related matters. In Myanmar, the medical association disseminates NITAG recommendations to its members. In Thailand, the NITAG has wide support among the government agencies, but has found that academics struggle to understand the balance that the committee must strike between the best decision for all versus the best decision for an individual.

Overall, NITAGs in the Region are integrated into the immunization decision-making infrastructure of their respective countries and well positioned to be sustained as advisory bodies. There are a few outstanding questions about the financial stability of some of them, and as some NITAGs move towards more independence from the MoH, they will need to ensure that the committees continue to be valued by the MoH to ensure their sustainability.
Challenges

Few countries reported difficulty establishing their committees, but one challenge identified was explaining the value of evidence-based decision-making (EBDM) to NITAG members, who had previously only been accustomed to giving expert opinion. Through active engagement of the Chair, demonstration on the part of the MoH officials of the value of EBDM, an increase in global attention on NITAGs and interaction with international partners in immunization, members’ perceptions changed to an appreciation of EBDM. A number of challenges were identified that impede the efficient and effective functioning of the Region’s NITAGs. Most importantly, the majority of committees lack a standard process by which the policy issue being addressed is framed, the appropriate evidence is identified and evaluated, and the dossier is prepared, deliberated and a recommendation decided upon. The recommendation notes were also reported to lack structure and not elaborate on the supporting evidence used in the decisions. These areas can be addressed by capacity-building by partner organizations for the secretariats, as well as the members. Indonesia emphasized the need for its technical staff to receive capacity-building, and Bhutan reported the need for access to external expertise, which could be facilitated by WHO, as it has done for other countries. Myanmar expressed an interest in having its NITAG members attend conferences or have other exposure to international associations to increase their knowledge and stay up-to-date on global advances in the field. Some countries such as the Maldives and Sri Lanka reported a lack of local data on which to base decisions, and would benefit from external support to fund studies.

Increased networking and awareness of the advances in the immunization field internationally would address the concerns of many countries. India and Thailand both reported that their members would benefit from increased awareness of the activities taking place at the meetings of the Strategic Advisory Group of Experts on Immunization (SAGE), as well as learning from their processes. All of the participants at the NITAG side meeting that took place at the regional ITAG meeting in June 2015 were very supportive of the idea of launching a regional network to share
experiences, data and best practices between committees and their secretariats. It was suggested that a regional resource centre be established that could facilitate the generation and evaluation of local evidence. Another issue that NITAGs face is access to the scientific literature for evidence, which is not unique to NITAGs. This problem must be addressed at a global level to enable countries to take full ownership of their public health decisions.

In April 2016, 23 participants representing NITAGs (including chairs and secretariats) from 8 countries of the 11 of the WHO-South-East Asia Region (Bhutan, India, Indonesia, Maldives, Nepal, Sri Lanka, Thailand and Timor-Leste) met in Colombo, Sri Lanka to discuss the establishment of a Regional NITAG Network as a platform for regular opportunities to share experiences and exchange information with the aim of enhancing the technical capacities of all NITAGs and their functioning. The call for the creation of the network was based on the acknowledgment that NITAGs in the Region face common needs and challenges related to availability of technical expertise, access to up-to-date information and strengthening capacity. Sri-Lanka ACCD was elected as the chair. The creation of the Network was endorsed at the WHO-South-East Asia Regional Immunization Technical Advisory Group during its meeting held in New Delhi, India from 6-10 June 2016.
Lessons learnt

Despite the challenges that have been identified in the Region, it is quite an accomplishment to have an established NITAG in every country. The lessons learnt in the Region may facilitate the establishment of NITAGs in countries in other regions that have yet to do so. Facilitating factors for NITAG establishment and success that countries identified were country ownership and willingness of the MoH; legal standing of the committee; a dedicated secretarial staff; institutional integration; acceptance of the committee by all stakeholders; and selecting members who actively participate. Multiple countries brought up the issue of communication. Communication of committee decisions and sharing of data with relevant stakeholders were identified as important success factors in Indonesia. Myanmar found that improved communication with members about the immunization programme and strategy, and providing technical updates, made members feel valued and resulted in more active participation. Sri Lanka also listed members feeling valued as an important factor in achieving a well-running NITAG. Myanmar cautioned that it took a few years for members to learn their roles and the committee to function well; therefore, other countries should be prepared for it to take a few years for the NITAG to run smoothly. Initial investment in orienting the members and the Secretariat to their roles on the committee, the inclusion of capacity-building in the work planning process, as well as developing communication strategies to guide interactions with various stakeholders, and elaborating a monitoring/evaluation plan provide committees with a strong base for their operations. Support for these and other strengthening activities is available for NITAGs from WHO and other partners.
Support from partners

Some countries in the South-East Asia Region have already received technical support from partners; since 2008, three partners have made significant contributions to the experience of the Region in establishing and operating NITAGs: the United States’ CDC, the HPI centre’s SIVAC Initiative and WHO-SEARO.

One of the unique features of NITAG establishment in the WHO South-East Asia Region was the individualized attention countries received from WHO-SEARO. With the exception of India, Sri Lanka, Thailand (whose NITAGs were established earlier) and Democratic People’s Republic of Korea (whose NITAG was formalized independently), by mid-2016, every other country will have had a 3-day orientation workshop led by WHO, with additional support from SIVAC, in collaboration with the International Vaccine Initiative (IVI) and CDC in some cases (e.g. Bhutan, Nepal). In these orientations, countries were given an overview of global immunization status and goals, told of the experience of NITAG establishment in other WHO-SEAR countries and introduced to immunization stakeholders the relationship between them and the structure and function of NITAGs. In every workshop, almost 100% of NITAG core members were in attendance, and it was often the first opportunity that these stakeholders had to spend three days together discussing immunization issues. Participants worked together over the course of the orientation to draft a charter for their own NITAG, which gave them a strong sense of ownership. For many countries, this was the first time that the conduct of a meeting related to health had been formalized. Another key component of the workshops were the practical exercises, originally developed by CDC and adapted to each country, which were designed to give participants the chance to openly discuss their real-life experiences. Countries identified this intensive level of support as one of the key factors for the successful establishment of their committees. As a specific example, Nepal credits the orientation workshop with helping the committee prioritize issues and become less reliant on recommendations made at the global level by learning the in-depth analysis process required for decision-making.
Following their establishment, SIVAC has provided technical support to NITAGs and secretariats in India, Indonesia and Nepal, and is currently discussing collaboration with Sri Lanka. SIVAC and IVI collaborated with Indonesia and Nepal to strengthen their NITAGs’ operating processes, introducing them to the best practices for issuing evidence-based recommendations, supporting secretariat staff, organizing study tours and facilitating attendance at vaccinology courses. In India, SIVAC has provided informal guidance to the Indian NITAG Secretariat on the development of its operating policies, and the Secretariat participated in a training of trainers on NITAG strengthening. SIVAC and the Indian NITAG Secretariat are currently defining the scope of a more formal collaboration. WHO has provided technical support to the NITAGs in our Region, often in the form of access to topic experts to many countries. Throughout the Region, SIVAC and WHO are collaborating to identify the countries that require additional or ongoing support to strengthen their processes.

Through the support of WHO and SIVAC, members of NITAGs and secretariats have been invited to participate in regional and global activities to further their understanding and awareness of NITAG operations and immunization priorities at those levels. Select members and secretariats from Indonesia and Nepal went on study tours to visit the well-established NITAGs in Australia. The participants shared experiences and learnt about the preparation of background materials and the conduct of meetings to generate ideas on how to improve their committees. In addition, participation of the Chairs of Bhutan, Indonesia, Myanmar, Nepal, Sri Lanka and Thailand NITAGs at SAGE meetings in Geneva was supported. Since 2010, WHO-SEARO has been inviting the Chairs of NITAGs to the regional ITAG meeting, which allows them to stay abreast of immunization issues throughout the Region and serves as a link to the regional network of NITAGs.
Limitations of this report

Several limitations of this report should be noted. Some information presented is based solely on the responses to the questionnaires and during interviews, not all documentation was provided (e.g. it was not possible to verify the existence of work plans in specific counties as the work plans themselves were not provided). There was a range of fluency in English in the interviewees and questionnaire recipients. Therefore, more details and examples may have been included from those countries with greater English language skills, and this report should not be considered an exhaustive representation of the experience of each country.
Conclusion

NITAGs are considered critical by WHO and are key to countries making evidence-based decisions and taking ownership of their vaccination policies. Lessons learnt through the establishment and operating of a NITAG can be applied to other areas of health policy. In 2015, WHO-SEAR accomplished its target of having a NITAG established in every Member State. Now that these NITAGs are established, there is work to do in strengthening the operation of the committees and to fostering a regional resource network to facilitate their work. A thorough assessment of each NITAG, as recommended by Blau et al. 2013 will be critical to identify the needs of NITAGs in the coming years. Through the provision of technical support at the individual country, subregional and regional levels, WHO-SEARO will continue to have a key role in linking the work of the individual countries to the regional targets as well as in the maturation of the committees.
Recommendations for NITAGs:

- Work with WHO-SEARO, SIVAC or other appropriate partners to conduct an assessment of the status of their NITAG, including an evaluation of whether the activities carried out by the committee match those listed in the terms of reference, the diversity of membership, independence of the committee with respect to leadership and also potential impact of the committee’s independence or lack thereof from the government.

- Ensure that members of the nascent regional network of NITAGs meet twice a year and share experiences and information to strengthen the Region in a collaborative fashion. Topics to cover include the following:
  - Thai experience of piloting new policies;
  - experience of using working groups to address specific topics;
  - Indian Secretariat model;
  - possibility of regional experts contributing to other countries’ deliberations when specific expertise is lacking.

Further recommendations for NITAGs (if consistent with the findings from the suggested assessment):

- develop an annual work plan for those committees lacking one;
- extend the charter documents to detailed standard operating procedures, including policies on confidentiality and conflict of interest;
- train members on conflict of interest and confidentiality (and periodic refresher trainings);
• consider revising the structure of the committees, in which the Chair reports to the Ministry of Health;
• build the capacity of secretariat and members on evidence-based decision-making, development of communication strategies and other topics as identified in the assessments.

Recommendation for partners: Continue, and potentially increase, support for the Region’s NITAGs to achieve adherence to the international norms for NITAG operations via the following:

• capacity-building;
• provision of topical experts;
• attendance of NITAG members and secretariats at meetings of WHO Strategic Advisory Group of Experts on Immunization (SAGE) and of other NITAGs;
• support for the establishment of a regional network of NITAGs and, potentially, a regional resource centre;
• support for increased human resources in secretariats, where a gap is identified during assessments;
• facilitation of access to funding for local studies;
• facilitation of access to scientific literature;
• other means of support that may be identified in the detailed assessments; and
• use of the regional Immunization Technical Advisory Group as a mechanism to track the status of the Region’s NITAGs.

Establishment of NITAG in Timor-Leste

With the establishment of the NITAG in Timor-Leste in November 2015, the South-East Asia Region achieved its target of having active NITAGs in all of its countries. The TL NITAG was established by a ministerial decree issued on 10 November 2015 by the Honourable Minister of Health, Dr Maria Saramento da Costa. The role of the committee was defined as providing recommendations to the MoH to ensure that immunization policy development is evidence-based and transparent. The Chair of the committee is a paediatrician, Dr Viarna Martins, who is the current Chairperson of the Timor-Leste Medical Association and National Committee for the Certification of Polio Eradication and Measles Elimination.
An orientation workshop was held in Timor-Leste from 23 to 25 November, 2015, whose objectives were to discuss the rationale for and role of the NITAG, the mechanism by which NITAGs operate, the information required for evidence-based decision-making, and the coordination between the various national immunization stakeholders. The workshop introduced the tools for NITAG functioning, including its work plan and charter, and covered topics such as the operating policies on membership, conflict of interest, confidentiality and the use of working groups.

The workshop was opened by the Honourable Minister of Health, and attended by over 20 participants, including the seven core members, 13 non-core members, the WHO Country Representative, WHO Country Medical Officer-EPI, the Mozambique NITAG Chair and representatives from WHO-SEARO, SAGE and SIVAC. The workshop accomplished the following: (1) orientation of NITAG members on the structure and functioning of NITAG; (2) development of a NITAG operational manual; (3) development of a 2015-2016 work plan; and (4) identification of next steps.