EVALUATION OF NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUPS (NITAG) IN SOUTH EAST ASIA REGION

Prepared for World Health Organisation, SEAR

The INCLEN Trust International

Evaluation of National Immunization Technical Advisory Group (NITAG) in South East Asia Region

Submitted to

World Health Organisation, South East Asia Region, New Delhi

Undertaken by

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Period of Evaluation

October 2019- June 2020

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Acknowledgements

The Evaluation Team gratefully acknowledges the contribution of the NITAG Chairpersons, NITAG members, national immunization programme managers and the NITAG Secretariat teams of the Member States/countries in the WHO South-East Asia Region for sharing the critical information, responding to the issues discussed and making this evaluation true learning experience for all of us.

The team highly values the contribution of the in-country immunization partners for their facilitation and providing their perspectives.

The team is highly appreciative and thankful of the opportunity and the assistance extended by the IVD Team of the WHO Regional Office for SEA and WHO national immunization focal persons from WHO country offices to accomplish the evaluation task.

List of abbreviations

AEFI	Adverse Event Following Immunization
cMYP	Comprehensive multiyear plan,
cVDPV	Circulating vaccine-derived poliovirus
EPI	Expanded program on immunization
GVAP	Global Vaccine Action Plan
HPV	Human papilloma virus
HSS	Health system strengthening (fund from Gavi)
ICC	Inter-agency Coordinating Committee
JE	Japanese encephalitis
MCV	Measles-containing vaccine
MCV1	First dose of measles-containing vaccine
MCV2	Second dose of measles-containing vaccine
MOH	Ministry of Health
NCCPE	National Certification Committee for Poliomyelitis Eradication
NIP	National immunization programme
NITAG	National Immunization Technical Advisory Group
NRA	National regulatory authority
NVC-MR	National Verification Committee for measles and rubella
PCV	Pneumococcal conjugate vaccine
SOP	Standard operating procedures
RCV	Rubella-containing vaccine
RVAP	Regional Vaccine Action Plan
SAGE	Strategic Advisory Group of Experts on immunization
SEAR	South-East Asia Region
SIVAC	Supporting National Independent Immunization and Vaccine Advisory Committees
TOR	Terms of reference
VPD	Vaccine preventable disease
WHA	World Health Assembly
WHO	World Health Organisation

EXECUTIVE SUMMARY

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Background

National Immunization Technical Advisory Groups (NITAGs) are considered critical for the countries to strengthen national processes of independent, evidence-based, transparent and credible decision making for immunization programmes. WHO South East Region (SEAR) was the second region to have established NITAGs in all the countries. Sri Lanka and Thailand were the initial member states of the region to have NITAG equivalent committees in 1960 and 1967 respectively. The Indian NITAG was established in 2001. During the period 2006-2013, six more countries established the NITAGs. Timor-Leste formed NITAG in 2015. Bangladesh National Committee of Immunization Practices (NCIP) was working since 2008 and re-structured to NITAG in 2019.

The immunization program coverage in the region has shown notable progress during last decade. In 2018, eight countries had achieved ≥90% national coverage with DPT3, two countries >80% and one was nearing 80%. The region achieved the goal of polio eradication in 2014. All countries have sustained the maternal and neonatal tetanus elimination status. As of 2018, five countries have been verified for elimination of endemic measles and six countries have controlled rubella and CRS. During last 5 years, member states have introduced several newer vaccines either nationally or sub-nationally. SEA Region has met polio eradication, MNT elimination and new vaccine introduction related goals of Global Vaccine Action Plan 2010 - 2020 and Regional Vaccine Action Plan 2016-2020.

To document the status of the NITAGs and their contribution to the immunization programs in the member states, WHO SEAR planned an external and independent evaluation of the NITAG's in the region. The scope of work for the evaluation of NITAGs in the region included:

- Review the contribution of NITAGs in advising MOH and national immunization program on policies and strategies relating to vaccination, in recommending new vaccines introduction and immunization schedule changes through evidence based process.
- Review NITAGs contribution in monitoring national immunization programmes in achieving SEAR-RVAP goals and other outcomes on NIP goals.
- Identify country-specific priority actions to strengthen NITAGs in providing guidance to the national immunization programmes.
- Formulate a set of generic lessons learned and recommendations on NITAGs for consideration of national governments and WHO Regional office to sustain the gains, accelerate and innovate to achieve the global, regional and national immunization targets.

Methodology

This evaluation was conducted by a six member team during October 2019 and June 2020. Mixed methods were used for the evaluation including desk review of the relevant documents from the countries and WHO SEAR and interactions/interviews with the key stakeholders including NITAG members and other stakeholders related to the immunization program through either country visits (five countries) or web/tele-conferences (six countries). The reference period for evaluation was 2016-2019. A total of 85 interviews with key stakeholders were conducted across these countries. Information collected through interviews from each country were included to a summary checklist.

Findings

Functionality of NITAGs as an Agency (Intention, Power and Rationality)

Most of the in-country stakeholders perceived new vaccine introduction as the key mandate of the NITAGs. Performance of the national immunization programs and implementation challenges were frequently discussed in the NITAG meetings. The NITAGs across the region had cumulative score of over 75%; the scores on structural viability, functional viability and productivity were also similarly high. All the NITAGs in the Region have legislative basis or have been established by a government order and are advisory in nature. Formal TORs and SOPs/internal procedure manuals were available for all but one; TOR of new NITAG in Bangladesh was awaiting approval from Ministry. The number of NITAG members varied widely between the countries, from 5 to more than 30 members and up to 57 members in one country. The NITAGs of four countries (Bhutan, Maldives, Nepal and Timor-Leste) lacked availability of the expected expertise as members. Seven NITAGs had independent chairpersons and four countries (India, Sri Lanka, Thailand and DPR-Korea) had senior health administrator as the chairperson. The tenure of membership usually ranged 3-5 years. Most of the NITAGs conducted 2-4 meetings annually, except India, which conducted only one meeting annually. In nine countries, members were asked to declare the conflicts prior to each meeting, and two sought annual declarations. Working groups for specific themes were available in six countries. Dedicated secretariat was available for three NITAGs (India, Indonesia and Thailand). National budget was fully funding the NITAG activities in six countries (Bhutan, India, Indonesia, Maldives, Sri Lanka and Thailand) and partially in three countries (Bangladesh, DPR-Korea and Timor-Leste) with part contribution from WHO and completely by WHO (from the Gavi HSS funds) in the remaining two countries (Myanmar and Nepal). There were multiple committees looking after different aspects of national immunization programs in the countries (like NCCPE, NVC-MR, AEFI committee and interagency coordination committee), but the formal linkages with the NITAG was observed in only three countries (DPR-Korea, Myanmar and Sri Lanka). A systematic approach to synthesize evidence was used by six NITAGs to make decisions. Annual work plan was prepared and followed for seven countries. The NITAG minutes were published on website for public display in India alone.

The functionality statuses of the NITAGs are summarised in Table 1.

Integration with the policies and programs of the immunization sector

NITAGs as an institution and its membership enjoyed high credibility and standing among the policy makers and decision makers. The recommendations from NITAGs were considered crucial by the national immunization program managers and policy makers for taking decisions on key immunization issues including immunization schedule and introduction of new vaccines. There was however limited involvement of the NITAGs in the systematic review of the routine immunization program and national efforts to improve the coverage. In almost all countries, there were no clear dynamics and or mechanisms for translation of the NITAG decisions/recommendations and feedback thereof. For effective integration and bundling, there were systemic mechanisms for co-implementation of UIP and programs like maternal and child health and communicable diseases in four countries (Bangladesh, Indonesia, Maldives, and Nepal) where the program managers or division leaderships of related programs were adequately represented in the committees. National Regulatory Authority (NRA) was part of the NITAGs in six countries (Bhutan, DPR-Korea, India, Maldives, Sri Lanka

and Thailand) as ex-officio members. NITAGs in general had limited orientation towards the vaccine development and research activities in their respective countries.
The WHO teams from region and country facilitated establishment of country NITAGs, supported capacity building of the members and provided technical assistance. In six countries WHO representative were members of the committee, special invitees in three countries and not involved in two countries. Unicef also played an important role of technical partner for the NITAGS. The Global NITAG Resource Centre was infrequently used by the members from the countries that required hand holding and technical support. None of the NITAG had considered the life-course immunization approach as part of their agenda and had limited orientation towards the immunization agenda 2030 (IA 2030).

Engagement/partnership and linkages with the regional and global agencies
The NITAG members and program managers highly valued the review and feedback by Regional ITAG on the annual program reports and guidance. The NITAGs were leveraging ITAG feedback and recommendations to guide the national programs. The country NITAGs were appreciative of the technical support from WHO SEAR team and the facilitation to identify appropriate technical expert/consultants and funding sources.

Conclusions
Based on the evaluation, it can be concluded that:

- NITAGs played a key role in supporting and advancing the national immunisation agenda. The recent introduction of new vaccines and improvements observed in the immunization coverage in the members states and region can be attributed to a significant extent to the active participation of the NITAGs in the country policy making processes.
- The level of evolution, competency, operations and governance mechanism of NITAGs varied across the member states but all the NITAGs in the SEA region are functional and scored over 75% in the functionality score (Table 1).
- The quantitative checklist is important for assessing overall performance of the NITAGs but could not identify important differences in their structure and productivity between the countries. Based on the quantitative checklist and subsequent qualitative assessment (formal and informal interactions with in-country stakeholders), the NITAGs could be categorised into three maturity and functional levels:
    - **Level 1: Sri Lanka and India**
        - The NITAGs in Sri Lanka and India have membership with diverse technical expertise, established processes for functionality and demonstrated productivity that resulted in smooth translation of the recommendations.
        - Sri Lanka: The NITAG's (ACCD) expanded mandate, technical expertise, alignment and integration the maternal-child and infectious diseases programs make the committee highly productive.
        - India: The NITAG's technical expertise, innovative organisation with dedicated secretariat enables the committee to be functional and productive.
    - **Level 2: Thailand, Nepal, Bangladesh, Indonesia, Myanmar and DPR Korea**
        - The NITAGs in this category meet most of the functionality requirements but have limitations in some domains that could be captured only after in-depth and informal interaction with stakeholders. The NITAGs in Thailand, Nepal and Bangladesh face challenges from structural aspect. The NITAGs

in Indonesia and Myanmar have functional challenges. DPR Korea NITAG has independence related challenge.

- Thailand: The immunization and vaccine governance and decision making in Thailand appears to be structurally comprehensive. But, the complex decision making processes delay translation of the NITAG's technical decisions into programmatic action. This affects the functionality and productivity of the NITAG, and eventually the immunization program.
- Nepal: The NITAG in Nepal is governed by the Immunization Act, which limits the membership and thereby influences the functionality and decision making. The recent episode of abrupt NITAG reconstruction without ensuring continuity poses an additional risks for the functionality and productivity.
- Bangladesh: The NITAG has suitable technical composition and shown efforts for functionality and productivity within a short period of its existence. The ToR and roles of the NITAG and working relationship with the existing NCIP needs to be elucidated and demarcated to avoid possible conflict.
- Indonesia: The NITAG has demonstrated efforts for improving the functionality in recent past. But the functionality and productivity of NITAG is affected by the additional layer of endorsement by the religious body and the program implementation in the decentralised political governance framework.
- Myanmar: The NITAG has been doing a good job and has composition and processes to make it functional and productive. The NITAG members are involved in the program. The committee need to stick to the advisory role and keep a distance from the program planning and implementation activities.
- DPR Korea: The NITAG is led by the national immunization program manager, which is a conflicted state and challenges the independence of the committee.

- **Level 3: Bhutan, Maldives and Timor-Leste**
  - The NITAGs in these countries face the challenges related to availability of suitable technical expertise and relevant capacity for evidence based decision making. Nevertheless, available experts were optimally engaged in these countries.

- Independence of the NITAGs: The WHO guiding document on NITAG states independence as "the absence of a direct or indirect supervisory relationships within the immunization program, or ideally, within the larger Ministry of Health". Four NITAGs in SEAR member states are chaired by senior health administrators. Sri Lankan and Indian NITAGs were considered most mature and productive with smooth policy and programmatic translation of their decisions. The NITAG in Thailand has also track record of effective functioning but for recent challenges of decision making financial allocations, the implementation of decision have been delayed. DPR Korea is the only NITAG where the Chairperson also heads the immunization program and indicated severe conflict of interest.

  The findings suggested that complete independence of the NITAGs is desirable for its functionality and productivity of NITAGs. However, several examples from the SEAR

member states also demonstrated that when the majority of the membership is independent, having a Chairperson from government may not affect the performance and on occasions can facilitate acceptance and smooth implementation of the recommendations.

- There is now need for further strengthen and empower the NITAGs in the region for achieving country specific targets, SEAR Vaccine Action Plan and Immunization Agenda 2030 goals and objectives. Support of dedicated NITAG-secretariats and competent team may be important to achieve these objectives.
- The SEAR WHO will have to play a critical role in facilitating the implementation of the proposed recommendations and further improve the functioning of NITAG in the member states.
- Evaluation tools: As mentioned above, the currently available checklists capture primarily the quantitative aspects of the structure, functionality and productivity domains. The qualitative tools and guides used in the study for interactions with in-country stakeholders were valuable complementary strategy for capturing the local governance processes and its influence on the maturity and functionality of individual NITAG performances.

Table 1: Functionality summary status of the NITAGs in the SEA region

Sl no	Domain	Indicator	Items assessed	BAN n (%)	BHU n (%)	DPR-K n (%)	IND n (%)	INDO n (%)	MAL n (%)	MYN n (%)	NEP n (%)	SL n (%)	THA n (%)	TL n (%)
1.1	Structural viability	Establishment of NITAG	3	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)
1.2		ToR for NITAG	9	8.5 (94)	8.5 (94)	9 (100)	9 (100)	9 (100)	8.5 (94)	7.5 (83)	8 (89)	8.5 (94)	6 (67)	9 (100)
		Sub-total Structural viability	12	11.5 (96)	11.5 (96)	12 (100)	12 (100)	12 (100)	11.5 (96)	10.5 (88)	11 (92)	11.5 (96)	9 (75)	12 (100)
1.3	Functional viability	Roles of NITAG	4	3.5 (63)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)
1.4		SOP for NITAG	19	17 (89)	15 (79)	17 (89)	17 (89)	17 (89)	14 (74)	11 (58)	13 (68)	16 (84)	16 (84)	17 (89)
1.5		Composition of NITAG	5	3.5 (70)	3.5 (70)	3 (60)	4.5 (90)	3 (60)	4.5 (90)	5 (100)	4.5 (90)	5 (100)	5 (100)	4.5 (90)
1.6		CoI declaration policy	6	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	3.5 (58)	1.5 (25)	6 (100)	6 (100)	6 (100)	6 (100)
1.7		Independence	2	2 (100)	2 (100)	1 (50)	1 (50)	2 (100)	2 (100)	2 (100)	2 (100)	1 (50)	1 (50)	2 (100)
1.8		Adherence to meeting frequency & timing	4	4 (100)	4 (100)	4 (100)	3.5 (88)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)
1.9		Work plan and execution	6	5.5 (92)	5 (83)	6 (100)	6 (100)	6 (100)	5 (83)	6 (100)	6 (100)	6 (100)	5 (83)	6 (100)
1.10		Access to data and resources	6	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)
1.11		Secretariat	7	0.5 (7)	0.5 (7)	6 (86)	7 (100)	5 (71)	1 (14)	4.5 (64)	1 (14)	6 (86)	7 (100)	5.5 (79)
1.12		Funding and sustainability	2	1 (50)	2 (100)	2 (100)	2 (100)	2 (100)	2 (100)	1 (50)	1 (50)	2 (100)	2 (100)	2 (100)
		Sub-total Functional viability	61	48 (79)	48 (79)	55 (90)	57 (93)	55 (90)	46 (75)	45 (74)	47.5 (78)	56 (92)	56 (92)	57 (93)
1.13	Productivity	Background document preparation	3	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	1.5 (50)	1.5 (50)	3 (100)	3 (100)	3 (100)	3 (100)
1.14		Meeting minute and documentation	4	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	3.5 (88)
1.15		Decision making procedure followed	3	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)
1.16		Consultation by MOH	6	5.5 (92)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)
1.17		Impact of NITAG recommendations	10	3 (30)	6 (60)	6 (60)	7 (70)	4 (40)	6 (60)	6 (60)	5 (50)	6 (60)	6 (60)	6 (60)
		Sub-total productivity	26	18.5 (71)	22 (85)	22 (85)	23 (88)	20 (77)	20.5 (79)	20.5 (79)	21 (81)	22 (85)	22 (85)	21.5 (83)
Grand Total			99	78 (79)	81.5 (82)	89 (90)	92 (93)	87 (88)	87 (88)	76 (77)	79.5 (80)	89.5 (90)	87 (88)	90.5 (91)

Recommendations

The recommendations are grouped under generic recommendations for the member states/countries, specific recommendations for the countries and for the WHO SEAR.

A. Generic recommendations for the member states/countries

- **Further strengthen the governance and functioning of NITAGs in the SEAR**
    - The region has a mix of NITAG leadership: NITAG chair is either a senior government functionary (4 countries) or an independent expert (7 countries). There was no observable difference in the functionality and performance of the NITAGs of the two types.
        - The WHO regional office and the countries need to take a balanced view of how the independence and transparency in decision making processes of NITAGs are maintained and carefully document the functionality of NITAG with different governance structures in the region.
    - The national governments should provide a dedicated budget line item for NITAGs to further their ownership and commitment.
        - The budget should adequately support the work by the NITAG and its Working Groups, capacity building including attendance at global, regional and workshops/meetings, inclusion of outside experts as needed, and
        - The member states should consider establishing or strengthening the secretariat by allocating at least one dedicated professional with expertise in epidemiology and vaccinology.
    - There is need for focus on capacity building of the NITAG members
        - In the field of public health, epidemiology and vaccinology, program implementation and evidence synthesis.
        - In-view of the challenges faced by the NITAGs in several countries related to the cost effectiveness analysis and vaccine hesitancy, inclusion of experts from health economics and social science/anthropology/communication should also be considered.
        - The countries should consider establishing a mentorship program for younger professionals who can be groomed to be inducted in to the NITAG at the appropriate time.
        - The experience of twinning of one NITAG with another more mature NITAG (refer Timor-Leste) may be tried on a larger scale.
- **Inclusion of structured monitoring and evaluation of National Immunization program review as an important mandate** for NITAGs with provision of feedback and follow up action at different levels
    - Members from across the NITAGs emphasized the need for including monitoring and evaluation of the immunization program as part of their TOR.
    - Special attention is needed for monitoring and evaluation of the program performance in urban, inaccessible and conflict/disturbed areas.
    - The NITAG's report to the Regional ITAG should include the observations from review of national immunization program and the country's progress towards achieving IA 2030 targets.

- **Integration and collaboration between different national immunization and VPD advisory committees:** The member states should consider inclusion of the Chairpersons of the other immunization and VPD advisory and monitoring committees like NCCPE, NVC for Measles-Rubella, and AEFI-surveillance as ex-officio members to establish formal linkage between these committees and NITAG for smooth information and activity sharing.
- **Improving transparency and accountability of NITAG:** The member states should consider making the decisions and recommendations by the NITAG publicly available after approval by Ministry.
    - The background papers and scientific reviews for key decisions should be placed on the website or submitted for publication in the scientific literature.

B. Specific recommendations for the member states/ countries

i. Bangladesh

- The TORs and roles of the NCIP (National Committee of Immunization Practices) and NITAG needs to be elucidated and demarcated to avoid duplication and possible conflict.
- Special attention for implementation and monitoring of the immunization program in urban areas is needed where NGOs are playing a critical role. This will require greater and effective collaboration between the immunization program and the NGO sector with facilitation and monitoring from NITAG.

ii. Bhutan

- In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership.
- The NITAG coordinator in the EPI Secretariat should be either from medical or public health background for more effective support to the functioning of NITAG.

iii. DPR-Korea

- NITAG should consider tenure based rotation of core members and establish a program for mentoring next generation of multi-disciplinary team for the NITAG.
- For greater independence and transparency of decision making, the chairperson of the NITAG should be other than the national EPI manager.
- .
- NITAG should work with MOPH for streamlining and strengthening the national NRAs and induct NRA representative in to NITAG.

iv. India

- Review the structure of the NITAG: The country may consider merger of the Standing Technical Sub-Committee (STSC) and two Standing Working Groups into one functional technical body (Technical NITAG) that can oversee and guide the technical work of the NITAG. Ad-hoc working groups could continue to be established as needed. The current NITAG can be designated as the Executive

NITAG that leads the policy decision-making based on the recommendations made from the technical arm of the NITAG.
    - Review the composition of the Technical NITAG and Executive NITAG in the context of the proposed refinement of roles and strategic direction.
    - Consider having the Executive NITAG meet at least twice a year or more frequently as needed.
    - Not all members of the Technical NITAG would need to attend the meetings of the Executive NITAG.
- Consider the inclusion of persons with implementation and programmatic expertise, representatives from one or two States, civil society, health economist and social scientist to the NITAG.
- Considering the emergence of India as a vaccine manufacturing hub including new vaccines, the NITAG needs to give attention for the vaccine research, post-licensure surveillance and national regulatory agency function.
- Strengthen the secretariat team by including at least one person with expertise in epidemiology and modelling. Other experts could be contracted as needed.

v. Indonesia

- The political and administrative setup of the country along with NITAG and NRA should work out strategies that help to de-link availability, access and use of life saving drugs, and biologics including vaccines from the religious screening and approvals and protect scientific decisions for the larger public good.
- NITAG should continuously review emerging issues of vaccine hesitancy including that due to religious screening and approvals and develop strategies to overcome these.
- Decentralization is a welcome political process for increasing the community participation and decisions making on issues related to their daily lives. Developmental issues like creating infrastructure and income generation schemes are likely to override and be given greater emphasis over preventive and promotive health care services and education. Provincial and local self-governments should receive and allocate dedicated resources for immunization program. In addition, they need constant guidence, capacity building and persistent reminders about the health benefits, social and economic consequences, and sustainability of immunization services.

vi. Maldives

- In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership. While acknowledging that there is a dearth of in-country expertise, training of the existing members and future members in specific issues such as health economics and social sciences should be considered.
- NITAG needs special attention to emerging challenges of vaccine hesitancy and work with other stakeholders to overcome these.
- The minutes of NITAG meetings should contain adequate details reflecting key discussions and issues considered for decision making.

vii. Myanmar

- The NITAG should maintain a healthy distance from the EPI program implementation.
- Leveraging on the experiences from high risk areas, the NITAG could advise for integration of maternal and child health services with immunization to improve the coverage and acceptance of UHC.
- The role played by the NITAG in designing and execution of innovations implemented in the high-risk areas to be documented and shared with other member states in the region.
- NITAG should adopt written conflict of interest declaration and mention accordingly in the SOP.
- NITAG should advise the Ministry of Health on increasing the NRA's role and preparedness for post-GAVI phase.

viii. Nepal

- The NITAG which has been established by an act of Parliament has limited number of members. The Government should consider bringing in appropriate flexibility in the Immunization Act related to the NITAG membership and operations to expand membership and accommodate additional members with suitable technical expertise.
- The NITAG's TOR and rotation and/or extension of membership should be specified in a manner ensuring that the total membership of the committee is not changed simultaneously.
- Decentralization is a welcome political process for increasing the community participation and decisions making on issues related to their daily lives. Developmental issues like creating infrastructure and income generation schemes are likely to override and given greater emphasis over preventive and promotive health care services and education. Provincial and local self-governments should receive and allocate dedicated resources for immunization program. In addition, they need hand-holding, capacity building and persistent reminders about the health benefits, social and economic consequences, and sustainability of immunization services.

ix. Sri Lanka

1. The experiences of NITAG (ACCD) focusing on communicable diseases mandate beyond immunization should be documented and shared with other countries in the region.

x. Thailand

- NITAG and EPI program needs to give special attention for implementation of immunization program in urban areas and among populations with vaccine hesitancy.
    - Better data sharing and coordination mechanisms among the Ministry of Public Health and the Bangkok Metropolitan Area are required.
- Current complex decision making processes and release of finances in relation to the immunization program and NITAG need review at political and bureaucratic levels for simplification.

- Partner organisations like WHO and Unicef should closely coordinate their technical assistance and interact with NITAG.

xi. Timor-Leste

- In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership.
- The innovations introduced for integration of primary health services with immunization including use of IT platform need to be used as case study for its operational feasibility and application in different contexts.
- The experience of twinning of one NITAG with another more mature NITAG (Australia) needs to be well documented for wider use.
- NITAG should advise the MOH on streamlining the NRA's role and preparedness for post-GAVI phase.

C. Recommendations for the WHO SEAR

i. Platform for learning and sharing: The WHO should create a platform for sharing the lessons and best practices adopted by the NITAGs in member states for cross learning.

- Create a web platform for posting the programmatic innovations and experiences- create NITAG network, update NITAG Resource Centre and encourage the members to use
- Conduct capacity and skill building workshops for NITAG members (not only chairs and EPI managers)

ii. Guidance for NITAGs: WHO should work with NITAGs and regional ITAG to develop guidance framework of national immunization monitoring, evaluation and providing structured feedback

iii. Strengthening NITAGs in the region: The regional office should explore and facilitate the capacity building of the NITAGs and their functionality:

- Facilitate twinning between the NITAGs in the region
- Decision making based on evidence synthesis and interpretation of cost effectiveness data- through preparation of resource documents and guidelines and workshops

iv. Revision of the NITAG evaluation tools

- There is need to review the currently available tools (quantitative checklist) for NITAG evaluation and prepare the next versions that enables differentiation between the NITAGs at different levels of functionality and productivity levels. Two sets of NITAG evaluation tools may be considered:
    - First, for self-evaluation by the NITAGs at periodic intervals, which can be reviewed by the Regional ITAG to guide and recommend appropriate action.
    - Second, for external and detailed evaluation of the NITAGs addressing both the quantitative and qualitative aspects.

DETAILED REPORT

Section 1

1. Background and context for the evaluation

Immunization is one of the most cost-effective public health interventions. The immunization scenario today comprises of ever growing number of vaccines, advocacy for expanding age groups to include the adolescents and elderly and induction of newer technologies for vaccine manufacturing and administration. The global and local epidemiology of vaccine preventable diseases (VPDs) has become a dynamic process with massive travel and globalization. Several of the newer vaccines are expensive and their introduction into the national immunization programmes (NIP) leads to multi-fold increase of the national vaccine budgets posing serious financial challenges. Most national health systems face financial constraints and have to decide amongst several competing priorities to maximise health benefits to the communities. Decision making for introducing new vaccines, rationalize schedule for the existing vaccines, and expansion of immunization services to new age groups and special populations are some of the constant challenges for national programs. The programmatic capacity for making for these decisions is limited for majority of the countries considering the complexities of VPDs, vaccines and available evidences.

1.1. Global Context

The first strategic objectives of WHO Global Vaccine Action Plan 2011–2020 stated that 'All countries commit to immunisation as a priority' and the key indicator for this objective as 'presence of a legal framework or legislation that guarantees financing for immunization and the presence of an independent technical advisory group that meets defined criteria' (2). In the World Health Assembly resolution WHA65.17, adopted at the WHA65 (2012), the Member States committed themselves to establish functional NITAGs by 2020 (3). World Health Organisation (WHO) recommends that a group of experts make locally appropriate, evidence based decision and recommendations to the Ministry of Health (MoH), policy makers and program managers in an independent and transparent manner. This groups has been named as National Immunisation Technical Advisory Group (NITAG) (1).

The presence of a NITAG is an indicator of country commitment for immunization as priority health intervention. For the NIP, NITAG is a critical technical resource and advisory body to guide the national authorities on policies and programmatic strategies for evidence-based decisions. The NITAGs are also expected to support and advice the national authorities through regular monitoring of the routine immunization program. Establishing and strengthening NITAGs is critical for making informed decisions about the introduction and financial sustainability of new and under-utilized vaccines.

In April 2017, the Strategic Advisory Group of Experts on immunization (SAGE) of WHO acknowledged the significant progress towards establishment of NITAGs in member states across the regions, stressed the need for collaboration at regional and global level and called on partners, donors, and countries to evaluate NITAGs to tailor their functions to contextual needs and identify gaps to fulfil the NITAG mandate (4). The SAGE recommendations were further reinforced by the 2017 WHA's resolution, requesting the Director General to support the Member States in strengthening NITAG to achieve national immunization goals.

1.2. WHO Regional Context

The WHO-South-East Asia Region (WHO-SEAR) was declared wild virus polio free in 2014, has sustained maternal and neonatal tetanus eliminated status, and is progressing towards measles elimination and rubella/congenital rubella syndrome (CRS) control. Newer vaccines like rotavirus vaccine (RVV), pneumococcal conjugate vaccine (PCV), human papilloma virus (HPV) vaccine are being progressively introduced by the member states in the region. For sustaining the advances in the immunization sector made during the last 5-10 years in WHO-SEAR, there is need for further reinforcing evidence based decision making and strategy planning in the countries. Presence of functional NITAGs demonstrate ownership and commitment, increase the credibility of decisions made for the immunization programmes, and which in turn leads to confidence building among the population and external bodies (1).

WHO SEAR Immunization and Vaccine Development (IVD) unit has facilitated and supported establishment and operationalization of the NITAGs in in the region. By 2015, the NITAGs (or equivalent committees) were established in all the eleven countries of the WHO SEAR. With establishment of the Bangladesh NITAG in 2019, all the countries have the functional NITAGs in true sense. The WHO SEAR IVD unit collaborates closely with the WHO country offices, to coordinate with NITAGs and provide technical support on all aspects of immunization and vaccine preventable diseases to the member states, including performance of the NIPs, introduce new vaccine and accelerate control of vaccine preventable diseases by developing and implementing national plans and promotion of capacities for sustainable improvements in alignments to the Regional Vaccine Action Plan (RVAP) goals (6). NITAGs are sending yearly reports in a structured format developed by IVD to Regional Immunization Technical Advisory Group, ITAG members review these reports, NITAG chairpersons present the reports in the ITAG meetings. These reports provide important information for ITAG to propose recommendations.

1.3. Functional NITAGs

Definition of a functional NITAG is not straight forward as several contextual and governance factors have to be taken in to account to arrive at any conclusion. Nonetheless, functional NITAG is essential for the country as part of the GVAP and SEAR RVAP. Since 2008, initiative for Supporting National Independent Immunization and Vaccine Advisory Committees (SIVAC) at Agence de Médecine Préventive or AMP in close collaboration with the WHO and other partners has been working to accelerate and systematize the establishment of NITAGs in low- and middle-income countries. SIVAC supported countries to establish advisory groups, and helps existing NITAGs to strengthen their capacity in the use of evidence-based processes for decision-making aligned with international standards. The initiative has been able to engage NITAG stakeholders and technical partners for the development of set of indicators to assess the effectiveness of NITAGs (7)(8). A list of 17 process, output and outcome indicators was developed and tested in 14 countries to determine the relevance, feasibility, usefulness (8). Based on the findings, a revised version of the indicators has been proposed for self-assessment in the countries, as well as for global monitoring of the NITAGs. In 2016, SIVAC and AMP prepared a tool for evaluation of the NITAGs (8). In 2018, US CDC developed a simplified assessment tool based on the WHO guidance and field experience of partners, which can be used either for a self-assessment or an externally conducted assessment to determine the NITAG's functionally, quality of work processes for development of evidence-based recommendations (9).

The performance of national immunization programs and disease elimination activities in WHO-SEAR have been commendable and attracted global attention. NITAGs were considered to have contributed significantly to these achievements.NITAGs in all the WHO SEAR member countries have been in existence for over five years in 2019 and ready to meet the indicators of being functional NITAGs by 2020. NITAGs are expected to contribute to make evidence based policy decisions on advancing the national immunization agenda, immunization system strengthening, elimination of vaccine preventable diseases and new vaccine introductions at the country level and technical support needed to further strengthen this endeavour. IVD at SEAR decided to determine the role NITAGs have played in contributing to improvements observed in the immunization programs of the member states. WHO SEAR planned for an external and independent evaluation of the NITAG's function in the WHO-SEA region to identify the unique strengths and understand gaps of NITAGs in general and country specific issues that could potentially help in refining their processes and initiate tailored country specific support.

1.4. Scope of the evaluation

The scope of work for the evaluation of NITAGs in the region included the following:

- Review the contribution of NITAGs in advising MoH and national immunization program on policies and strategies relating to vaccination, in recommending new vaccines introduction and immunization schedule changes through an evidence based process.
- Review NITAGs contribution in monitoring national immunization programmes in achieving SEAR-RVAP goals and other outcomes on NIP goals.
- Identify country-specific priority actions to strengthen NITAGs in providing guidance to the national immunization programmes.
- Formulate a set of generic lessons learned and recommendations on NITAGs for consideration of national governments and WHO Regional office to sustain the gains, accelerate and innovate to achieve the global, regional and national immunization targets.

Section 2

2. Methodology

A six-member evaluation team was constituted. The team members had longstanding and sound experience in the fields of research, evaluation, program and policy related to immunization and vaccine safety with understanding of the global, regional and national immunization program and policy perspectives including NITAG functions. Secretariat support was provided by the Immunization and Vaccine Division, WHO Regional Office for South-East Asia and the respective country offices that were visited.

2.1 Activities time frame

This activity was undertaken during October 15, 2019 – June 30, 2020. The timeline was affected by the global COVID-19 pandemic.

Table 2: The timeline of the activities for the NITAG evaluation

Time period	Activities
October 15- November 30, 2019	Desk review Communication with the countries
December 15- February 10, 2020	Country visits to five countries (Thailand, Bhutan, India, Indonesia and Myanmar)
January 23 – April 15, 2020	Teleconferences and interactions with stakeholders for the six countries not visited (Bangladesh, Maldives, Nepal, Sri Lanka, Timor-Leste, and DPR-Korea)
April 16- June 30, 2020	Discussion and report drafting Debriefing with the WHO SEAR Team
June 30, 2020	Submission of report

2.2 Process of evaluation

Mixed methods were used for the evaluation exercise: (i) desk review of the relevant documents from the countries and WHO SEAR office and (ii) interactions/interviews with key stakeholders including the NITAG members and other stakeholders related the immunization program through either country visits (five countries) or web/tele-conferences (six countries). The reference period for evaluation was 2016-2019.

2.2.1. Desk review of relevant documents

- *Country NITAGs:* Composition/membership, terms of references (TORs), Standard Operating Procedures (SOPs) or Internal Procedures, legislation or ministerial decree for formation of NITAG, annual work plans, annual progress reports to Regional Immunization Technical Advisory Group (R-ITAG), meeting minutes and recommendations made by the NITAG during the reference period;
- *Country immunization program:* Comprehensive multiyear plan (cMYP), immunization coverage and fact sheets, coverage evaluation survey reports and other relevant documents;
- *Regional and global documents:* South East Asia Regional Vaccine Action Plan (SEAR-RVAP), ITAG recommendations, Global Vaccine Action Plan (GVAP) and SAGE documents on NITAG.

Based on the review of literature and available tools for the NITAG's function and evaluations, the team drafted *a questionnaire and checklist for obtaining information from the NITAGs.* The questionnaire and checklist was shared with the country NITAG and EPI team for obtaining the desired information and relevant documents.

2.2.2. Interviews/interactions with the key stakeholders

- *Development of the interview guide:* Based on the desk review, an in-depth interview (IDI) guide for interview/interaction with the key stakeholders was prepared.
- *The interviews/interactions* with the key stakeholders were done to understand the barriers, facilitators and strengths of the NITAGs and their operation in the specific country context. The interviews/interactions were conducted in-person during country visits or through web/teleconferences to gain an in-depth understanding of the processes and progress made.
    - Five country visits were made (Bhutan, India, Indonesia, Myanmar, and Thailand).
    - Web-meetings/teleconferences were conducted with the stakeholders from five countries (Bangladesh, Maldives, Nepal, Sri Lanka and Timor-Leste).
      No web/teleconference could be undertaken with DPR-Korea NITAG due to logistic challenges and the information was collected through email.

During the country visits or through web/teleconferences, the team members conduct in-depth interviews with the key stakeholders involved with the NITAG including NITAG chair, core NITAG members, Secretariat team, EPI program manager, Director of Public Health, administrative leadership/Secretary (wherever feasible), health financing division (wherever feasible), and key partners (WHO and UNICEF). The IDI guide was used and observations from the desk review were referred for obtaining relevant information.
The number of interviews conducted across the different countries are given in Table 3.

Table 3: The in-depth interviews conducted with the key stakeholders in countries

Country	Number of interviews	Country	Number of interviews
Bangladesh	8	Myanmar	10
Bhutan	8	Nepal	6
DPR-Korea	NA (by email)	Sri Lanka	6
India	14	Thailand	10
Indonesia	13	Timor-Leste	5
Maldives	5		

Thus a total of 85 interviews with key stakeholders were conducted. For DPR-Korea no interview could be conducted, the feedback from the stakeholders were obtained through email on the IDI guide. The information obtained were summarized and included in a summary checklist for each country. They are included section six of this report.

2.3. Analysis and presentation of observations

The information and data collected through the desk review and interviews with the stakeholders were synthesized under the following headings:

- Country specific observations and recommendations
    - The findings were summarized under four major domains: Functionality; Integration with national program and policies; engagement with national and international stakeholders; and innovations or challenges

    - Specific recommendations
- Summary for the SEA region and recommendations
    - Summary observations for the region
    - Generic recommendations for the countries and WHO SEAR

The observations for the NITAGs were summarised under four themes:

2.3.1. The functionality of NITAG as an agency focusing on the intention, power and rationality

- Structural organisation and viability
- Functional capacity (composition, ToRs, competence, independence, execution, transparency and confidentiality)
- Conduct of meetings (agenda setting, discussions, decisions & documentation)
- Secretariat capacity and functions
- Sub-committees and working groups
- Linkages with the other standing committees related to immunization program: National Certification Committee for Poliomyelitis Eradication (NCCPE), National Verification Committee - Measles and Rubella elimination (NVC-MR), Adverse Event Following Immunization (AEFI) Committee, Interagency Coordinating Committee (ICC), etc.
- Process of review and quality of analysis and quality of outputs
- Orientation towards program financing

2.3.2. Integration with the policies and programs of the immunization sector

- Integration with the immunization program
- Linkages with the vaccine development
- Interaction and engagement with decision makers
- Sustainability and accountability

2.3.3. Engagement/partnership and linkages with the regional and global agencies

- Engagement with WHO, Unicef and other global agencies
- Interaction and collaboration with regional ITAG and SAGE
- Collaboration with the NITAGs in the region and outside

2.3.4. Innovations/ aberrations

- Special efforts at for improving the function of NITAG or immunization

Section 3

Observations: Regional Summary

3.1 NITAGs and Immunization Programs

3.1.1 ***Journey of the NITAGs in SEAR till 2019*****:** All countries in the SEA region have established NITAGs. Sri Lanka and Thailand were the first in the region to establish NITAG equivalent committees in 1960 and 1967 respectively. The Indian NITAG was established in 2001. During 2006-2009, Indonesia, Nepal and Bhutan constituted the NITAGs to support their national immunization programs. During 2012-13, three more countries, DPR-Korea, Maldives and Myanmar constituted the NITAGs. Finally, Timor-Leste in 2015 and Bangladesh in 2019 formed the NITAGs. Although Bangladesh formed the NITAG formally in 2019, she had the National Committee of Immunization Practices (NCIP) established in 2008. With the passage of time and recognizing its important advisory role, the Sri Lankan and Thailand committees have evolved to adapt to the changing field of immunization and the country needs. Similarly the India's NITAG has advanced in structure and function to better fulfil its national mandate.

3.1.2 ***Status of the immunization programs in SEAR:*** The immunization coverage in the region has shown significant progress with 6 out of 11 countries (Bangladesh, Bhutan, DPR Korea, Maldives, Sri Lanka and Thailand) having achieved 90% or more coverage for all infant vaccines in 2018. Eight countries (Bangladesh, Bhutan, DPR Korea, Maldives, Myanmar, Nepal, Sri Lanka and Thailand) had achieved ≥ 90% national coverage with DPT3 and coverage in remaining three countries was 89% (India), 83% (Timor-Leste) 79%(Indonesia). The regional MCV1 (89%), MCV2 (80%) and RCV (83%) was also over 80%. As of end-2019, all countries in the Region were administering two doses of MCV and RCV (as MRCV) in their routine immunization programmes. The JE vaccine was used in six countries, nationally in four (Myanmar, Nepal, Sri Lanka and Thailand) and sub-nationally in India and Indonesia. Birth dose of Hepatitis B vaccine (HBV) is given in 8 countries (Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Thailand, and Timor-Leste). The HBV3 coverage in the region was >90% in eight countries (Bangladesh, Bhutan, DPR Korea, Maldives, Myanmar, Nepal, Sri Lanka, Thailand). The coverage status for the various vaccines in 2018 under the national immunization program are summarised in Table 4.

Table 4: Status of immunization coverage (%) for vaccine doses under national immunization program in the countries

Vaccines	BAN	BHU	DPR-K	IND	INO	MAL	MYN	NEP	SLK	THA	TL
BCG	114	99	96.1	90	93.7	100	90	96	96	95.2	94.7
HBV-0	NR	96*	98.4	75	91.6	100	7	-	-	95.8	66.2
DPT-3/ Penta3	114	99	97.1	87	93.2	99	91	91	96	90.1	83
OPV-3	116	98	98.6	85	94.8	99	91	91	96	90.2	83
PCV-2/3	115	-	-	44	-	-	91	82	-	-	-
IPV-1	117	43	64.8	79	-	99	82	-	97	88.2	80
IPV-2	91	-	-	74	-	-	-	-	96	-	-
MCV-1	115	98*	98.2	86	93	100	93	91	97	89.4	83.3
MCV-2	113	94*	98.7	73	67.9	99	87	69	98	86.5	54.4
JE-1	-	-	-	69	-	-	89	81	97	85.2	-
JE-2	-	-	-	-	-	-	-	-	-	-	-
DPT-4	-	-	-	79	-	-	-	-	95	87.1	54.8
Td/DT (School)	-	97*	-	-	-	-	-	-	90	94.9	62
TT-2/Td-2 for pregnant women	97	83*	98.8	82	65[@]	100	89	75	97	96.1	68.2
HPV-2	-	97*	-	-	-	-	-	-	70	96.2[#]	-
Rotavirus	-	-	-	73	-	-	-	-	-	-	-

*Notes: Bhutan: * Coverage data for 2018, rest vaccine coverage data for 2015.*

Indonesia: @ data for 2015.

Thailand: # coverage data for HPV 1 dose.

3.1.3. VPD eradication and elimination status: Although the SEA Region has achieved the goal of polio eradication and maintained its polio-free status for last eight years, the risk of importation of wild poliovirus (WPV) and outbreak due to circulating vaccine-derived poliovirus (cVDPV) persists. All countries have achieved and sustained the maternal and neonatal tetanus elimination status. Five countries in the region (Bhutan, DPR Korea, Maldives, Sri Lanka and Timor-Leste) have been verified for elimination of endemic measles since 2017. Six countries (Bangladesh, Bhutan, Maldives, Nepal, Sri Lanka and Timor-Leste) have been verified as having controlled rubella and CRS in 2018.

The continued outbreak of diphtheria, pertussis, and measles in India, Indonesia, Myanmar, and Nepal indicated population immunity gap and vulnerability to VPDs.

3.1.4. Introduction of new vaccines: The countries are moving ahead with introducing or deciding on introduction of newer vaccines either nationally or sub-nationally in last five years; rotavirus vaccine (India, sub-nationally in 2016 and expanded countrywide in 2019; Myanmar in 2020; and Timor-Leste in 2019), HPV vaccine (Bhutan in 2010; India, sub-nationally in 2016; Indonesia, sub-nationally in 2016; Maldives in 2019; and Sri Lanka in 2017; Thailand in 2017), PCV (Bangladesh, 2015; Bhutan, 2019; India, sub-nationally 2017; and Indonesia, sub-nationally 2017; Myanmar, 2016; Nepal, 2015), and Influenza vaccine (Bhutan, 2019). The NITAGs have played crucial role in deciding and advising the country programs and policy makers for the introduction of newer vaccines in the region.

3.2. NITAGs - Functionality, Quality of processes and outputs and Integration

3.2.1. Functionality as an Agency (Intention, Power and Rationality)

- Every NITAGs of the region has a legislative basis or government order for their establishment. The NITAGs in Thailand and Nepal were established by an Act of Parliament.
- All of the committees have advisory role for vaccination in the country and the national immunization program. Formal TORs and SOPs/internal procedure manuals were available for all of the NITAGs, except for the Nepal, which have been completely re-drafted recently and await approval by MOH. The NITAG documents varied in the format, content and details of their functioning.
- The number and composition of membership also varied widely across member states. NITAGS have between 6 and 57 members: two countries - 6-7 members; five countries 12-20 members; three countries have 30-38 members; and one country has 57 members. The multi-disciplinary nature of membership was maintained in the NITAGs of seven countries but four countries (Bhutan, Maldives, Nepal and Timor-Leste) had limited diversity of experts. The tenure of membership ranged from 3-5 years, except DPR-Korea, which has does not specify the duration of tenure. NITAGs members in general are respected professionals and their advice valued for programmatic and technical matters.
- Independent chairpersons were leading the committee in seven countries in 2019. NITAGs in three counties, India, Sri Lanka and Thailand had senior health administrators as chairperson. In DPR-Korea, the national EPI manager is the NITAG Chairperson.

- NITAG meetings were conducted 2-4 annually in 10 countries. India has modified the structure of NITAG such that a Standing Technical & Scientific Committee (STSC) has been created that held quarterly meeting but the NITAG meeting under the chairmanship of Health Secretary is convened once annually.
- The practice of conflict of interest declaration existed for all NITAGs. In nine countries, members were asked to declare the conflicts prior to every meeting, two sought annual declarations.
- All the NITAGs were circulating the agenda and documents well in advance for the meeting. Work plan is prepared and available for seven countries. Indian NTAGI is the only committee publishing its minutes on website for public display.
- NITAG working groups are formed for reviewing and collating evidence focusing on specific vaccines in six countries (Bangladesh, India, Indonesia, Myanmar, Sri Lanka and Thailand). In rest of the member states (usually smaller countries), NITAGs have been doing this task. Structured systematic synthesis of evidence methods were used by six NITAGs (Bangladesh, DPR-Korea, India, Indonesia, Sri Lanka and Thailand). Seven NITAGs (Bangladesh, DPR-Korea, India, Indonesia, Myanmar, Sri Lanka and Thailand) frequently based their decisions and recommendations on the locally available evidence.
- Dedicated secretariat is available for four NITAGs (India, Indonesia, Thailand and Timor-Leste) and for others, the EPI team in MOH has been supporting. National budget has been fully funding the NITAG activities in five countries (Bhutan, India, Indonesia, Sri Lanka and Thailand), partially in three countries (Bangladesh, DPR-Korea, and Timor-Leste) and by the partners (WHO, Gavi-HSS funds) for the remaining. It emerged during the discussion, the NITAG secretariats and EPI teams require targeted capacity building to optimally support the functioning of NITAGs. In some member states, WHO primarily and occasionally UNICEF have been supporting the countries in this task. Some of the NITAGs have been supported by WHO and Gavi HSS funding for technical support and peer-learning from other NITAGs like twinning program between Timor-Leste and Australian NITAGs.
- The committees are generally aware of the source of budget for new vaccines (especially the Gavi eligible ones), but none of the committees has orientation towards the financial and programmatic sustainability of immunization activities in the country.

The status and functional indicators for the NITAGs in different countries are summarised in the Table 5.

3.2.2. Integration with the policies and programs of the immunization sector

- The NITAGs are considered important by the national program managers and policy makers for supporting and advising on the decisions related to key immunization issues including vaccine schedule linked to the VPDs and new vaccines.
- The in-country stakeholders majorly perceived new vaccine introduction as the key mandate of the NITAGs.
- Performance and implementation related challenges were discussed by NITAGs of the region infrequently and inadequately. There is limited orientation and involvement of the NITAGs in the implementation, monitoring and review of

routine immunization programs. Six NITAGs (DPR-Korea, Maldives, Myanmar, Nepal, Sri Lanka and Timor-Leste) have some orientation towards the periodic review of routine immunization, but was not considered as part of the regular agenda of the NITAG.

- Every member state has multiple committees related to immunization in the countries (like NCCPE, NVC-MR, AEFI committee and interagency coordination committee), but the linkages with the NITAG are limited, and often by default due to common memberships across these committees. The linkages with other specific immunization programs for effective integration and bundling at implementation level were present in only 4-5 countries.
- NRA is part of the NITAGs in six countries (Bhutan, DPR-Korea, India, Maldives, Sri Lanka and Thailand) as ex-officio members to assist in vaccine related regulatory issues.
- Most of the NITAGs have limited orientation towards the vaccine development and research except Indian and Thai NITAGs which included the vaccine R&D development as part of their agenda.
- Dynamics of translation of the NITAG decisions and recommendations was considered challenging by NITAG members. In four countries (DPR-Korea, India, Sri Lanka and Thailand), which had senior health administrators as NITAG Chairs, probably helped in smooth translation of the recommendations. Arbiters
- There are stifling influences of extrinsic arbiters like “Halal Councils” or similar religious bodies (in Indonesia) in the decision making process on procurement/production of vaccines, biological and medications, inclusion of a new vaccine into the immunization program or conduct of SIA.
- While decentralization of power and decision making process is a strength for addressing sub-national realities, respective NITAGs in some countries (like Indonesia and Nepal) are finding this too complex to leverage. More often than not, they see this as an impeding factor during translation of immunization program activities, conducting SIAs or introduction of a new vaccine in the immunization program.
- The WHO teams at the regional and country level has been facilitating and supporting establishing, capacity building and technically supporting the NITAGs in the countries. While the participation of international partners like WHO and Unicef in NITAG process has been good in most of the countries, six countries have WHO members as members of the committee, special invitees in three countries and not involved in two countries. The NITAG Resource Centre is infrequently used by the members from the countries that require hand holding and technical support. Considering the member’s capacity, funding availability, secretariat support, special attention is needed for sustainability and quality of the NITAGs in countries like Bhutan, Maldives, Nepal and Timor-Leste for optimal contribution and impact. For the NITAG members in majority of the countries, targeted capacity building and ongoing support like NITAG Resource Centre and NITAG network needs to be revamped. Several of the NITAGs, especially in the smaller countries face challenges for preparedness to respond to the fragility and emergencies. None of the NITAG has considered the life-course vaccine issues as part of the agenda and orientation towards the immunization agenda 2030, although few of the members from some countries have some idea about it.

a. Engagement/partnership and linkages with the regional and global agencies

The NITAGs and Program managers highly value the review and feedback by Regional ITAG on the annual program reports and guidance. The NITAGs have been guiding the program teams based on these feedbacks. The country NITAGs are appreciative of the technical support from WHO SEAR team and facilitation in identifying appropriate technical expert/consultants along with funding provisions as appropriate. The NITAGs expect better coordination and linkages between the NITAGs from the region and outside as appropriate for peer-learning and demonstration. A platform for sharing the experiences, challenges and potential solutions for the NITAGs is expected for capacity building. The expectations for linkages with SAGE and other global relevant advisory body varies according to the capacity and maturity level of the NITAGs and needs to be strategically.

3.3. Overall functionality status of the NITAGs

- The quantitative checklist is important for assessing overall performance of the NITAGs but could not identify important differences in their structure and productivity between the countries. Based on the quantitative checklist and subsequent qualitative assessment (formal and informal interactions with in-country stakeholders), the NITAGs could be categorised into three maturity and functional levels:
    - **Level 1: Sri Lanka and India**
        - The NITAGs in Sri Lanka and India have membership with diverse technical expertise, established processes for functionality and demonstrated productivity that resulted in smooth translation of the recommendations.
        - Sri Lanka: The NITAG's (ACCD) expanded mandate, technical expertise, alignment and integration the maternal-child and infectious diseases programs make the committee highly productive.
        - India: The NITAG's technical expertise, innovative organisation with dedicated secretariat enables the committee to be functional and productive.
    - **Level 2: Thailand, Nepal, Bangladesh, Indonesia, Myanmar and DPR Korea**
        - The NITAGs in this category meet most of the functionality requirements but have limitations in some domains that could be captured only after in-depth and informal interaction with stakeholders. The NITAGs in Thailand, Nepal and Bangladesh face challenges from structural aspect. The NITAGs in Indonesia and Myanmar have functional challenges. DPR Korea NITAG has independence related challenge..
        - Thailand: The immunization and vaccine governance and decision making in Thailand appears to be structurally comprehensive. But, the complex decision making processes delay translation of the NITAG's technical decisions into programmatic action. This affects

the functionality and productivity of the NITAG, and eventually the immunization program.

- Nepal: The NITAG in Nepal is governed by the Immunization Act, which limits the membership and thereby influences the functionality and decision making. The recent episode of abrupt NITAG reconstruction without ensuring continuity poses an additional risks for the functionality and productivity.
- Bangladesh: The NITAG has suitable technical composition and shown efforts for functionality and productivity within a short period of its existence. The ToR and roles of the NITAG and working relationship with the existing NCIP needs to be elucidated and demarcated to avoid possible conflict.
- Indonesia: The NITAG has demonstrated efforts for improving the functionality in recent past. But the functionality and productivity of NITAG is affected by the additional layer of endorsement by the religious body and the program implementation in the decentralised political governance framework.
- Myanmar: The NITAG has been doing a good job and has composition and processes to make it functional and productive. The NITAG members are involved in the program. The committee need to stick to the advisory role and keep a distance from the program planning and implementation activities.
- DPR Korea: The NITAG is led by the national immunization program manager, which is a conflicted state and challenges the independence of the committee.

o **Level 3: Bhutan, Maldives and Timor-Leste**

- The NITAGs in these countries face the challenges related to availability of suitable technical expertise and relevant capacity for evidence based decision making.

- Independence of the NITAGs: The WHO guiding document on NITAG states independence as “the absence of a direct or indirect supervisory relationships within the immunization program, or ideally, within the larger Ministry of Health”. Four NITAGs in SEAR member states are chaired by senior health administrators. Sri Lankan and Indian NITAGs were considered most mature and productive with smooth policy and programmatic translation of their decisions. The NITAG in Thailand has also track record of effective functioning but for recent challenges of decision making financial allocations, the implementation of decision have been delayed. DPR Korea is the only NITAG where the Chairperson also heads the immunization program and indicated severe conflict of interest.

  The findings suggested that complete independence of the NITAGs is desirable for its functionality and productivity of NITAGs. However, several examples from the SEAR member states also demonstrated that when the majority of the membership is independent, having a Chairperson from government may not affect the performance and on occasions can facilitate acceptance and smooth implementation of the recommendations.

- There is now need for further strengthen and empower the NITAGs in the region for achieving country specific targets, SEAR Vaccine Action Plan and Immunization Agenda 2030 goals and objectives. Support of dedicated NITAG-secretariats and competent team may be important to achieve these objectives.
- The SEAR WHO will have to play a critical role in facilitating the implementation of the proposed recommendations and further improve the functioning of NITAG in the member states.
- Evaluation tools: As mentioned above, the currently available checklists capture primarily the quantitative aspects of the structure, functionality and productivity domains. The qualitative tools and guides used in the study for interactions with in-country stakeholders were valuable complementary strategy for capturing the local governance processes and its influence on the maturity and functionality of individual NITAG performances.

The status and functional indicators for the NITAGs in different countries are summarised in the Table 5. The functionality summary scores for the NITAGs in the SEA region are summarised in Table 6.

Table 5: The summary status of NITAGs in the WHO SEAR

Sl no	Parameters	BAN	BHU	DPR-K	IND	INDO	MAL	MYN	NEP	SRL	THA	TLS
1	Process indicators											
1.1	Year of formation/ reconstitution	2019	2009/ 2018	2012	2001/ 2013	2006/ 2019	2013/ 2019	2013/ 2017	2009/ 2017	1960/ 2019	1967/ 2019	2015
1.2	Legislative basis	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1.3	Advisory role only	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1.4	Formal ToR available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
1.5	SOP available	Yes [a]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
1.6	Members (total/core/ex-officio/liaison)	13/12/ 1/0	12/5/ 5/2	14/11/ 3/0	38/20/ 13/5	17/17/ 0/0	6/3/2/1	36/11/ 23/2	7/4/2/1	57/27/ 21/9	30/10/ 14/6	20/7/ 8/5
1.7	Availability of all desired expertise	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No
1.8	Independent chairperson	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes
1.9	Tenure of membership	3 years	5 years	NR [b]	3 years	4 years	5 years	4 years	4 years	5 years	4 years	3 years
1.10	Meetings per year	2	2	2-3	1/4	3-4	3	2	3-4	4	3	2
1.11	Agenda/documents circulation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1.12	Declaration of interests (at joining/annual/each meeting)	Yes/-/ Yes	Yes/-/ Yes	Yes/Yes/ Yes[c]	Yes/No/ Yes	Yes/No/ No	Yes/No/ Yes	Yes/No/ Yes	Yes/No/ Yes	Yes/No/ Yes	Yes/No/ Yes	Yes/Yes/ No
1.13	Working groups	Yes	No	No	Yes	Yes	No	Yes	No	Yes	Yes	No
1.14	Dedicated secretariat[d]	No	No	No	Yes	Yes	No	No	No	No	Yes	Yes
1.15	Funding from national budget	Partial	Yes	Partial	Yes	Yes	No	No	No	Yes	Yes	Partial
1.16	Work plan available	No	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes
1.17	Immunization program in ToR	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1.18	Linkages with other immunization committees	No	No	Yes	Partial	Partial	Partial	Yes	No	Yes	Partia	Partial
1.19	Partner representation (WHO/Unicef)	Special invitees	Yes	No	Yes	Special invitees	Yes	Yes	Special invitees	Yes	No	Yes

Sl no	Parameters	BAN	BHU	DPR-K	IND	INDO	MAL	MYN	NEP	SRL	THA	TLS
2	Output indicators											
2.1	Adopts evidence-based methodology	Yes	Partial	Yes	Yes	Yes	Partial	Partial	Partial	Yes	Yes	Partial
2.2	Country-specific criteria for recommendation	Yes	Partial	Yes	Yes	Yes	Partial	Yes	Partial	Yes	Yes	Partial
2.3	Vaccine availability & delivery capacity criteria	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3	Outcome indicators											
3.1	MoH consults NITAG for decisions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3.2	Recommendations accepted by MoH	Awaited	Yes	Yes	Yes	Yes	Yes	Yes	Awaited	Yes	Yes	Yes
3.3	NITAG minutes & documents made public	No	No	No	Yes	No	No	No	No	No	No	No

Note: [a] *Drafted and waiting for approval from MoH*

[b] *NR: No definite tenure reported*

[c] *Oral conflict of interest declaration before each meeting*

[d] *Dedicated secretariat separate from the EPI or any other ministry program team*

Table 6: Functionality summary score status of the NITAGs in the SEA region

Sl no	Domain	Indicator	Items assessed	BAN n (%)	BHU n (%)	DPR-K n (%)	IND n (%)	INDO n (%)	MAL n (%)	MYN n (%)	NEP n (%)	SL n (%)	THA n (%)	TL n (%)
1.1	Structural viability	Establishment of NITAG	3	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)
1.2		ToR for NITAG	9	8.5 (94)	8.5 (94)	9 (100)	9 (100)	9 (100)	8.5 (94)	7.5 (83)	8 (89)	8.5 (94)	6 (67)	9 (100)
		Sub-total Structural viability	12	11.5 (96)	11.5 (96)	12 (100)	12 (100)	12 (100)	11.5 (96)	10.5 (88)	11 (92)	11.5 (96)	9 (75)	12 (100)
1.3	Functional viability	Roles of NITAG	4	3.5 (63)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)
1.4		SOP for NITAG	19	17 (89)	15 (79)	17 (89)	17 (89)	17 (89)	14 (74)	11 (58)	13 (68)	16 (84)	16 (84)	17 (89)
1.5		Composition of NITAG	5	3.5 (70)	3.5 (70)	3 (60)	4.5 (90)	3 (60)	4.5 (90)	5 (100)	4.5 (90)	5 (100)	5 (100)	4.5 (90)
1.6		CoI declaration policy	6	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	3.5 (58)	1.5 (25)	6 (100)	6 (100)	6 (100)	6 (100)
1.7		Independence	2	2 (100)	2 (100)	1 (50)	1 (50)	2 (100)	2 (100)	2 (100)	2 (100)	1 (50)	1 (50)	2 (100)
1.8		Adherence to meeting frequency & timing	4	4 (100)	4 (100)	4 (100)	3.5 (88)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)
1.9		Work plan and execution	6	5.5 (92)	5 (83)	6 (100)	6 (100)	6 (100)	5 (83)	6 (100)	6 (100)	6 (100)	5 (83)	6 (100)
1.10		Access to data and resources	6	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)
1.11		Secretariat	7	0.5 (7)	0.5 (7)	6 (86)	7 (100)	5 (71)	1 (14)	4.5 (64)	1 (14)	6 (86)	7 (100)	5.5 (79)
1.12		Funding and sustainability	2	1 (50)	2 (100)	2 (100)	2 (100)	2 (100)	2 (100)	1 (50)	1 (50)	2 (100)	2 (100)	2 (100)
		Sub-total Functional viability	61	48 (79)	48 (79)	55 (90)	57 (93)	55 (90)	46 (75)	45 (74)	47.5 (78)	56 (92)	56 (92)	57 (93)
1.13	Productivity	Background document preparation	3	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	1.5 (50)	1.5 (50)	3 (100)	3 (100)	3 (100)	3 (100)
1.14		Meeting minute documentation	4	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	4 (100)	3.5 (88)
1.15		Decision making procedure followed	3	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)	3 (100)
1.16		Consultation by MOH	6	5.5 (92)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)
1.17		Impact of NITAG recommendations	10	3 (30)	6 (60)	6 (60)	7 (70)	4 (40)	6 (60)	6 (60)	5 (50)	6 (60)	6 (60)	6 (60)
		Sub-total productivity	26	18.5 (71)	22 (85)	22 (85)	23 (88)	20 (77)	20.5 (79)	20.5 (79)	21 (81)	22 (85)	22 (85)	21.5 (83)
Grand Total			99	78 (79)	81.5 (82)	89 (90)	92 (93)	87 (88)	87 (88)	76 (77)	79.5 (80)	89.5 (90)	87 (88)	90.5 (91)

3.4. Conclusions

Based on the evaluation it can be concluded that

- NITAGs played a key role in supporting and advancing the national immunisation agenda. The recent introduction of new vaccines and improvements observed in the immunization coverage in the members states and region can be attributed to a significant extent to the active participation of the NITAGs in the country policy making processes.
- The level of evolution, competency, operations and governance mechanism of the NITAGs varied across the member states but all the NITAGs in the SEA region are functional and scored over 75% functionality score (Table 6).
- There is now need for further strengthen and empower the NITAGs in the region for achieving country specific targets, SEAR Vaccine Action Plan and Immunization Agenda 2030 goals and objectives. Support of dedicated NITAG-secretariats and competent team may be important to achieve these objectives.
- The SEAR WHO will have to play a critical role in facilitating the implementation of the proposed recommendations and further improve the functioning of NITAG in the member states.
- Evaluation tools: As mentioned above, the currently available checklists capture primarily the quantitative aspects of the structure, functionality and productivity domains. The qualitative tools and guides used in the study for interactions with in-country stakeholders were valuable complementary strategy for capturing the local governance processes and its influence on the maturity and functionality of individual NITAG performances.

3.5. Recommendations

The recommendations are grouped under generic recommendations for the member states/countries, specific recommendations for the countries and for the WHO SEAR.

3.5.1. Generic recommendations for the member states/countries

- **Further strengthen the governance and functioning of NITAGs in the SEAR**
    - The region has a mix of NITAG leadership: NITAG chair is either a senior government functionary (4 countries) or an independent expert (7 countries). There was no observable difference in the functionality and performance of the NITAGs of the two types.
        - The WHO regional office and the countries need to take a balanced view of how the independence and transparency in decision making processes of NITAGs are maintained and carefully document the functionality of NITAG with different governance structures in the region.
    - The national governments should provide a dedicated budget line item for NITAGs to further the ownership and commitment.
        - The budget should adequately support the work by the NITAG and its Working Groups, capacity building including attendance at global, regional and workshops/meetings, inclusion of outside experts as needed, and

        - The member states should consider establishing or strengthening the secretariat by allocating at least one dedicated professional with expertise in epidemiology and vaccinology.
    - There is need for focus on capacity building of the NITAG members
        - In the fields of public health, epidemiology and vaccinology, program implementation and evidence synthesis.
        - In-view of the challenges faced by the NITAGs in several countries related to the cost effectiveness analysis and vaccine hesitancy, inclusion of experts from health economics and social science/anthropology/communication should also be considered.
        - The countries should consider establishing a mentorship program for younger professionals who can be groomed to be inducted in to the NITAG at the appropriate time.
        - The experience of twinning of one NITAG with another more mature NITAG (refer Timor-Leste) may be tried on a larger scale.
- **Inclusion of structured monitoring and evaluation of National Immunization program review as an important mandate** for NITAGs with provision of feedback and follow up action at different levels
    - Members from across the NITAGs emphasized the need for including monitoring and evaluation of the immunization program as part of their TOR.
    - Special attention is needed for monitoring and evaluation of the program performance in urban, inaccessible and conflict/disturbed areas.

    - The NITAG's report to the Regional ITAG should include the observations from review of national immunization program and the country's progress towards achieving IA 2030 targets.
- **Integration and collaboration between different national advisory committees:** The member states should consider inclusion of the Chairpersons of the other immunization and VPD advisory and monitoring committees like NCCPE, NVC for Measles-Rubella, and AEFI-surveillance as ex-officio members to establish formal linkage between these committees and NITAGs for smooth information and activity sharing.
- **Improving transparency and accountability of NITAG:** The member states should consider making the decisions and recommendations by the NITAG publicly available after approval by Ministry.
    - The background papers and scientific reviews for key decisions should be placed on the website or submitted for publication in the scientific literature.

3.5.2. Specific recommendations for the member states/ countries

3.5.2.1. Bangladesh

1. The TORs and roles of the NCIP (National Committee of Immunization Practices) and NITAG needs to be elucidated and demarcated to avoid duplication and possible conflict.
2. Special attention for implementation and monitoring of immunization program in urban areas is needed where NGOs are playing a critical role. This

will require greater and effective collaboration between immunization program and the NGO sector with facilitation and monitoring from NITAG.

3.5.2.2. Bhutan

1. In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership. While acknowledging that there is a dearth of in-country expertise, training of the existing members and future members in specific issues such as health economics and social sciences should be considered.
2. The NITAG coordinator in the EPI Secretariat should be either from medical or public health background for more effective support to the functioning of NITAG.

3.5.2.3. DPR-Korea

1. NITAG should consider tenure based rotation of core members and establish a program for mentoring next generation of multi-disciplinary team for the NITAG.
2. For greater independence and transparency of decision making, the chairperson of the NITAG should be other than the national EPI manager.
3. The NITAG should work with the program to further strengthen the VPD surveillance in the country.

3.5.2.4. India

1. Review the structure of the NITAG: The country may consider merger of the two Working Groups and the Standing Technical Sub-Committee (STSC) into one functional technical body that can oversee and guide the technical work of the NITAG. Ad-hoc working groups would continue to be established as needed. The current NITAG can be designated as the Executive NITAG that continues to lead the policy decision-making with respect to recommendations arising from the technical arm of the NITAG.
    - Review the composition of the technical NITAG and Executive NITAG in the context of this refinement of roles and strategic direction.
    - Consider having the Executive NITAG meet at least twice a year or more frequently as needed.
    - Not all members of the Technical NITAG would need to attend the meetings of the Executive NTAGI.
2. Consider the inclusion persons with implementation and programmatic expertise, representatives from one or two States, civil society, health economist and social scientist to the NITAG.
3. Considering the emergence of India as a vaccine manufacturing hub including new vaccines, the NITAG needs to give attention for the vaccine research, post-licensure surveillance and national regulatory agency function.
4. Strengthen the secretariat team by including at least one person with expertise in epidemiology and modelling. Other experts could be contracted as needed.
5. The agenda of the NITAG should be set by the chair and co-chairs following consultation and input from all members of the NITAG.

3.5.2.5. Indonesia

1. The political and administrative setup of the country along with NITAG and NRA should work out strategies that help to de-link availability, access and use of the lifesaving drugs, and biologics including vaccines from the religious screening and approvals and protect scientific decisions for the larger public good.
2. NITAG should continuously review emerging issues of vaccine hesitancy including that due to religious screening and approvals and develop strategies to overcome these.
3. Decentralization is a welcome political process for increasing the community participation and decisions making on issues related to their daily lives. Developmental issues like creating infrastructure and income generation schemes are likely to override and be given greater emphasis over preventive and promotive health care services and education. Provincial and local self-governments should receive and allocate dedicated resources for immunization program. In addition, they need hand-holding, capacity building and persistent reminders about the health benefits, social and economic consequences, and sustainability of immunization services.

3.5.2.6. Maldives

1. In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership. While acknowledging that there is a dearth of in-country expertise, training of the existing members and future members in specific issues such as health economics and social sciences should be considered.
2. NITAG needs special attention to emerging challenges of vaccine hesitancy and work with other stakeholders to overcome these.
3. The minutes of NITAG meetings should contain adequate details reflecting key discussions and issues considered for decision making.

3.5.2.7. Myanmar

1. The NITAG should maintain a healthy distance from the EPI program implementation.
2. Leveraging on the experiences from high risk areas, the NITAG could advise for integration of the maternal and child health services with immunization to improve the coverage and acceptance of UHC.
3. The role played by the NITAG in designing and execution of innovations implemented in the high-risk areas to be documented and shared with other member states in the region.
4. NITAG should adopt written conflict of interest declaration and mention accordingly in the SOP.
5. NITAG should advise the Ministry of Health on increasing the NRA's role and preparedness for post-GAVI phase.

3.5.2.8. Nepal

1. The NITAG which has been established by an act of Parliament has limited number of members. The Government should consider bringing in appropriate flexibility in the Immunization Act related to the NITAG membership and operations to expand membership and accommodate additional members with suitable technical expertise.

2. The NITAG's TOR and rotation and/or extension of membership should be specified in a manner ensuring that the total membership of the committee is not changed simultaneously.
3. Decentralization is a welcome political process for increasing the community participation and decisions making on issues related to their daily lives. Developmental issues like creating infrastructure and income generation schemes are likely to override and given greater emphasis over preventive and promotive health care services and education. Provincial and local self-governments should receive and allocate dedicated resources for immunization program. In addition, they need constant guidence, capacity building and persistent reminders about the health benefits, social and economic consequences, and sustainability of immunization services.

3.5.2.9. Sri Lanka

1. The experience of ACCD focusing on communicable diseases mandate beyond immunization should be documented and shared with other countries in the region.

3.5.2.10. Thailand

1. NITAG and EPI program needs to give special attention for implementation of immunization program in urban areas and among populations with vaccine hesitancy.
    - Better data sharing and coordination mechanisms among the Ministry of Public Health and the Bangkok Metropolitan Area are required.
2. Current complex decision making processes and release of finances in relation to the immunization program and NITAG need review at political and bureaucratic levels for simplification.
3. Partner organisations like WHO and Unicef should closely coordinate their technical assistance and interact with NITAG.

3.5.2.11. Timor-Leste

1. In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership. While acknowledging that there is a dearth of in-country expertise, training of the existing members and future members in specific issues such as health economics and social sciences should be considered.
2. The innovations introduced for integration of primary health services with immunization including use of IT platform need to be used as case study for its operational feasibility and application in different contexts.
3. The experience of twinning of one NITAG with another more mature NITAG needs to be well documented for wider use.
4. NITAG should advise the MOH on streamlining the NRAs role and preparedness for post-GAVI phase.

3.5.3. Recommendations for the WHO SEAR

1. **Platform for learning and sharing:** The WHO should create a platform for sharing the lessons and best practices adopted by the NITAGs in member states for cross learning.
    - Create a web platform for posting the programmatic innovations and experiences- create NITAG network, update NITAG Resource Centre and encourage the members to use
    - Conduct capacity and skill building workshops for NITAG members (not only chairs and EPI managers)
2. **Guidance for NITAGs:** WHO should work with NITAGs and regional ITAG to develop guidance framework of national immunization monitoring, evaluation and providing structured feedback
3. **Strengthening NITAGs in the region:** The regional office should explore and facilitate the capacity building of the NITAGs and their functionality:
    - Facilitate twinning between the NITAGs in the region
    - Decision making based on evidence synthesis and interpretation of cost effectiveness data- through preparation of resource documents and guidelines and workshops
4. **Revision of the NITAG evaluation tools**
    - There is need to review the currently available tools (quantitative checklist) for NITAG evaluation and prepare the next versions that enables differentiation between the NITAGs at different levels of functionality and productivity levels. Two sets of NITAG evaluation tools may be considered:
        - First, for self-evaluation by the NITAGs at periodic intervals, which can be reviewed by the Regional ITAG to guide and recommend appropriate action.
        - Second, for external and detailed evaluation of the NITAGs addressing both the quantitative and qualitative aspects.

3.5.4. Lessons from the current evaluation

- The NITAGs are considered as valuable technical asset for the immunization policy and program decision making in the member states in the region. The recent improvements in the immunization program performance and new vaccine introduction in the member states and the region can be attributed to a significant proportion to the NITAGs. The NITAGs and members are demonstrating the commitment towards the purpose and process.
- The NITAGs in several member states require special measures to ensure technical capacity building among the current members and prepare a pipeline of professionals with potential. Different capacity building measures and processes may have to be adopted according to the specific NITAG's need including virtual, face-to-face and twinning programs.
- The independence of NITAGs needs to be relooked and weighed with the productivity. It was interesting to observe that four of the NITAGs with health leaderships as Chairpersons were rated as highly functional and productive. Bangladesh has recently established an independent NITAG although the NCIP led by Health Secretary existed for over a decade. Once the majority of the membership are independent having a Chairperson from government can facilitate acceptance and implementation of recommendations. The member states and advisory bodies need to consider maintaining an effective balance between independency and productivity.
- The availability of dedicated Secretariat with competent staff for NITAG is aspirational to improve the NITAG's productivity. While three of the better performing NITAGs had dedicated secretariat, Sri Lanka continues to perform well with support from the EPI team. The secretariat in Timor-Leste is still evolving technically to provide effective support to NITAG. The budgetary provision for secretariat and NITAG activities reflect the country ownership of the NITAG.
- The tools available for evaluation of NITAGs appear to have limitation in true assessment of the functionality and productivity components, as these change with the country and programmatic context. Further work needed to improve the tools, which can be used for periodic self-evaluation of the NITAGs and may be for external evaluation. The areas that require better tools for assessment are independence, broad representation, technical competency and decision making.

Section 4

COUNTRY SPECIFIC OBSERVATIONS

4.1. Bangladesh

4.1.1. NITAG & Immunization Program

4.1.1.1. ***Journey of the NITAG till 2019:*** The NITAG in Bangladesh is the youngest committee in the region (established in June 2019). It was formed as per a ministerial decree to advise the NCIP (National Committee of Immunization Practices), EPI and relevant agencies. The NITAG has 13 independent members and Director MNC&AH (Ministry of maternal, new born, child and adolescent health) as member secretary. After its formation, the NITAG has proposed the internal procedure manual (awaiting approval from Ministry) documenting the procedures for function. It has also developed annual work plan.

The terms of reference for the NITAG include immunization policy analysis and formulation, introduction of new vaccines, program monitoring, VPDs surveillance and research. The NITAG also provided suggestions on the draft Vaccination Act 2018. The NITAG has proposed a website for archiving and showcasing the activities.

Three technical working groups (WGs) on (i) new and underused vaccines, (ii) existing vaccines in EPI and immunization program and (iii) VPD surveillance have been constituted. The Working Groups have initiated discussion on introduction of HPV, JE and typhoid vaccines. Bangladesh has introduced fractional IPV and is preparing for introduction of HPV and rotavirus vaccine soon on the advice of NITAG. The research and evidence generation at country level has been good and NITAG has encouraged the efforts.

Bangladesh has another immunization committee, the *National Committee of Immunization Practices (NCIP)* established in 2008 with a similar and overlapping mandate. The NCIP is chaired by the Secretary-Health and has 32 members with 2 independent and 26 ex-officio members. Between two committees, only 1-2 members are common. The ministerial decree guides that the NITAG submits its report every six month to NCIP, but the in its TOR (pending approval), NITAG has proposed to submit the reports to the Secretary Health.

There are four more committees including the Interagency Coordination Committee (ICC), NCCPE, NVC-MR and AEFI committee, related to immunization program.

4.1.1.2. ***Status of the National Immunization Program*****:** NIP in Bangladesh has been performing well with consistent high coverage in most geographical regions and for almost all the vaccines. According to the most recent reports, the immunization coverage has been >95% for the first year vaccines and >90% for the second year vaccines. The coverage evaluation survey of 2016 also reported coverage of all EPI vaccines above 95%.

Compared to other areas, Dhaka urban area has relatively higher dropout for penta-3 and MR-2. In urban areas, increasing the access to vaccination is a challenge, especially among the migrant population.

VPDs outbreaks have been occurring among the Rohingaya refugees from Myanmar. Vaccine hesitancy is minimal in most areas of Bangladesh with high community demand for vaccine.

4.1.1.3. ***VPD eradication and elimination status*****:** Last case of wild virus polio was observed in 2006 and Bangladesh was certified as polio free in 2014. Bangladesh remains

endemic for measles and rubella. Elimination of maternal and neonatal tetanus was achieved in 2008.

4.1.1.4. ***New vaccine introduction:*** PCV vaccine was introduced in 2015. The rotavirus vaccine was scheduled for introduction during 2018, but deferred till 2020 due to unavailability of vaccine. HPV is also in pipeline for introduction.

4.1.2. NITAG - Functionality, Quality of processes and outputs and Integration

4.1.2.1. Functionality as an Agency (Intention, Power and Rationality)

The Bangladesh NITAG has been established to ensure independence of decision making with transparency and by diverse expertise. The committee has 13 independent members from various disciplines and 2 ex-officio members. Term of the members is 3 years with provision of extension for one more term. The draft SOPs and internal procedures are waiting approval from the Ministry. The procedures to address conflict of interest and confidentiality appear to be sound. After its formation, a three-day orientation for the members was conducted. The NITAG is still in evolution and members are rapidly getting orienting towards the new roles, responsibilities and procedures. Members expressed need for another refresher orientation on evidence synthesis, handling conflict of interest, industry linkages, and liaising with the other immunization bodies.

The NITAG is expected to meet at least twice annually and during the initial five months, the NITAG has already met five times. The technical WGs have started working and taking up relevant issues. For the evidence synthesis on HPV, the WG used the framework from the WHO-NITAG resource centre.

There is no NITAG Secretariat or focal person within the EPI team to support NITAG activities. Current strength of the EPI team is too burdened to support the NITAG activities. The NITAG members themselves are preparing the background papers and documents including the literature review. The NITAG has made recommendations on HPV vaccine and accorded structured suggestions on the Vaccine Act – 2018 awaiting final decision by the Government of Bangladesh.

The NITAG minutes of the meetings are presently circulated to the stakeholders. The NITAG has intentions for sharing selected activities with the public.

NITAG demonstrated its proactive approach to immunization issues within the short period of its existence.

Although the structure and functioning of NITAG is independent compared to NCIP but there is a significant overlap in the mandate of two committees. The NCIP has wider representation of ex-officio and liaison members, and appears to be an executive arm of the Government for EPI, structured towards programmatic integration and execution of the recommendations. The understanding of the members and dynamics of interaction between the two committees are gradually evolving. Notwithstanding these, misperceptions do exist among the members with potential for conflicts in future.

4.1.2.2. Integration with the policies and programs of the immunization sector

Immunization is a priority program for the Government and national leadership is keen to push the program agenda in the context of proposed Vaccination Act. The immunization program is largely dependent on donor funding.

Usually the Chair and Co-chair along with the EPI team set the NITAG agenda including any suggestion from other members. In view of the limited period of

operation, introduction of new vaccines have dominated the agenda so far apart from specific program related requests from EPI. The processes of approval and implementation of the NITAG recommendations by the Ministry are still evolving.

There is need for orientation of NITAG committee members on how the NITAG can best coordinate/integrate with the other child and maternal health programs. The NITAG is still discussing how to align their activities with the comprehensive multiyear plan 2018-2022.

The common membership across the different immunization related committees (viz. NCCPE, NVC, AEFI committees) allows sharing of information, although there is ex-officio status for the other committees in NITAG.

Given the considerable role non-government organizations (NGOs) play in Bangladesh for implementing the national immunization program particularly in urban and migrants areas and collecting associated data, the NITAG needs to collaborate and work closely with NGOs. Currently there is no representation of the NGOs (implementing immunization program in urban areas) in the NITAG.

Vaccine hesitancy is not reported often in Bangladesh. An exception to this was the reported hesitancy among the displaced and migrant population from Myanmar, which have been addressed with proactive efforts from programs focused on counselling and trust building.

4.1.2.3. Engagement/partnership and linkages with the regional and global agencies

The NITAGI has no formal interaction with the SEAR RITAG till now. There are some members who have engagement with the WHO, GAVI, CDC and other international agencies in their individual capacity for new vaccine research and advocacy. There is good coordination and participation of the country offices of WHO and UNICEF in NITAG meetings for the implementation and technical aspects of immunization program.

4.1.2.4. Innovations/ aberrations

The government's effort towards bringing a 'Vaccine Act' is welcome step which has the support of NITAG; it provided suggestions soon after its constitution. This act will ensure immunization as a right for the children and further consolidate the commitment of government towards children in general and immunization in particular.

The immunization program is being implemented through NGOs in urban areas. The reporting, monitoring and data quality has been a challenge.

The vaccine hesitancy among the displaced and migrant population from Myanmar has been reduced with improvement in coverage, which assisted in controlling the outbreaks. The program team, health functionaries and partner agencies have progressively made effort for trust building, which improved the vaccine acceptance and coverage.

4.1.3. Preparedness for the journey ahead -
Country Specific Recommendations

1. The need and role of NCIP after the constitution of NITAG is not clear. The TORs and roles of the NCIP and NITAG needs to be elucidated and demarcated to avoid duplication and possible conflict.
2. Special attention for implementation and monitoring of the immunization program and documentation in urban areas is needed where NGOs are playing a

critical role. This will require greater and effective collaboration between NITAG and the NGO sector.

3. Special attention for implementation and monitoring of the immunization program in urban areas is needed where NGOs are playing a critical role. This will require greater and effective collaboration between the immunization program and the NGO sector with facilitation and monitoring from NITAG.

4.2. Bhutan

4.2.1. NITAGs and Immunization Programs

4.2.1.1. ***Journey of the NITAG till 2019:*** The NITAG in Bhutan, Bhutan National Committee for Immunization Practice (NCIP) was first established in 2009 by an order of the Ministry of Health. The NCIP was reconstituted twice, in 2012 and 2018. The TOR was adopted in 2012 and Internal Procedure Manual was adopted in 2018 to document the responsibilities, structure, functioning and procedures of the NCIP. The focus of the Bhutan NCIP has been primarily on the introduction of new vaccines. Based on RITAG guidance, the NCIP has included program implementation as an agenda from 2018-19. Primarily the NCIP reviews and advices on the Ministry of Health requests for new vaccines, vaccine schedule issues and emergency situations. The NITAG is one of the most active national health committees.

4.2.1.2. ***Status of the National Immunization Program:*** The Immunization program has been functioning well with the coverage above 90% for most of the routine vaccines. The coverage is lower than national average in Gasa province due to limited access and geographic and climatic challenges.

4.2.1.3. ***VPD eradication and elimination status*****:** Bhutan did not report any indigenous circulation of wild virus polio since 1986, in 2017 was verified as measles eliminated and rubella eliminated in 2018. Elimination of neonatal tetanus was achieved in 2000.

4.2.1.4. ***Introduction of new vaccines:*** Bhutan introduced HPV vaccine in 2010 and revised to two doses schedule since 2016. The PCV vaccine was introduced in 2019. Influenza vaccine was also introduced in 2019 targeted at five high risk populations. Rotavirus vaccine is awaiting introduction.

4.2.2. NITAG - Functionality, Quality of processes and outputs and Integration

4.2.2.1. Functionality as an Agency (Intention, Power and Rationality)

The NCIP Bhutan is a relatively small group of experts, which is active, productive and well supported by the Ministry of Health. The composition of the NCIP includes four independent experts and six ex-officio members. According to the recent ACIP manual, independent members serve for a term of 5 years with an option for three terms. Two independent members have been there for over a decade and are well conversant with the immunization issues.

There is no dedicated secretariat and human resources for ACIP. The EPI team supports the NCIP activities and budget for meetings supported by government. No separate sub-committees or Working Groups exist and the NCIP discusses the issues and make recommendations. NCIP members take the lead to prepare the background documents for discussion and decision with assistance from the country WHO team as per need.

The NCIP has recently introduced procedures to address conflict of interest and confidentiality.

Almost all NCIP recommendations have been accepted by the MOH so far, as per the availability of funding. The NCIP minutes of the meetings are circulated to the members and partners, and not available for public display. Same is true for the background papers and review of the literature.

4.2.2.2. Integration with the policies and programs of the immunization sector

The Government shows strong ownership of the Immunization program. The ACIP chair in consultation with EPI team drafts the agenda for meetings. The recommendations of the NCIP for the new vaccine introduction have been accepted by the Government. The primary funding for vaccines and cold chain equipment comes from donor support (GAVI, JICA). Bhutan is expected to graduate from GAVI support in 2025. Annual review of immunization program by NCIP was initiated in 2019. Some of the members made field visits during the recent MR supplementary campaign (SIA), which gave the members first exposure to field operations and the challenges. The NCIP also functions as the AEFI committee. Several of the ACIP members are common across the NCCPE and MR NVC committees due to limited availability of individuals with desired expertise. However, there is no formal sharing of the information between committees. For specialised advise like vaccine cost-effectiveness, the NCIP and EPI seeks assistance from the WHO and HITAP, Thailand.

The routine immunization program faces challenge of the migrant workers from neighbouring countries, several of them unregistered. Border areas are at risk of importation of VPDs, like the recent measles outbreak.

4.2.2.3. Engagement/partnership and linkages with the regional and global agencies

The NCIP has good engagement with the SEARO RITAG, WHO, UNICEF, and important international agencies involved in immunization. The NCIP Chair has exposure to SAGE activities and NITAG network.

4.2.2.4. Innovations/ aberrations

Bhutan Health Trust Fund (BHTF) was formed in 2000 to ensure uninterrupted supplies of drugs, vaccines, supplies and equipment for health care. The funds and grants from donors and soft loans are invested in capital stock market to generate interest. Over the years the capital stock value of BHTF has increased significantly. BHTF has been also been trying to raise resources through various in-country and external sources. It is expected that by 2025 BHTF shall be able to introduce 1-2 new vaccines in to the program.

4.2.3. Preparedness for the journey ahead -

Country specific Recommendations

1. In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership. While acknowledging that there is a dearth of in-country expertise, training of the existing members and future members in specific issues such as health economics and social sciences should be considered.
2. The NITAG coordinator in the EPI Secretariat should be either from medical or public health background for more effective support to the functioning of NITAG.

4.3. DPR-Korea

4.3.1. NITAG and Immunization Program

4.3.1.1. ***Journey of the NITAG till 2019:*** The NITAG in DPR-Korea was constituted in 2012 with core and ex-officio members. NITAG has 11 independent/core and 3 ex-officio members. The independent members include one paediatrician, two immunologists, two virologists, two microbiologists, three epidemiologists and one infectious disease expert. The three ex-officio members include the chairperson (the national EPI Manager) and two EPI program officials, who are also part of the Secretariat. The internal procedures and work plan are in place. The EPI division is functioning as the Secretariat since inception. The NITAG is comprised of 11 core members and the chairperson is the national EPI Manager. There are two more ex-officio members from EPI program. Out of the 11 core members 7 were inducted in 2018. NITAG is asked to technically guide the MOPH for immunization.

4.3.1.2. ***Status of the National Immunization Program:*** Immunisation agenda is primarily driven by the Ministry of Public Health. The performance of the routine immunization is reported to be very high. The coverage for all the antigens in the national program is over 95% for last several years; BCG 96.1%, HBV-0 98.4%, penta-3 97.1%, OPV-3 98.6% in 2018. The IPV coverage was 64.8% in 2018. MCV1 coverage was 98.2% and MCV2 was 98.7%. Maternal TT vaccine coverage is 98.8%. The program has achieved remarkable near-universal immunization coverage for the routine vaccines and well maintained it as validated by the coverage evaluation survey (2017). Country has also achieved the global and regional immunization coverage targets of > 90% nationally and > 80% in all districts for all vaccines except for the IPV due to vaccine shortage.

4.3.1.3. ***VPD eradication and elimination status:*** DPR-Korea is polio free since 1997 and elimination of maternal and achieved maternal and neonatal tetanus elimination for last two decades. The country was verified to have eliminated measles in 2017.

4.3.1.4. ***Introduction of new vaccines:*** IPV was reintroduced in 2018 and MR in 2019. Rotavirus and PCV vaccines are yet to be introduced. The sentinel surveillance for rotavirus infection is on-going. The NRA has undergone self-evaluation with support from WHO and was assigned Level 1 maturity in 2018. The AEFI surveillance and reporting started from 2017.

4.3.2. NITAG - Functionality, Quality of processes and outputs and Integration

4.3.2.1. Functionality as an Agency (Intention, Power and Rationality)

The independent members have no definite tenure and can serve until their transfer or death: four of the 11 core members are serving for last 7 years, one member for 2 years and six members for one year. The ex-officio members including the chairperson and the Secretariat team has been serving for last 7 years. The NITAG members are oriented on the TOR, SOP and procedures annually. There are no working group or sub-committee in the NITAG. The budget for the NITAG and Secretariat is supported by the Ministry and Gavi (HSS fund).

The members declare conflict of interest in writing annually and verbally before every meeting.

The NITAG has been meeting 2-3 times annually. Almost all NITAG recommendations have been accepted by the MOPH, as per the availability of funds

and vaccine. The NITAG has separate SOP for evidence review and synthesis for making decision and recommendation. The NITAG minutes of the meetings are circulated to the members and partners, but not available for public display. The background papers and reviews of the literature are neither available for the public nor published.

While making the decisions the committee is conscious about the programmatic and financial sustainability of the new vaccines for implementation. The NITAG members make field visits for monitoring and supervision for challenging areas.

4.3.2.2. Integration with the policies and programs of the immunization sector

Immunization Programme is a priority program of DPR-Korea and has sustained high coverage nationally and regionally. The country primarily supports the program and ownership is evident with the funding for traditional vaccines by government and co-funding for new vaccines supported by Gavi. The NITAG members are highly regarded and advise the MOPH.

The Chairperson, the EPI Manager with EPI team drafts the agenda for the meetings. NITAG recommendations for the introduction of new vaccines have been accepted by the Government. The NITAG is cognisant of the sustainability and vaccine security while making decisions about new vaccines.

Several of the members are common across the NCCPE, MR-NVC and AEFI committees, which ensures sharing the proceedings of the various committees with each other.

4.3.2.3. Engagement/partnership and linkages with the regional and global agencies

The NITAG regularly engages with the country WHO and UNICEF offices for technical support and attend SEARO RITAG meetings.

The GAVI HSS support is routed through the WHO and UNICEF. The Gavi, WHO and UNICEF have been supporting and facilitating the NITAG and country immunization division with strategy planning and capacity building.

4.3.2.4. Innovations/ aberrations

The SOP for evidence review and synthesis for making recommendations by NITAG is a good effort and serves as a guide.

4.3.3. Preparedness for the journey ahead -

Country specific Recommendations

1. NITAG should consider tenure based rotation of core members and establish a program for mentoring next generation of multi-disciplinary team for the NITAG.
2. For greater independence and transparency of decision making, the chairperson of the NITAG should be other than the national EPI manager.
3. The NITAG should work with the program to further strengthen the VPD surveillance in the country.
4. NITAG should work with MOPH for streamlining and strengthening the national NRAs and induct NRA representative in to NITAG.

4.4. India

4.4.1. NITAG and Immunization Program

4.4.1.1. ***Journey of the NITAG till 2019:*** The National Technical Advisory Group for Immunization (NTAGI) in India has made significant progress since it was first established in 2001 by an order of the Ministry of Health and Family Welfare (MHFW). The NTAGI has since been reconstituted thrice, in 2010, 2013 and 2018.

A written Code of Practice was adopted in 2015 to document the responsibilities, structure, functioning and procedures of the NTAGI. As part of this re-structuring, a Standing Technical Sub-Committee (STSC) and the Working Groups (Standing and other ad-hoc ones) have been established.

The focus of the India NTAGI has been primarily on the introduction of new vaccines. The Ministry of Health has been accepting most of the recommendations related to introduction of new vaccines by the NTAGI.

Apart from the STSC, eleven technical working groups focusing on specific vaccines were constituted recently: (a) hepatitis A, (b) typhoid, (c) human papilloma virus (HPV), (d) influenza, (e) Japanese encephalitis, (f) leprosy, and other generic issues like (g) vaccine preventable disease surveillance, (h) maternal immunization, (i) vaccine confidence, (k) research and capacity building.

The scientific community in the country has been active to generate program relevant evidence. NTAGI has been encouraging the practice and helped in articulating appropriate research questions.

4.4.1.2. ***Status of the National Immunization Program:*** The Immunization program has made remarkable progress in India in last 6-7 years. Immunization coverage has increased significantly and several new vaccines introduced. The periodic intensification of routine immunization (PIRI), called Mission Indradhanush (MI) and Intensified Mission Indradhanush (IMI) efforts have been instrumental in pushing the full immunization coverage from 62% to almost 80% since 2014. BCG coverage was 90% in 2018 and pentavalent vaccine 87% though 64% of districts still had coverage below 80%. MCV1 coverage was 86% and MCV2 was 73% in 2018 indicating a high dropout rate that needs to be addressed. After tOPV to bOPV switch in May 2016, 2-doses of intradermal IPV vaccine have been introduced countrywide though the coverage remains low.

Immunization program is stronger in rural areas compared to the urban bodies; in the last IMI rounds urban areas have been taken up as priority areas.

Vaccine hesitancy has been observed in several parts of the country during the polio eradication efforts and later in MR campaign. Vaccine hesitancy was encountered in new areas like north-eastern states during IM campaigns also,

4.4.1.3. ***VPD eradication and elimination status*****:** Wild poliovirus type 1 was the last sero-type that was eliminated in 2011 and India was declared polio free in 2014 along with the SEA-region. India achieved elimination of maternal and neonatal tetanus in 2015. Wide age measles-rubella (MR) campaign started in 2017 and till March 2020, 35 out of 37 states have been covered. The country remains endemic for measles and rubella.

Tuberculosis remains prevalent and there have been outbreaks of diphtheria, pertussis, measles, typhoid and cholera indicating that much more remains to be done to improve vaccination coverage.

4.4.1.4. ***Introduction of new vaccines:*** Since 2014, India has introduced several newer vaccines like JE (part of the country), rotavirus vaccine (expanded countrywide), Rubella as part of the MR-vaccine and conjugated pneumococcal vaccine (being scaled up in a phased manner). During the same period, tOPV to bOPV switch took place along with intradermal IPV (two doses) in 2016. PCV vaccine was introduced in 2017 sub-nationally and expanding in phases. HPV vaccine was introduced in a few states with funds from the states from 2016-17 onwards; nationwide rollout is awaiting clearance from the apex court.

4.4.1.5. ***Emergence as vaccine manufacturing hub:*** India has emerged as a major vaccine manufacturing hub with the industry contributing the largest share of vaccine doses used globally. Currently, several the new vaccine development researches are being undertaken by these industries; rota virus vaccine in the country was completely indigenous. Conjugated typhoid is another such example.

4.4.2. NITAG: Functionality, Quality of processes and outputs and Integration

4.4.2.1. Functionality as an Agency (Intention, Power and Rationality)

Indian NTAGI is active, functional and productive and fully supported by the Ministry of Health and Family Welfare. The structure of the NTAGI is creative and effective. Secretary of the Ministry of Health and Family Welfare is the chairperson, and the Secretaries of the Departments of Biotechnology and Health Research are co-chairpersons of NTAGI. In this framework, the NTAGI links closely with the decision-making processes and resources.

The India NTAGI has 38 members including 25 core members and 13 non-core members. Out of the core members, 20 are independent members (including four ex-officio representatives, one member with twin representation -independent and ex-officio representative and one vacant position) and five administrators from health and science ministries. Out of the 13 non-core members, four officials are from health ministry, representatives from three professional association, WHO and Unicef representatives and four members from states (on rotation basis). India has a large pool of experts that can be called on to participate in the NTAGI's work. Members serve for a term of 3 years with an option for one renewal. The new members undergo a one-day orientation by the Secretariat on NITAG TOR, SOP and operations.

There are established procedures to address conflict of interest and confidentiality. Members sign COI before every meeting.

There is one Standing Technical Sub-Committee (STSC), eleven standing Working Groups. The STSC is chaired by two secretaries of Government of India (Departments of Biotechnology and Health Research) and meets quarterly to discuss the agenda items at length and with input from working groups. The full NITAG meets once annually to take up the issues already debated and deliberated in the STSC for final decision and approval. The full NITAG meeting therefore meets for a short period. WG on VPD surveillance and research and capacity building are standing WGs and regularly take up relevant issues. Seven working groups were formed during last five years to focus on specific vaccines (Hepatitis A, Typhoid, HPV, Leprosy, Cholera, Influenza and JE) and have already submitted their reports to STSC. Currently four working groups on broader immunization agenda including standing WGs are active (VPD surveillance, research and capacity building,

maternal immunization and vaccine confidence). The working groups meet as per need and submit their findings and recommendations to STSC.

NTAGI has a dedicated secretariat with three fulltime scientists and is housed at an institution outside the Ministry. The Secretariat is fully funded by Government of India and supports all the activities of the NTAGI and STSC and Working Groups. The Secretariat was established with the support of donor funding (BMGF) till 2017. In 2017, the Secretariat was completely taken over by the GOI. The Secretariat in consultation with the Chairs and the Immunization Division, prepares the agenda background papers that include a review of the literature and are circulated in advance of STSC meetings. The Secretariat has a dedicated office setup and separate budget allocation under annual work plan of the MOHFW.

Recommendations from the STSC are submitted to the full NTAGI which meets annually. Nearly all recommendations have been accepted by the NTAGI and supported by the MOHFW. NTAGI has taken decisions regarding introduction of newer vaccines, interchangeability of vaccines with multiple products (rotavirus vaccine, JE vaccine), strengthening VPD and vaccine safety surveillance related to the newer vaccines.

The NTAGI minutes of the meetings are circulated to the relevant stakeholders and put on the MOHFW website (since 2013). The background papers and reviews of the literature are not available to the public through the website and are not published.

4.4.2.2. Integration with the policies and programs of the immunization sector

The Government shows strong ownership of the Immunization program. The government of India funds almost all the expenditure of the immunization program. There has been partial support for the vaccine used in MR wide age campaign and surveillance from GAVI.

The NTAGI activities are completely funded by the Government. The chairperson and co-chairpersons set the agenda for the NTAGI meetings with a primary focus on new vaccines and reports from the working groups. Several senior Government officials including the maternal child health, health services, communicable diseases including the EPI program managers, are the ex-officio members of the NTAGI. The EPI team attend the annual NTAGI meeting and STSC meetings but are frequently absent from the Working Group meetings.

The composition of the NTAGI includes independent experts though some members may make limited contribution due to their unfamiliarity with vaccine and program related matters. Some of the members also are part of the NCCPE and MR NVC and AEFI committees but there is no institutional mechanism for exchange of information with different vaccine advisory committees.

The routine immunization program faces several challenges related to in-and inter-country migration from neighbouring countries, geographic accessibility, programmatic performance and occasionally vaccine hesitancy. Currently implementation challenges related to routine immunization are not frequently part of the agenda and discussed in the NITAG structure. This has implications for the composition of the NTAGI and there is need for inclusion of social scientists, health economics and persons with prior program experience.

4.4.2.3. Engagement/partnership and linkages with the regional and global agencies

The NTAGI has good engagement with the SEARO RITAG, the WHO, UNICEF, and important international agencies involved in Immunization. The Chair of the RITAG and SAGE member from India are members of the NTAGI.

4.4.2.4. Innovations/ aberrations

Involvement of the administrative leaderships from Department of Biotechnology (the nodal ministry/department for vaccine development) and Department of Health Research (the health research agency in the country) enables smooth collaboration and translation of the decisions.

To escalate the coverage of routine immunization, periodic intensification of routine immunization (PIRI) efforts, Intensified Mission Indradhanush (IMI) efforts have been implemented targeting the areas with low coverage and unimmunized/missed beneficiaries. The IMI has been instrumental in pushing the coverage from 62% to near 80% quickly.

Considering the state and region specific challenges related to disease epidemiology, immunization coverage and health system capacity, NTAGI has been inviting four state health administrators by rotation to listen to the voices from the ground and improve the transparency in decision making.

4.4.3. Preparedness for the journey ahead –

Country Specific Recommendations

1. Review the structure of the NTAGI: The country may consider merger of the two Working Groups and the Standing Technical Sub-Committee (STSC) into one functional technical body that can oversee and guide the technical work of the NTAGI. Ad-hoc working groups would continue to be established as needed. The current NTAGI can be designated as the Executive NTAGI that continues to lead the policy decision-making with respect to recommendations arising from the technical arm of the NTAGI.
    - 1.1. Review the composition of the technical NTAGI and Executive NTAGI in the context of this refinement of roles and strategic direction.
    - 1.2. Consider having the Executive NTAGI meet at least twice a year or more frequently as needed.
    - 1.3. Not all members of the Technical NTAGI would need to attend the meetings of the Executive NTAGI.
2. Consider the inclusion on the NTAGI of persons with implementation and programmatic expertise, representatives from one or two States, civil society, health economist and social scientist.
3. Considering the emergence of India as a vaccine manufacturing hub including new vaccines, the NTAGI needs to give attention for the vaccine research, post-licensure surveillance and national regulatory agency function.
4. Strengthen the secretariat team by including at least one person with expertise in epidemiology and modelling. Other experts could be contracted as needed.
5. The agenda of the NTAGI should be set by the chair and co-chairs following consultation and input from all members of the NTAGI.

4.5. Indonesia

4.5.1. NITAG and Immunization Program

4.5.1.1. ***Journey of the NITAG till 2019:*** The NITAG in Indonesia is called the Indonesia Technical Advisory Group on Immunization (ITAGI) and was formed by the decree of Ministry of Health of 2006 with later amendments in 2010, 2013, 2015 and 2019.

The immunization program in Indonesia is backed by the Health Law 23/2002 and Law 36/2009; and included in the five-year National Medium-Term Development Plan (RPJMN) indicator. The immunisation program has been functioning since 1977 has recently aligned itself with Regional (SEAR-VAP) and Global (GVAP) framework.

There are 17 members and a dedicated Secretariat with three full time staff. The Chair and other members of ITAGI are appointed by the Ministry of Health for a term of four years. The Chair is required to have expertise and knowledge in the field of immunization practices and public health issue. An Executive Secretary is selected from among the members. There is provision for extension of membership for a second term of four years.

4.5.1.2. ***Status of the National Immunization Program:*** The national coverage of the following vaccines is above 90%: BCG (93.7%), DTP3 (93.2%), OPV3 (94.8%), MCV1 (93.0%) and Hep-B birth dose (91.6%). The 1st to 3rd dose dropout for DPT is low (<5%) in the first year. The MCV 1 to MCV 2 drop is much wider (25%). At least 22-25% of the districts have coverage <80% for most of the routine vaccines.

The central government provides vaccines and related logistics, formulation of technical guidelines, monitoring and evaluation and training of the healthcare workers. Around 460 regencies and 98 cities in 34 provinces having their own parliaments to decide about their health priorities and proportionate allocation of health expenditure creates a unique terrain for the translation of national health agenda at the community level. The local governments, enjoying a large degree of autonomy, are responsible for implementation including managing budgetary support and operational issues. Introduction of new vaccines often becomes a challenge in provinces and regencies with relatively weaker administrative and fiscal management capacity. The private sector contributes to approximately 11% of the total vaccines and usually offers the add-on vaccines.

4.5.1.3. ***VPD elimination and eradication status:*** Indonesia has achieved maternal and neonatal tetanus elimination status in 2016. Last case of wild polio virus was identified in 1995. Polio surveillance challenges for sustaining polio eradication are persisting. In addition to this, there is high risk of cross-border transmission for VDPVs from Papua New Guinea where recently VDPV outbreak occurred. Large number of diphtheria outbreaks has been occurring across 170 districts in 30 provinces (954 cases, 44 deaths) in 2017-18; most of these areas are in East Java, West Java and Banten provinces.

4.5.1.4. ***Introduction of new vaccines:*** Based on the ITAGI recommendation, the central and local governments have introduced four new vaccines in a phased manner in recent past: Japanese Encephalitis (JE) Vaccine (sub-nationally since 2018), Pneumococcal Conjugate Vaccine (PCV) (sub-nationally since 2017), Human Papillomavirus (HPV) Vaccine (sub-nationally since 2016), in addition to IPV. The HPV and PCV are expected to be expanded countrywide soon. The introduction of rotavirus and dengue vaccines are under discussion at ITAGI level.

4.5.2. NITAG Functionality, Quality of processes and outputs and Integration

4.5.2.1. Functionality as an Agency (Intention, Power and Rationality)

The ITAGI has 17 members representing the disciplines of paediatrics, public health, epidemiology, internal medicine, microbiology, infectious diseases, social paediatrics and health economics. The Secretariat has three full time staffs and is led by a retired public health expert as Executive Secretary of ITAGI. Twelve members have been serving on ITAGI since 2006. Some of the Government representatives attend the ITAGI meetings as ex-officio members, as special invites as per the agenda and they are not regular members of the ITAGI.

The roles and responsibilities of the ITAGI are defined by a set of TOR that includes: reviewing and recommending national immunization policy, vaccination schedules, recommendation for new vaccines introduction, conducting policy analysis and providing technical advice and developing and standardizing AEFI reporting and mechanism through the National AEFI Committee. The ITAGI has a formal written SOP specified by the MOH decree and the last SOP was approved in 2011.

The ITAGI is supported by a budget from the central government for secretariat activities, plenary meeting, and technical support for working group activities. ITAGI is supported by a dedicated Secretariat with three fulltime members, one member has been continuing since 2006. An agenda is prepared in advance by the secretariat and approved by the Chairperson.

The ITAGI prepares annual work plans and conducts 2-3 plenary meetings and about 4-6 working group meetings. Majorly, four meetings are scheduled annually, but due to budgetary insufficiency, occasionally shorter and small core meetings are held. The ITAGI is unable to follow standard frameworks for literature review and evidence synthesis on account of lack of trained human resources and capacities. On occasions external technical expertise is sought by the ITAGI. The parameters considered by the ITAGI for reviewing evidence and making decisions (by use of customised templates) include burden of disease; vaccine availability, efficacy, immunogenicity, safety, sustainability; program readiness, price; and, funding sustainability. There have been eight working groups on the themes of: Measles Rubella (MR), Pneumococcal Vaccine (PCV), Human Papillomavirus Vaccine (HPV), Polio, Dengue, Rotavirus, Japanese Encephalitis and Health Economics.

The ITAGI prepares annual reports that are submitted to the Ministry of Health. Training workshops are also organised. If necessary, special invitees and vaccine industry representative attend or present in the meetings but are not part of the deliberations and decision making process. The minutes of meeting are prepared by the Executive Secretary, reviewed by the Chairperson and circulated within 1-2 weeks. Urgent core team meetings are held to address issues of outbreaks or vaccine shortages. All decisions are taken by consensus.

The ITAGI minutes of the meetings are circulated to the stakeholders, but not put for public display. The background papers and reviews of the literature used for decision making are not available to the public and are not published.

Members declare and sign a conflict of interest document annually and recently the practice of signing such a document before each meeting has also been introduced.

The current ITAGI was perceived to be the best in recent times and taking evidence based processes in decision making.

4.5.2.2. Integration with the policies and programs of the immunization sector

The ITAGI aligns its agenda and discussions with the national immunization policy and vaccination schedules for both public and private sectors and functions closely with the Director General of Disease Control of Ministry of Health.

It also works closely with the national AEFI committee and the chair of the AEFI committee is a member of the ITAGI. The ITAGI aligns its agenda with the EPI comprehensive Multi Year Plan (cMYP) including introduction of new vaccine and routine immunization imperatives. The ITAGI also responds to urgent matters such as vaccination for Haj pilgrims and exigent situations such as outbreaks of vaccine preventable diseases. The NCCPE, NVC-MR and AEFI committees briefs the ITAGI annually, but the minutes are not shared regularly with each other.

The ITAGI also works in close collaboration with the national regulatory authority (NRA) regarding vaccine approvals and with vaccine manufacturers in the country (who are not part of the decision making process though).

There is however poor coordination and integration with the relevant programs at central level. The representation from provinces in the immunization policy and program is also missing. Barring the procurement of vaccines, most of the program related cost, including the human resource, is borne by local self-governments, and this makes consensus a long and hard to reach process.

The Indonesian Paediatric Society supports the ITAGI on issues of immunization in the private sector and the Port Health Office for international vaccination.

4.5.2.3. Programmatic Challenges

The country has about 460 regencies and 98 cities in 34 provinces; each having their own parliaments, which finally decide their health priorities and accordingly resource allocation. This creates unique situations and sometimes barriers for the translation of national health agenda at the community level. The widely scattered 17,850 islands also pose geographic challenges for access, and travel for implementation of the program. Barring the procurement of vaccines, most of the program related cost, including the human resource, is borne by the local self-governments, which makes negotiation and reaching consensus a long and hard journey.

While the ITAGI's independence is kept at a high level, the translation of its recommendations is a long drawn process. To address these governance challenges, the government through the Ministry of Home Affairs (MoHA) has prescribed and mandated implementation of "Minimum Standards Program (MSP)" by the local self-governments. The relevant central technical ministries and regional governments collaborate for effective decentralization with identified explicit minimum service standards associated with obligatory responsibilities for implementation of the MSP. However, there seems to a lack of clarity about the extent to which immunization related items are part of the MSP and the consequences of non-compliance by a local self-governments which are tilted more towards tertiary care and diagnostics, often at the cost of promotive and preventive arms.

Additionally, the medicines and biologics, including vaccines, undergo a process of approval from the religious/Muslim body for strict Halal compliance. This makes the job even more complex, considering the extrinsic nature of the religious body that makes the final decision. Procurement of Halal compliant vaccines is emerging as a big issue for both, the program managers as well as the manufacturers. The same is applicable for the other biological and medications.

Vaccine hesitancy has emerged as a critical challenge for pushing and sustaining immunization coverage in some areas. In some pockets, this hesitancy and resistance in the community has also influenced a section of frontline healthcare workers and further compounded the task. The recent MR SIA experience pointed towards the issues mentioned above and needs focussed attention to address.

There are stringent vaccine requirements of Halal compliance. This had led to some issues of vaccine hesitancy. The government is now working in close collaboration with the decentralized provincial and district apparatus as well as development partners to overcome this challenge.

The UNICEF offices at national, provincial and local levels are working closely and expanding the scope with regard to issues of vaccine hesitancy, AEFI and social mobilisation.

4.5.2.4. Engagement/partnership and linkages with the regional and global agencies

The ITAGI works in close collaboration with the WHO's country office which provides technical support and fulfils training needs. Development partners such as the Clinton Health Access Initiative (CHAI) and the local Centers for Disease Control (CDC) office also provide specific need based support such as research and introduction of new vaccines. Close collaboration is also maintained with the GNN (Global NITAG Network), and SEAR-NITAG.

Other collaborators include: the International Paediatric Association (for resource persons in immunization advocacy workshop); NESI University of Antwerp (for HPV training workshop). The national UNICEF office and its field units support social mobilisation activities. There are no clear guidelines for an ongoing interaction with RITAG and SAGE. However, there are occasional/one-off interactions with other NITAGS such as Australia, Bangladesh and Korea.

4.5.2.5. Innovations/ aberrations

The 'Minimum Standards Program (MSP)' is an innovation of the central government to ensure standards of key basic services for implementation by the local self-government. The immunization program is now part of the MSP. It is the unanimous perception that this will strengthen the program across all districts.

The Golden Generation Program (GGP) in select province to support optimal child development adds context to the recent state initiatives.

While vaccine procurement is done by the central government, implementation costs are borne by the districts. The provision of special allocation funds may support some of the resource challenged districts more effectively.

The Indonesian Pediatric Society has taken the lead in capacity building of pediatricians and general practitioners in the private sector on vaccinology (burden of diseases, vaccinology, management of AEFI and clearing misconceptions and social hesitancy); 4,000 plus pediatricians have been trained so far.

Demonstration sites are being set up for phased introduction of new vaccines. However, the success of these experiments will depend upon financial commitment at both central and district levels.

4.5.3. Preparedness for the journey ahead – Recommendations

1. The political and bureaucratic setup of the country along with NITAG and NRA should work out strategies that help to de-link availability, access and use of life saving drugs, and biologics including vaccines from the religious screening and approvals and protect scientific decisions for the larger public good.
2. NITAG should continuously review emerging issues of vaccine hesitancy including that due to religious screening and approvals and develop strategies to overcome these.
3. Decentralization is a welcome political process for increasing the community participation and decisions making on issues related to their daily lives. Developmental issues like creating infrastructure and income generation schemes are likely to override and be given greater emphasis over preventive and promotive health care services and education. Provincial and local self-governments should receive dedicated resources for immunization program. In addition, they need hand-holding, capacity building and persistent reminders about the health benefits, social and economic consequences, and sustainability of immunization services.

4.6. Maldives

4.6.1. NITAG and Immunization program

4.6.1.1. ***Journey of the NITAG till 2019:*** The NITAG in Maldives, earlier known as National Committee for Immunization Practice (NCIP) was first established in 2008 by a Ministerial Decree of the Ministry of Health. The NCIP was renamed as Maldives Technical Advisory Group on Immunization (MTAGI) in 2013 following a consultation with WHO. After that the MTAGI was reconstituted in 2015 and recently in 2019. The Charter of MTAGI was adopted in 2015 specifying the responsibilities, structure, functioning and procedures of the MTAGI. The focus of the MTAGI has been on the policies, program monitoring, schedule, introduction of new vaccines and AEFIs.

4.6.1.2. ***Status of the National Immunization Program:*** The Immunization program has been functioning well with the coverage near 100% for most of the routine vaccines. BCG coverage was 100% in 2018 and pentavalent vaccine 99%. MCV1 coverage was 100% and MCV2 was 99%. The recent measles outbreak indicates immunity gap, coverage and data quality challenge. In view of social media misinformation campaign about linkage between MR and autism, there has been delays and reluctance in receiving MRCV doses.

4.6.1.3. ***VPD elimination and eradication status:*** Maldives was certified as a polio-free country in 1980 and IPV vaccine coverage is 99%. Elimination of neonatal tetanus has been achieved. The island state is also verified eliminated both measles and rubella.

4.6.1.4. ***New vaccine introduction*****:** HPV vaccine was introduced in 2019. The rotavirus, PCV and influenza vaccines are under consideration.

4.6.2. NITA Functionality, Quality of processes and outputs and Integration

4.6.2.1. Functionality as an Agency (Intention, Power and Rationality)

The composition of the MTAGI includes six independent experts, two ex-officio members and two liaison members. Three independent members have been there for long period and are well conversant with the vaccine issues. The MTAGI Maldives is a relatively small group of experts (six members), mainly paediatricians. The MTAGI membership has been expanded recently with inclusion of additional independent members from additional disciplines, not readily available in the country. Health Protection Agency (HPA), the executive body for implementation of immunization program in Maldives. Surveillance in-charge from Health Protection Agency (HPA) has been inducted as a core member. Recently NRA representative has also been made an ex-officio member (earlier core member) to further improve MTAGI and NRA engagement. WHO NPO is a core member of the MTAGI. According to the Charter, independent members serve for a term of 5 years.

There is no dedicated secretariat and manpower. The EPI team supports the MTAGI activities and budget for meetings supported by government. No separate sub-committee or Working Groups are made and the whole MTAGI discusses the issues. The MTAGI members prepare the background documents for discussion and decision with assistance from the WHO team as per need.

MTAGI enjoys independence in making recommendations after the agenda is set by HPA. Almost all MTAGI recommendations have been accepted by the HPA, as per the funding availability. However the implementation of MTAGI recommendations often slows down due to manpower constraints in the HPA.

The MTAGI has started recently procedures to address conflict of interest and confidentiality before each meeting.

The MTAGI minutes of the meetings are circulated to the members and partners, not available for public display. The minutes are short and don't capture in detail the issues discussed during the meetings. The background papers and reviews of the literature are neither available for the public nor published.

4.6.2.2. Integration with the policies and programs of the immunization sector

The Government shows ownership of the Immunization program and values the role of MTAGI. The immunization program including vaccines is fully funded by government and procurement done through Unicef. Maldives has recently amended the 'Child Rights Protection Act' which includes provisions of right to health care and vaccination is one of the rights.

The chairperson in consultation with EPI team drafts the agenda for meetings. While several recommendations of the MTAGI for the new vaccine introduction and schedule have been accepted by the Government, some have not been implemented yet.

There is challenge of availability of suitable members for the MTAGI and other advisory bodies. MTAGI members are not equipped to generate or synthesis evidence on their own. Mechanisms for their skill building are not operational – and are ad-hoc in nature. For specialised advice like vaccine cost-effectiveness, the MTAGI and EPI depend on the evidences from other countries and seek assistance from the WHO.

The MTAGI members have only recently started participating in the monitoring of immunization activities and visited several islands.

The MTAGI also functions as the AEFI committee. Two MTAGI members are also part of the polio and MR NVC committees. Except as shared membership across the committees, there is no formal sharing of the information between these committees.

Vaccine hesitancy has been a concern and is slowly rising. The social media (Viber chat) has been very active in spreading the misinformation, especially about MR and autism and now even related to birth dose of HBV. Several of these social media groups are organized by religious groups and from outside the country. Routine immunization also faces challenges from limited knowledge of the health workers to satisfy the parent/community queries. The measles outbreaks indicated gaps in the population immunity and challenges importation.

Reasons behind outbreaks of measles in spite of high vaccine coverage may be: (a). heavy influx of international tourists; and (b). fear of autism leading to delayed immunization in many cases leading to immunity gap. Some pockets of social or cultural resistance to immunization have been identified, mainly in three islands where religious groups have also shown violent reactions. Social Media has a strong negative impact in harming the program and damaging public confidence.

4.6.2.3. Engagement/partnership and linkages with the regional and global agencies

The MTAGI has good engagement with the SEARO RITAG, WHO and UNICEF. The MTAGI Chair and former Chair have good exposure about the SAGE and NITAG network.

Local data to inform local immunization agenda is very limited and weak. MTAGI relies largely on WHO and UNICEF to provide international data for decision making.

4.6.2.4. Innovations/ aberrations

The 'Child Rights Protection Act' entrusts the government for ensuring health services for the children which includes provisions of right to health care and vaccination is now one of the rights of every child.

4.6.3. Preparedness for the journey ahead –

Recommendations

1. In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership. While acknowledging that there is a dearth of in-country expertise, training of the existing members and future members in specific issues such as health economics and social sciences should be considered.
2. MTAGI needs special attention to emerging challenges of vaccine hesitancy and work with other stakeholders to overcome these.
3. The minutes of MTAGI meetings should contain adequate details reflecting key discussions and issues considered for decision making.

4.7. Myanmar

4.7.1. NITAG and Immunization program

4.7.1.1. ***Journey of the NITAG till 2019:*** The NITAG in Myanmar, earlier called the National Committee for Immunization Practices (NCIP) was reconstituted in 2007. The committee then had 25 members, Chaired by Director General, Department of Health. Following a consultation facilitated by WHO in 2012, the NCIP was re-established with categorisation of membership into core, ex-officio, liaison members and Secretariat. In 2012, the NCIP Charter was also adopted. With adoption of the Charter, in 2013, the composition of NCIP was amended with 37 members. After five years of operation, in 2017, Ministry of Health and Sports issued a standing order for transforming NCIP into NITAG with an independent Chairperson. The Charter remains almost same except the characteristics and number of members and Chairperson.

There are five Committees related to immunization program; NITAG, NCCPE, NVC for MR, AEFI and the Interagency Coordination Committee (ICC). ICC is the oversight committee chaired by Permanent Secretary, Ministry of Health.

Immunisation agenda is primarily driven by the Government. NITAG is asked to respond to the government's requirements. Earlier NITAG had primary focus on new vaccines. Since 2018, NITAG has started participating in the annual immunization program review and advice.

A research agenda development workshop was organised in 2018 to identify various EPI related research for the country.

4.7.1.2. ***Status of the National Immunization Program:*** The coverage for BCG, penta-3, OPV-3, PCV-3 and IPV were 90%, 91%, 91%, 91% and 82% respectively in 2018. MCV1 coverage was 93% and MCV2 was 87%. HBV birth dose remains low due to lower institutional deliveries. School vaccine check and vaccination for the missed ones have been initiated in 2019. Vaccine coverage has been low and challenging in several areas, especially the three borders with Bangladesh, India and Thailand. Vaccine hesitancy is increasingly recognised because of the socio-political and religious issues.

EPI program has prioritised 96 townships (out of the total 330 townships) due to conflict affected areas (38 townships), geographically hard to reach areas (36 townships), socially hard to reach areas (15 townships) and ethnic controlled areas (47 townships), with several of the factors overlapping. For many of these high risk areas, the EPI team in partnership with WHO and Unicef has been engaging with local communities through various strategies to make the vaccination accessible and available to the population. For the geographically/climatic hard to reach areas, Crash/Catch-up strategy is being adopted with immunization drive during three months annually. A coverage evaluation survey is currently underway and results are expected by end of 2020.

4.7.1.3. ***VPD elimination and eradication status:*** The country was certified to have eliminated wild polio virus in 2014. Four cases of VDPV1 were isolated in 2019, from one state, where the immunization coverage was around 40%. Elimination of neonatal tetanus has been achieved in 2010. Myanmar continues to be endemic for measles and rubella.

4.7.1.4. Introduction of new vaccines: PCV vaccine was introduced in 2016. JE vaccine has been introduced in routine immunization in 2018. Rotavirus vaccine has been recently introduced (Jan 2020) and HPV vaccine is scheduled for introduction in July 2020.

4.7.2. NITAG Functionality, Quality of processes and outputs and Integration

4.7.2.1. Functionality as an Agency (Intention, Power and Rationality)

The NITAG Myanmar has 11 independent, 23 ex-officio and 2 liaison members. The independent members are retired professionals and highly respected in the Ministry of Health and professional circle. The independent members serve for a term of four years with option of renewal. Although no formal orientation for the NITAG members have been conducted, several of the members have been on earlier NCIP (who underwent the training on NITAG processes), so are well aware of the processes.

The NITAG is primarily focussed on the introduction of new vaccines and little discussion occurs for implementation issues and review of the routine immunization.

NITAG has no dedicated secretariat manpower (EPI team provides the support) and budget. The activities of NITAG are primarily supported from GAVI HSS fund received through WHO. Working groups are formed for specific vaccine issues as per need. The EPI team with assistance from WHO and Unicef prepare the background documents for review and discussion by the NITAG/Working Group members. Based on need, the NITAG seeks external technical assistance, which is facilitated by WHO and CDC.

Overall government has high regard for the NITAG which is conscious about the programmatic and financial sustainability of the new vaccines. Almost all NITAG/NCIP recommendations have been accepted by the MOHS, as per the funding availability and program readiness.

The declaration of conflict of interest before each meeting is still verbal in nature. The minutes of the NITAG meetings are circulated to the members and partners, but not available for public display. The background papers and reviews of the literature are neither available for the public nor published.

4.7.2.2. Integration with the policies and programs of the immunization sector

Immunization Programme is a priority program of Myanmar, which has been able to reach to large sections of population despite socio-political and geographic access challenges. Country ownership is visible with allocation of funds from government budget for vaccines and the national contribution is gradually increasing. The funding for traditional vaccines come from government, while the new vaccines from GAVI. Myanmar is expected to graduate from GAVI support in 2025. The Regional Surveillance Officers (RSOs), seconded from government to WHO for polio surveillance program, are expected to be absorbed into the government system by 2024/2025 as part of GPEI transition.

The NITAG members are highly regarded and have influence in both government and professional community.

The Chair in consultation with EPI team drafts the agenda for meetings. The recommendations of the NCIP for the new vaccine introduction has been accepted by the Government, but delayed for some in view of fund and vaccine availability.

The NITAG is cognisant of the vaccine security and sustainability issues while making decisions about new vaccines in view of some past bitter experiences.

The NITAG Chairperson (former Director General, DOPH and former Chairperson of NCIP) has been involved in the EPI program at national and regional level and is well conversant with the vaccine issues. The NITAG has been participating in annual EPI review since 2018 and members made field visits (even to conflict areas) to understand the implementation challenges. The NITAG also participated in the EPI research agenda development in 2017. Several of the members are common across the NCCPE and MR NVC committees. Joint meetings of the committees have been organised as needed (NITAG and NCCPE for the polio outbreak). A separate AEFI committee is functional in the country.

There is no formal mechanism of sharing the proceedings of the various committees with each other.

Public health service delivery has been a challenge in the non-government controlled (ethnic controlled) and conflict areas apart from the geographically or socially hard to reach areas. Additionally, the urban area of Yangon has pockets of low immunization and there is poor reporting from private hospitals. In the ethnic controlled areas (ECAs), the Ethnic Health Organisations (EHOs) are receiving supplies and training from government and providing the immunization and other public health services in their regions. In the conflict affected areas (CAAs) some of the services are provided through volunteers like Back Pack Health Worker Team (BPHWT) in eastern boarder (adjacent to Thailand). The outbreaks of measles and VDPV1 in these high risk areas indicate low coverage in pockets.

Vaccine hesitancy has been a concern in several regions of the country influenced by the political, and socio-religious conflicts and AEFI related social media misinformation campaigns.

4.7.2.3. Engagement/partnership and linkages with the regional and global agencies

The NITAG has good engagement with the WHO and Unicef at country level and SEARO RITAG. The GAVI HSS support is routed through the WHO and Unicef. The NITAG Chair and members have good exposure about the NITAG, RITAG and SAGE activities. Some of the NITAG members have also good linkage with the Myanmar Medical Association.

4.7.2.4. Innovations/ aberrations

The NITAG has been advising the program for adoption of various strategies and activities to expand the coverage and improve performance. Few key activities include:

Crash/Catch-up strategy: Crash/Catch-up strategy has been adopted to reach the areas inaccessible due to geographic/climate factors for immunization during three-four consecutive months of the year. The left-out children until five years are targeted through these campaigns. All the other possible public health programs are integrated along with immunization.

Negotiation and engagement with agencies in the conflict and non-government controlled areas: In the CAAs and ECAs, the government has not been able to deliver the health services. For curative services, usually the people come out to the nearest public health institution, which also allows capturing the VPDs and other diseases under surveillance. For the ECAs, government has been providing training (to the local health volunteers nominated by the local leadership) and

supplies (vaccines, medicine, bed nets) to the EHOs public health programs including the immunization. For the CAAs, the UN agencies (Unicef and WHO) has been negotiating and brokering on behalf of the government for public health service delivery. The vaccines, supplies and even the cold chain equipment are provided from government side. The equipment is installed by the locals themselves and vaccination is done by their local volunteers. The local leadership has occasionally allowed Unicef and WHO teams but not the government representatives to monitor the implementation. . In some areas the local health functionaries are being paid through international NGOs (INGOs) and supplies from the government source.

QGIS mapping in urban area: Urban immunisation coverage has been a challenge. To improve the mapping and microplanning, QGIS piloting in townships of Yangon has been very informative for identifying the missed out areas and improve the microplanning. It will be expanded further in 2020.

4.7.3. Preparedness for the journey ahead -

Recommendations

1. The NITAG should maintain a healthy distance from the EPI program implementation.
2. Leveraging on the experiences from high risk areas, the NITAG could advise for integration of maternal and child health services with immunization to improve the coverage and acceptance of UHC.
3. The role played by the NITAG in designing and execution of innovations implemented in the high-risk areas to be documented and shared with other member states in the region
4. NITAG should adopt written conflict of interest declaration and mention accordingly in the SOP.
5. NITAG should advise the Ministry of Health on increasing the NRA's role and preparedness for post-GAVI phase.

4.8. Nepal

4.8.1. NITAG and Immunization Program

4.8.1.1. ***Journey of the NITAG till 2019:*** The NITAG in Nepal, earlier called the National Council for Immunization Practices (NCIP) was reconstituted in 2017 with new members. In December 2018, the NCIP was renamed as National Immunization Advisory Committee (NIAC) and reconstituted with new members. The Nepal Immunization Act (2016) provided regulatory basis for formation of three immunization related committees; National Immunization Committee (NIC), National Immunization Advisory Committee (NIAC), and AEFI Investigation Committee, including the membership, terms and functions.

The NIAC serves as an advisory committee for the development, expansion and implementation of immunization program and response to natural calamity or epidemic. The NIAC and AEFI Investigation Committee report to the NIC. The NIC is the executive body headed by Secretary, Ministry of Health and represented by secretaries from other departments including Finance. Nepal Constitution (2015) confers right to each child for health. The Nepal Immunization Regulation, 2018 provides guidance for the operations of the NIAC and AEFI committee, licensure of vaccines, vaccination documentation, and monitoring. The NIAC/NITAG is now governed as per the Immunization Act, and any change in the structure shall need amendment in the act passed by the parliament.

4.8.1.2. ***Status of the National Immunization Program:*** The coverage for BCG, penta-3 and PCV-3 were 96%, 91% and 88% respectively in 2018. MCV1 coverage was 91% and MCV2 was 69%. According to the NHDS-2016, the proportion of unimmunized children (not received any vaccine) was 1%. There was a drop in coverages of all antigens during 2016 following major earthquake and fuel-strike, which have improved in 2017 and maintained. The immunization coverage figures again declined in 2018 in several provinces with decrease in the number of districts/ municipalities with full infant vaccine coverage >80%. The federalisation/decentralization framework adopted by the Government in 2018 has influenced the overall governance and health manpower organisation, which also affected the immunization program performance and reporting. Some areas have low coverage due to challenges of physical access and climatic challenges.

4.8.1.3. ***VPD elimination and eradication status:*** Nepal was certified as a polio-free country in 2014. Elimination of neonatal tetanus has been achieved in 2005. The country remains endemic for measles. SIA for measles and rubella was conducted in 2019

4.8.1.4. ***Introduction of new vaccines:*** JE vaccine was expanded nationwide in 2017 and PCV vaccine in 2015. Rotavirus and HPV vaccines are planned for introduction in near future, but are delayed due to lack of fund availability. The IPV (fractional) vaccine was introduced in 2018, however, its coverage status is not exactly known.

4.8.2. NITAG Functionality, Quality of processes and outputs and Integration

4.8.2.1. Functionality as an Agency (Intention, Power and Rationality)

The NIAC composition, membership and rotation norm are guided by the Act, which makes it restrictive and an amendment in the Act (from Parliament) is needed for any change. The membership is limited in several required expertise. The NIAC/NITAG Nepal is a relatively small group of experts and well supported by the

Ministry of Health. The NIAC is comprised of four independent members and three ex-officio members; thus total number is now lesser than the earlier NCIP. According to the Immunization Act, independent members serve for a term of four years with no clear guidance for rotation or continuation. The NIAC members were oriented through a workshop in November 2019 facilitated by WHO.

There is no detailed Terms of Reference (TOR) for the NIAC although the operational guidelines are given in the Immunization Regulation (2018). The NIAC usually refers to the TOR of the earlier NCIP till now; has initiated drafting detailed procedural document for the NCIP functioning in November 2019, and is to be submitted to the MOH.

The NIAC has no dedicated secretariat manpower (EPI team supports the NCIP activities) and funds are primarily contributed by WHO.

The NIAC is mandated to meet 3-4 times annually and additional, as per need. NIAC members take the lead to prepare the background documents for discussion and decision with assistance from the WHO team. NCIP has established one Working Group on Missed Opportunities and have planned for establishing two more WGs, Typhoid and HPV vaccines respectively.

NIAC is primarily driven by the Government. NIAC is asked to respond to the government's requirements. The Government decides about "what is to be done", while NIAC advises about "how is it to be done". The NIAC Chair in consultation with EPI team drafts the agenda for meetings. The recommendations of the NIAC for the new vaccine introduction has been accepted by the Government, but delayed for some due to availability of fund and vaccine.

NIAC earlier had primary focus on introduction of new vaccines. But NIAC has started discussing the program implementation issues recently and some members also made field visits during the MR SIAs. The NIAC members also attended the EPI review workshop last year.

The declaration of conflict of interest before each meeting has started recently.

Almost all NIAC recommendations have been accepted by the MOH, as per the funding availability. The Interagency Coordination Committee (ICC) involving the different partners facilitates translation of NIAC recommendations in to policy and program. For specialised advice like vaccine cost-effectiveness, the NIAC and EPI seek assistance from the WHO country office.

The NCIP minutes of the meetings are circulated to the members and partners, and not available for public display. The background papers and review of the literature are neither available for the public nor published.

4.8.2.2. Integration with the policies and programs of the immunization sector

National Immunization Programme (NIP) is the top priority health program of Nepal.

Nepal is the first country promulgating Immunization Act (2016) in the Region, which moved from program-based approach to right based approach for immunization. The Act also enables National Immunization Fund (NIF) to ensure financing and sustainability of immunization programs in the country. The Act envisions a public private partnership model. However, the NIF is yet to become fully operational. The NIAC has recognised the challenge of the age limit in EPI policy till 2 years and has recommended to the Parliament to expand the age covered under the ACT till five years.

The funding for traditional vaccines come from government, while the new vaccines from GAVI. For MR vaccine partial funding is from GAVI and government is expected to contribute fully from next year. Nepal is expected graduate from GAVI support in 2025. With the delay in receipt of GAVI funding for Rotavirus vaccine, government is hesitant to seek funds for HPV and postponed the application.

A separate AEFI committee is in force and governed by the Immunization act. The NIAC shares one common member with the NVC-MR and AEFI committee and none with the NCCPE. There is no formal sharing of the information between committees.

NIAC is not involved in the GEPI transition planning or discussion. There are challenges of immunization coverage and reach in urban pockets of Kathmandu.

4.8.2.3. Engagement/partnership and linkages with the regional and global agencies

The NIAC has good engagement with the SEARO RITAG, WHO-HQ, and UNICEF. Although USAID supports the immunization program funding, but not involved in the NITAG process. The NIAC Chair has good exposure about the NITAG, RITAG and SAGE activities. The former NCIP/NIAC chairperson is a current member of the Regional ITAG committee.

4.8.2.4. Challenges

Rapid decentralization of power to Local Self-government in Nepal has led to challenges of transferring lot of responsibility without adequate capacity to execute the program activities. In rural areas, the health agenda is not very strong at the local self-government level. Health coordinators are not well oriented to preventive interventions and program related issues. This may be seen as a concern for equity related issues and significant sub-national variance in service delivery. The changes are to recent and are rapidly evolving; the health system needs some time to respond and determine its impact.

Vaccine hesitancy or poor coverage may be a proxy for inadequate reach of health care delivery system in urban areas. Urban areas have large poorly served pockets of populations, mainly migratory populations. This contributes to low immunization coverage. The routine immunization program faces challenge of the migrant workers from neighbouring countries, several of them unregistered. Nepal is at risk of importation of polio and other VPDs due to porous border and free movement from India.

The coverage dip between 2015 and 2018 may be apparent but not real. There can be several reasons behind this: reporting problems; estimation of birth cohort; and variance between the methods of HMIS and Coverage Evaluation Surveys. These are yet to be factored in to arrive at the ground reality.

4.8.2.5. Innovations/ aberrations

During the MR SIA, immunization card with colour codes has been issued that enables the health workers to follow the children with missed RI doses. This allows linking the SIA with RI activities.

As part of the appreciative enquiry strategy, the villages have been making the full immunization declaration that targets the first year. Declaration of full immunization by the local self-governments continues as before. The declaration process has moved from the Village Development Committees to the districts as of date. Although the district structure is not recognised under the federalisation

restructuring, the health system is still going on with the district approach. Till 2019, 58 of the 77 districts and one province declared full immunization achievement. There is a proposal for expanding the full immunization declaration criteria to the 2nd year also.

4.8.3. Preparedness for the journey ahead – Recommendations

1. The NITAG which has been established by an act of Parliament has limited number of members. The Government should consider bringing in appropriate flexibility in the Immunization Act related to the NITAG membership and operations to expand membership and accommodate additional members with suitable technical expertise.
2. The NITAG's TOR and rotation and/or extension of membership should be specified in a manner ensuring that the total membership of the committee is not changed simultaneously.
3. Decentralization is a welcome political process for increasing the community participation and decisions making on issues related to their daily lives. Developmental issues like creating infrastructure and income generation schemes are likely to override and given greater emphasis over preventive and promotive health care services and education. Provincial and local self-governments should receive dedicated resources for immunization program. In addition, they need hand-holding, capacity building and persistent reminders about the health benefits, social and economic consequences, and sustainability of immunization services.

4.9. Sri Lanka

4.9.1. NITAGs and Immunization Program

4.9.1.1. ***Journey of the NITAGs till 2019:*** In Sri Lanka the National Advisory Committee on Communicable Diseases (ACCD), was established in 1960s as per The Quarantine and Prevention of Diseases Ordinance of 1897. The ACCD has been instrumental in decision-making in the country's well-regarded immunization program since its inception and has also been responsible for reviewing the communicable diseases status in the country and making recommendations concerning all major changes in the national program on immunization and other non-vaccine preventable diseases (non-VPDs) in the country.

In view of the well-functioning ACCD and the role played, the ACCD was considered as the NITAG. The MOH has been accepting almost all of the recommendations made by the ACCD/NITAG. The ACCD/NITAG is reconstituted every five years and the most recent in 2019.

The terms of reference for ACCD/NITAG include advising on communicable diseases as a whole including VPDs and new vaccines, vaccine scheduling, program implementation, VPD epidemiology, VPD and vaccine research and non-VPDs communicable disease control. The ACCD/NITAG has guided Ministry of Health (MOH) on the introduction of Pentavalent, MMR, IPV, HPV vaccines, and influenza vaccine for pregnant women.

4.9.1.2. ***Status of the National Immunization Program:*** The performance of immunization program in Sri Lanka is considered among the best in the region with well-established primary health care infrastructure. According to the available reports, the immunization coverage has been >96% for the first year vaccines and >95% for the second year vaccines. About 90% of the immunization is given by the public health institutions. Sri Lanka has adopted National Immunization Policy in 2014 to further strengthen the immunization system and implementation.

4.9.1.3. ***VPD elimination and eradication status*****:** Sri Lanka is polio free since 1993 and elimination of maternal and neonatal tetanus has been achieved in 2009. Sri Lanka has interrupted indigenous transmission of Measles and Rubella and verified since 2017-2018.

4.9.1.4. ***Introduction of new vaccines:*** HPV was the latest new vaccines introduced into the program in 2017. The decision for rotavirus is yet to be made and discussion on PCV is underway.

4.9.2. NITAG Functionality, Quality of processes and outputs and Integration

4.9.2.1. Functionality as an Agency (Intention, Power and Rationality)

Sri Lanka ACCD/NITAG has been well functioning and productive since its inception and is supported by the Ministry of Health. The ACCD/NITAG is chaired by Director General Health Services, MOH and Chief Epidemiologist, Epidemiology Unit, manager of the NIP serves as the Member Secretary. The ACCD has 57 members including EPI program team based Central Epidemiology Unit (three members), four health administrators, leaderships from 10 divisions/programs, representation from NRA and medical supply division (four members), heads of 11 departments from various institutions, heads of four laboratories, seven independent members from various institutes (faculties and ex-faculties), Colombo municipality, medical

research institute, other immunization committee and WHO (one member each) and representatives from eight professional associations and WHO.

There is lack of clarity between the independent members and technical experts from various institutions as ex-officio members. The independent members serve for five years term, while the institution linked positions are coterminous with the official positions.

The NITAG has a no dedicated secretariat, but supported by the Epidemiology Unit, which consists of three scientists with immunization/epidemiology expertise, supported by other technical support staffs. The Secretariat prepares background papers and documents that include a review of the literature and are circulated well in advance of the meetings. The Epidemiology Unit has been supporting the ACCD effectively and critical for committee's performance.

ACCD/NITAG is considered highly regards by the policy and decision makers. Nearly all recommendations of ACCD/NITAG have been accepted by MOH and implemented as per fund availability. The presence of DGHS as the Chairperson has strategically facilitated the translation of the recommendation. The ACCD/NITAG recommendations are legally binding for the MOH and the Deputy Director General (Public Health), on behalf of the DG of Health Services, oversees the implementation of these recommendations. The ACCD also follows the progress in implementing its recommendations and any issues that have arisen in subsequent meetings.

The ACCD/NITAG has expanded its mandate beyond the immunization program and VPDs to include all the communicable diseases and integration with all relevant sectors across the ministry, academia and health professional associations. National NIP review is conducted periodically with guidance from ACCD. Country level district EPI-VPD reviews are conducted annually to assess field level performances.

There are established procedures to address conflict of interest and confidentiality. The ACCD/NITAG meets quarterly and lasts for about 150-180 minutes. The working groups are formed as per need. During the meetings NIP and VPDs are discussed followed by information sharing on other relevant issues. Recommendations from the working groups are submitted to the ACCD/NITAG and which considers them and takes decision.

The NITAG minutes of the meetings are circulated to the stakeholders, but not posted for public display. The background papers and reviews of the literature used for decision making are not available to the public and are not published.

4.9.2.2. Integration with the policies and programs of the immunization sector

The strong Government ownership for the immunization program is evident in view of the national immunization policy and the program architecture. The immunization program is fully funded by the national government, except few of the newer vaccines till recent past. The agenda setting is beyond the immunization program and new vaccines and has a comprehensive approach to all communicable diseases (including the emergencies) and health system wide integration for effective implementation. Usually the ACCD/NITAG recommendation for new vaccine undergoes rigorous review and assessment based on the available evidence from national, regional and global levels. The leaderships from different divisions including maternal and child health, health education, medical research, various

disease control programs (AIDS/STD, Tuberculosis, Dengue, Malaria, Leprosy, and Filariasis) along with the veterinary health and environmental health participate in the deliberations of ACCD/NITAG. Representation from key VPD laboratories (polio, MR, rabies and vaccine QC), NRA, infectious disease hospital and departments of paediatrics, community medicine, microbiology, parasitology, and pharmacology make the ACCD/NITAG all-inclusive. Representatives from seven professional associations allow uniform and consistent communication across their membership. The chairperson of NCCPE and NVC-MR is represented in the committee and ACCD/NITAG has an AEFI sub-committee. The wide based membership and representation from diverse sectors and expertise allows a comprehensive and integrated approach to communicable diseases and population groups. There is no health economist or immunologist in the ACCD/NITAG.

Annual Immunization Stakeholders' Forum provides a platform for arriving at national consensus to identify the new vaccines for introduction and potential areas of concern and obstacles. The ACCD/NITAG is yet to consider the global Immunization Agenda 2030 and life course immunization framework into its discussion.

ACCD/NITAG led the adoption of the open vial policy for the NIP and inclusion of adrenaline in the AEFI emergency kit to manage anaphylaxis. Recently the committee also provide recommendations for administration of vaccines under medical observation for the children with congenital heart diseases.

4.9.2.3. Engagement/partnership and linkages with the regional and global agencies

The NITAGI has engages with the SEAR RITAG. The Epidemiology Unit team has long standing exposure and collaboration with the Regional ITAG. Several current and former members of the epidemiology unit have been part of the WHO-SAGE and immunization divisions of UN agencies. There is limited participation of partners like WHO and Unicef in NIP.

4.9.2.4. Innovations/ aberrations

The governance including mandate and membership of ACCD/NITAG is comprehensive-based, includes all communicable diseases along with immunization; this has helped the country to have all-inclusive approach to communicable disease and attempts integration across programs and sectors.

The electronic data management systems including "e-surveillance" for online reporting of communicable diseases and web based immunization information system (WBIIS) have been initiated to improve the efficiency of VPD surveillance and EPI management. System also has online AEFI surveillance. The WEBIIS enables tracking of each child for vaccine encounter and maintenance of real time vaccine stock for appropriate decision making.

Annual Immunization Stakeholders' Forum is a platform to discuss the different views regarding new vaccine introduction with representation from administrators, technical experts from the MOH, academia, representatives from professional medical organizations, the NRA and international agencies (WHO and UNICEF). The Forum discusses the global advances, local evidences, needs assessment for the vaccine, economic considerations, and proposed vaccination strategies. The recommendations made by the Forum are submitted to the ACCD/NITAG for further review and follow up.

4.9.3. Preparedness for the journey ahead - Recommendations

1. The experiences of NITAG (ACCD) focusing on communicable diseases mandate beyond immunization should be documented and shared with other countries in the region.

4.10. Thailand

4.10.1. NITAGs and Immunization Program

4.10.1.1. ***Journey of the NITAG till 2019:*** The NITAG in Thailand, also known as Advisory Committee on Immunization Practice (ACIP) is the second oldest committee in the region (established in 1967). In 2001, with establishment of the National Vaccine Committee (NVC), ACIP became a sub-committee under NVC. The NVC is chaired by Prime Minister. The NVC has other three subcommittees to advice on the development of policies related to immunization and vaccines: Vaccine Research and Development, Vaccine Production and Vaccine Quality Control. Some of the recent changes in structure and policy have been shaped by the country's commitment to Universal Health Coverage (UHC). The NITAG/ACIP has been formalised by the Act of National Vaccine Security in 2019. The NITAG/ACIP was recently reconstituted in 2019.

The committee has 10 independent members from various disciplines and 19 ex-officio or liaison members from various concerned departments or institutions. Out of the ten independent members, three are holding positions in Ministry. The NITAG is chaired by Director General, Department of Disease Control.

NITAG adopted the SOP in 2017 to document the responsibilities, structure, functioning and procedures of the NITAG/ACIP and the Working Groups (WGs). The terms of reference for NITAG/ACIP include new vaccines, vaccine scheduling, program implementation, and VPD epidemiology and vaccine research.

There are four immunization WGs: JE vaccine, HPV vaccine, vaccine priority setting and adult immunization. Since 2016, the NITAG/ACIP has guided Ministry of Public Health (MOPH) on Pentavalent vaccine, Dengue vaccine, HPV vaccine, Measles eradication, IPV schedule, introduction of Tdap for pregnant women, Influenza for pregnant women and rabies vaccine. The MOPH has accepted almost all of the recommendations made by the NITAG/ACIP.

4.10.1.2. ***Status of the National Immunization Program:*** The Immunization program performance in in Thailand has been generally robust with well-established primary health care infrastructure in all the sub-districts. About 80% of the immunization services are delivered from public health institutions and the remaining from private providers. According to the available reports, the immunization coverage has been >90% for the first year vaccines and >80% for the second year vaccines. MCV1 coverage was 96% and MCV2 was 86% indicating a sizable dropout rate that needs to be addressed. Compared to the national OPV3 coverage of 90%, the coverage in some of Southern provinces range around 64-65%. Measles and polio immunity gap in Southern Provinces remains main obstacle for the Measles elimination in Thailand.

Despite a successful track record, a weakening of monitoring and evaluation of routine immunization, data capturing and integration are areas of concern during last 5 years or so. The immunization status of the migrants in urban Bangkok is also a challenge. The emerging vaccine hesitancy and resistance in some of the southern provinces and some population pockets require special attention.

4.10.1.3. ***VPD eradication and elimination status:*** Last polio case was reported from Thailand in 1997. Elimination of maternal and neonatal tetanus has been achieved in 1993. Thailand conducted the subnational MR SIAs in 2016 and national SIA in

2019. Booster dose of dT vaccine every 10 years for adults was implemented in 2019.

4.10.1.4. ***Introduction of new vaccines*****:** Two new vaccines have been introduced into the program recently, HPV vaccine (2017) and Pentavalent vaccine (2019). Thailand gives one dose of IPV (intra-muscular) as part of the program. The rotavirus vaccine is scheduled for introduction in 2020 and PCV is also in the pipeline.

4.10.2. NITAG - Functionality, Quality of processes and outputs and Integration

4.10.2.1. Functionality as an Agency (Intention, Power and Rationality)

Thailand NITAG/ACIP has been highly functional and productive, which is well supported by the Ministry of Public Health. The reorganised governance structure of National Vaccine Committee (NVC) has put diverse immunization related institutions under it including the National Vaccine Institute, NITAG/ACIP, National Health Security Organisation (NHSO), Health Intervention and Technology Assessment Program (HITAP). The NITAG/ACIP is chaired by Director General, Department of Disease Control, MOPH with representation from other agencies represented in NVC and financing agencies; this strategic framework links the NITAG effectively to the decision-making level and access to critical resources.

ACIP has 30 members including 10 independent/core members, 14 ex-officio members including chairperson and 6 liaison members. The ten independent members are with relevant and diverse expertise. The WHO and Unicef are not represented in the ACIP. Members usually serve for a term of 4 years with maximum of two consecutive terms.

There are established procedures to address conflict of interest and confidentiality. The NITAG/ACIP meets thrice a year (October, February and June) and meeting dates are notified two months in advance. NITAG/ACIP established four working groups, out of which, currently only WG on adult immunization is active now.

Thailand has a dedicated ACIP Secretariat which consists of four scientists with immunization/vaccine related expertise. The Secretariat prepares background papers and documents that include a review of the literature and are circulated well in advance of the meetings.

Recommendations from the working groups are submitted to the NITAG/ACIP and which considers them and takes decision. Nearly all recommendations of NITAG/ACIP have been accepted by NVC and either implemented by the MOPH or in pipeline for fund allotment for implementation.

The NITAG minutes of the meetings are circulated to the stakeholders. The meeting minutes and background papers for the meetings and reviews of the literature used for decision making are not available to the public display and are not published.

4.10.2.2. Integration with the policies and programs of the immunization sector

The strong Government ownership for the Immunization program is evident in view of the act and the program architecture. The umbrella NVC is chaired by Prime Minister. The immunization program is fully funded by the national government. Usually Chair and NITAG secretariat set the agenda including any suggestion from EPI and other members.

The primary focus of NITAG is usually on new vaccines, vaccine safety issues or emergencies. The NITAG recommendation for new vaccine undergoes cost-

effectiveness evaluation (by HITAP) before placing them before the National Vaccine Committee for approval and financial allocation.

Given the recent challenges in immunization coverage particularly in Southern provinces, emerging vaccine hesitancy and urban coverage issues, NITAG needs to pay greater attention to the program implementation. Programmatic issues are not discussed in the NITAG meetings. Some of the members make limited contribution to the proceedings of the NITAG due to their unfamiliarity with vaccine and program related matters. The NITAG members expressed the need for orientation to NITAG functioning (currently no such sessions are available for the new members) and exposure to the operations related to routine immunization program. Induction of social scientist will be a valuable addition to the Committee for emerging challenges of vaccine hesitancy.

The common membership across the other immunization related committees allows sharing of information, although there is no formal representation of different immunization advisory committees in NITAG.

4.10.2.3. Engagement/partnership and linkages with the regional and global agencies

The NITAG has good engagement with the SEAR RITAG. The Chair of the RCCPE is member of the NITAG. The Chair and members have exposure about the SAGE and other relevant regional bodies. There is no representation of partners like WHO and UNICEF in NITAG/ACIP. WHO have been assisting in immunization activities in urban areas, and UNICEF is participating in developing communication strategies for addressing vaccine hesitancy in some areas.

4.10.2.4. Innovations/ aberrations

The architecture and organisation of vaccine policy making bodies appear very comprehensive and allows input from multiple bodies for decision making. The Health Intervention and Technology Assessment Program (HITAP) undertakes the cost effective analysis for informed decision making. The National Health Security Organisation (NHSO) examines the vaccine financing independently.

The complex organisation of these bodies also make sometime the decision making process time taking.

Nationwide implementation of adult vaccination program is encouraging.

4.10.3. Preparedness for the journey ahead

Country specific Recommendations

1. NITAG and EPI program needs to give special attention for implementation of immunization program in urban areas and among populations with vaccine hesitancy.
    - Better data sharing and coordination mechanisms among the Ministry of Public Health and the Bangkok Metropolitan Area are required.
2. Current complex decision making processes and release of finances in relation to the immunization program and NITAG need review at political and bureaucratic levels for simplification.
3. Partner organisations like WHO and Unicef should closely coordinate their technical assistance and interact with NITAG.

4.11. Timor-Leste

4.11.1. NITAG and Immunization Program

4.11.1.1. ***Journey of the NITAG till 2019:*** The NITAG in Timor-Leste, earlier called the National Committee for Immunization Practices (NCIP) was formed in 2007. With advocacy and facilitation by WHO, the NITAG was constituted in 2015. The internal procedures and work plan were developed. As per the internal procedure manual, the NITAG is comprised of 7 core members and an independent chairperson. There are 8 ex-officio non-core members from various departments and 5 liaison members.

There are five Committees related to immunization program; NITAG, NCCPE and NVC for MR, AEFI and the Working Group for EPI. The Working Group for EPI has been functioning before NITAG formation, which meets monthly to guide the program. Immunisation agenda is primarily driven by the Ministry of Health. NITAG provides technical guidance to the Ministry of Health for immunization, especially to introduce new vaccines.

The EPI division functioned as the Secretariat till Jan 2017. In February 2017, a dedicated Secretariat was established with provision of a separate office.

4.11.1.2. ***Status of the National Immunization Program:*** The coverage for BCG, penta-3, OPV-3 and IPV were 95%, 83%, 83%, and 80% respectively in 2018. MCV1 coverage was 83% and MCV2 was 54%. HBV birth dose introduced in the national program in 2016 remains around 66%, primarily due to low institutional delivery. Maternal TT vaccine coverage is about 68%.

Vaccine coverage has been low and challenging in several areas, especially the rural areas due to poor physical accessibility, coupled with community knowledge and awareness. Vaccine hesitancy is not considered a challenge now. To improve the immunization coverage, monthly integrated primary health care package (including immunization) through mobile clinics are implemented in several areas. A unique information technology platform, *"Saude na Familia"* is being implemented to capture all health-related information including immunization with a vision to develop national electronic immunization register.

4.11.1.3. ***VPD elimination and eradication status*****:** Timor-Leste is polio free since 1995 and elimination of maternal and neonatal tetanus has been achieved in 2012. The country has been verified measles (2017) and rubella (2018) eliminated.

4.11.1.4. ***Introduction of new vaccines:*** IPV, MR DPT and DT booster doses have been introduced in 2016. Rotavirus vaccine has been recently introduced (December 2019) with Gavi support. The PCV and HPV vaccines are scheduled for introduction in July 2020/2021 with Gavi support for one birth cohort.

4.11.2. NITAG Functionality, Quality of processes and outputs and Integration

4.11.2.1. Functionality as an Agency (Intention, Power and Rationality)

The NITAG Timor-Leste has 7 independent, 8 ex-officio and 5 liaison members. The independent members include three paediatricians, and one each from clinical medicine, infectious disease, epidemiology and laboratory. The independent members serve for a term of three years with option of one renewal at present. NITAG members have been oriented on the procedures and processes of the Committee after it was constituted.

There are seven working groups/sub-committees on specific vaccine issues (PCV, HPV, JE, MR control), strengthening routine EPI and VPD surveillance) and AEFI. All the sub-committees have been functioning well except the one for JE vaccine. The dedicated NITAG Secretariat with a doctor has been functional since 2017. The incumbent secretariat person is in position for a year and gradually gaining skills. The WHO team supports to a large extent in preparing the background documents for review and discussion by the NITAG/Working Groups. The budget for the Secretariat and meetings come from Ministry, while the capacity building cost is borne by WHO (from GAVI HSS fund).

Almost all NITAG recommendations including new vaccines introduction have been accepted by the MOH, as per the funding availability and program readiness. Some of the recommended vaccines (HPV, PCV) are scheduled for introduction, subject to funding and vaccine availability. The NITAG is cognisant of the financial and programmatic sustainability while making decisions about new vaccines but not aware of the budgetary projection/availability. Following the decision on the new vaccine, the committee meets the Minister to brief the recommendations. Overall government has high regard for the NITAG and its membership.

The members declare conflict of interest in writing annually and not before each meeting.

Timor-Leste NITAG has twinning collaboration with Australian NITAG (NCIRS), which facilitated several capacity building workshops including the evidence synthesis process. The TL NITAG and secretariat has also visited Australia to observe the proceedings. WHO team has been facilitating the twinning process and arranging for external technical consultants.

The country has limited availability of experts in vaccinology, public health and infectious disease. For the future NITAG, grooming of members and systematic capacity building process is to be put in place.

The NITAG minutes of the meetings are circulated to the members and partners. The meeting minutes and background papers and reviews of the literature are not available for the public display.

4.11.2.2. Integration with the policies and programs of the immunization sector

Immunization Programme has emerged as a priority health program of Timor-Leste, with an effort to expanding the reach.

Country ownership is visible with the funding for traditional vaccines by government and commitment of funds for new vaccines beyond the Gavi support. Despite the political instability and budgetary challenges, the funds for vaccine and immunization have been maintained.

Public health service delivery has been a challenge in the rural areas due to the physical access during rainy seasons. Disease surveillance has also been challenge and country data for several conditions are not available.

The NITAG members are highly regarded and have influence in both government and professional community. The Chairperson has been leading the other immunization and VPD related committees and is well conversant with the vaccine issues. The Chair in consultation with EPI team drafts the agenda for meetings. The different sub-committees/working groups of NITAG present the progress during the meeting.

The AEFI committee is a sub-committee of NITAG and active. The NITAG Chairperson is also chairing the NCCPE and MR-NVC. Several of the members are common across the NCCPE, MR-NVC and AEFI committees, which ensures sharing the proceedings of the various committees with each other. EPI Working Group has with members from WHO, UNICEF, HMIS, Surveillance, Central Stores, Training Centre and EPI team is coordinating. The NITAG Secretariat member also attends EPI WG meeting. The NITAG has no interaction with national regulatory authorities.

There is no formal process to develop research agenda and EPI program at present does not see much role of NITAG beyond the introduction of new vaccines.

The stakeholders did not perceive vaccine hesitancy as an important issue in Timor-Leste at present.

4.11.2.3. Engagement/partnership and linkages with the regional and global agencies

The NITAG chair and membership is actively engaged with the WHO and UNICEF at country level and SEARO RITAG. The GAVI HSS support is routed through the WHO and UNICEF. The NITAG Chair is a member of RCCPE. The NITAG members have limited exposure to the NITAG Resource Centre.

4.11.2.4. Innovations/ aberrations

A twining arrangement between NITAG-TL and Australia NTAGI/NCIRS exists for capacity building of the members and secretariat through technical workshops and exchange visits. Also this partnership is assisting in AEFI causality assessment and planning studies on data collection for VPD and vaccine effectiveness. WHO has been supporting and facilitating these twinning program.

Servisu Integradu da Saúde Communitária (SISCa) or Integrated Community Health Services are conducted monthly for the '*sucos'* (villages) without health posts, by the associated Community Health Centre (CHC). During these SISCa sessions integrated health services including immunization are delivered.

'Saúde na Família' or 'health in the family' is a flagship program of Ministry designed for expanding the health care coverage and bring the health services closer to families and communities in rural areas through domiciliary visits. The visits are conducted by integrated teams composed of a doctor, a midwife and a nurse and target at primary health care including immunization. This program uses unique information technology platform to capture all health-related information including immunization and plans to develop national electronic immunization register.

4.11.3. Preparedness for the journey ahead -
Country specific Recommendations

1. In view of the shortage of appropriate technical expertise for NITAG and other immunization advisory committees, the EPI program may consider identification and grooming of younger professionals for future membership. While acknowledging that there is a dearth of in-country expertise, training of the existing members and future members in specific issues such as health economics and social sciences should be considered.
2. The innovations introduced for integration of primary health services with immunization including use of IT platform need to be used as case study for its operational feasibility and application in different contexts.

3. The experience of twinning of one NITAG with another more mature NITAG needs to be well documented for wider use.
4. NITAG should advise the MOH on streamlining the NRAs role and preparedness for post-GAVI phase.
5. Consider adding a second person into the Secretariat to ensure continuity.

Section 5

Challenges encountered during the evaluation

- Delay in obtaining the information from the country NITAGs: The time taken for obtaining information from the country NITAG and EPI program team was longer than anticipated.
- Delay in visits to some countries: The time schedule for some country visits were delayed due to the holidays during December 2019 and January 2020 months and unavailability of several key stakeholders. The country visit timings were dependent on the Ministry of Health and NITAG member's availability.
- The web/tele-conference interaction with stakeholders from DPR Korea was not feasible due to logistic problems.
- COVID-19 outbreak challenge: Time schedule for conducting in-depth interviews with the stakeholders from the countries not visited were delayed due unavailability of several stakeholders for holidays (December 2019- January 2020) and later COVID-19 response (February- April 2020). Several of the program and NITAG members were engaged with the COVID outbreak response activities, which delayed their availability for the interactions/interviews. Some of the evaluation team members were also engaged in the COVID response and related activities at their institute and national level, which delayed finalising the report.

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Section 6

Country Assessments Checklists

6.1. BANGLADESH

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	■ Fully met	☐ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	■ Fully met	☐ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	☐ Fully met	■ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	☐ Fully met	■ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	■ Fully met	☐ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	■ Fully met	☐ Partially met	☐ Not met

6.1. BANGLADESH

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2019	
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2019	
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Partial	Structure not mentioned. more technical expertise needed
1.2.7	TOR for technical working groups	Yes	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Partial	For new vaccines, but not established vaccines
1.3.4.4	Surveillance of vaccine-preventable diseases	Yes	
1.3.4.5	Vaccine safety	No	
1.3.4.6	Vaccine policy	No	
1.3.4.7	Vaccine development	No	
1.3.4.8	Any other, specify	Yes	Research
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	Yes	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	Yes	
1.4.15	Mentions performance evaluation including process and outcome indicators	Yes	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	No	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	13	
1.5.2.1	Epidemiology	2	
1.5.2.2	Pediatrics	2	
1.5.2.3	Clinical medicine/Clinical research	3	
1.5.2.4	Infectious diseases		
1.5.2.5	Public health	1	
1.5.2.6	Vaccinology		
1.5.2.7	Immunology	1	
1.5.2.8	Microbiology (incl. Virology)	4	
1.5.2.9	Health systems and delivery		
1.5.2.10	Health economics		

Sl no	Area/Topic	Status	Comments/Note
1.5.2.11	Regulatory practice		
1.5.2.12	General practice		
1.5.2.13	Social science		
1.5.2.14	Ethics/Other disciplines		Medical council
1.5.2.15	NGOs/ Civil society/ Lay members		
1.5.2.16	Pharmaceutical industry		
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	3 years	
1.5.3.2	Tenure of membership for core members	3 years	
1.5.4	Ex-officio membership composition and expertise	2	
1.5.4.1	EPI	1	
1.5.4.2	Maternal and child health		
1.5.4.3	Disease control	1	
1.5.4.4	NRA		
1.5.4.5	Finance		
1.5.4.6	Procurement		
1.5.4.7	Other related departments/Ministries		
1.5.4.8	University faculty		
1.5.5	Liaison membership	0	
1.5.5.1	Paediatric professional association		
1.5.5.2	Public health professional association		
1.5.5.3	Physician professional association		
1.5.5.4	Other professional association		
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	Yes	
1.7	**Independence of the committee**		
1.7.1	The core members are independent	13/15	
1.7.2	Independent Chairperson	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	2	
1.8.2	No. of meetings held during reference period	5	
1.8.2.1	2016	NA	
1.8.2.2	2017	NA	
1.8.2.3	2018	NA	
1.8.2.4	2019	6	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Partially	Still to align with cMYP
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	Yes	
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	No	EPI Team,

Sl no	Area/Topic	Status	Comments/Note
			Dedicated Secretariat proposed
1.11.2	MoH officially appoints NITAG secretariat	NA	
1.11.3	Number of human resources in the Secretariat	0	No HR dedicated to NITAG Secretariat
1.11.3.1	Fulltime members	NA	
1.11.3.2	Part-time members	NA	
1.11.4	Human resources have the appropriate technical skills	NA	
1.11.5	Training of the Secretariat team in related disciplines	No	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Partially	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	No	
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	Budget proposed, awaiting approval
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	No	
1.12.3	Source of budget (if not covered by MOH)	WHO	
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	Yes	
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.2.2	The criteria used for review and decision making	Yes	
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Yes	
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Yes	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Yes	
2.4.2.3	Results to present the findings per key outcome	Yes	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Yes	
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed.	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Descent note by any member is documented	Not experienced	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Partially	Not considered the cMYP

Sl no	Area/Topic	Status	Comments/Note
3.1.4	The NITAG reports to a designated high-level official of the MOH, who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yet to happen	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yet to happen	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	HPV	Recommendation submitted
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	No	Not yet started
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	No	
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	Yes	Vaccine Act
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	Suggested
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	Suggested
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Partially	Limited circulation
3.3.4	The general population is aware of the NITAG's role	Not sure	
3.4	**Collaboration with relevant partners based on interest**		
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Not formal	
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Not formal	
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Not yet happened	

6.2. BHUTAN

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	☐ Fully met	■ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	■ Fully met	☐ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	☐ Fully met	■ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	☐ Fully met	■ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	■ Fully met	☐ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	☐ Fully met	■ Partially met	☐ Not met

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COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2009/2012	
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2019	
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Partial	VPDP- Managerial RCDC- Technical
1.2.7	TOR for technical working groups	Yes	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	Yes	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	No	
1.3.4.8	Any other, specify	Yes	Research
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	Yes	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	No	
1.4.15	Mentions performance evaluation including process and outcome indicators	No	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	No	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	5	
1.5.2.1	Epidemiology		
1.5.2.2	Pediatrics	2	
1.5.2.3	Clinical medicine/Clinical research	1	
1.5.2.4	Infectious diseases		
1.5.2.5	Public health		
1.5.2.6	Vaccinology		
1.5.2.7	Immunology		
1.5.2.8	Microbiology (incl. Virology)	1	
1.5.2.9	Health systems and delivery		
1.5.2.10	Health economics		
1.5.2.11	Regulatory practice		
1.5.2.12	General practice		
1.5.2.13	Social science		

Sl no	Area/Topic	Status	Comments/Note
1.5.2.14	Ethics/Other disciplines	1	Medical council
1.5.2.15	NGOs/ Civil society/ Lay members		
1.5.2.16	Pharmaceutical industry		
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	5 years	
1.5.3.2	Tenure of membership for core members	5 years	
1.5.4	Ex-officio membership composition and expertise	4	
1.5.4.1	EPI	1	
1.5.4.2	Maternal and child health		
1.5.4.3	NRA	1	
1.5.4.4	Finance		
1.5.4.5	Procurement		
1.5.4.6	Other related departments/Ministries	3	
1.5.4.7	University faculty		
1.5.5	Liaison membership	0	
1.5.5.1	Paediatric professional association		
1.5.5.2	Public health professional association		
1.5.5.3	Physician professional association		
1.5.5.4	Other professional association		
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	Yes	
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	
1.7.2	Independent Chairperson	Yes	
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	3	
1.8.2	No. of meetings held during reference period		
1.8.2.1	2016	4	

Sl no	Area/Topic	Status	Comments/Note
1.8.2.2	2017	4	
1.8.2.3	2018	6	
1.8.2.4	2019	5	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	No	
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	No	VPDP team
1.11.2	MoH officially appoints NITAG secretariat	No	
1.11.3	Number of human resources in the Secretariat	0	
1.11.3.1	Fulltime members	NA	
1.11.3.2	Part-time members	NA	

Sl no	Area/Topic	Status	Comments/Note
1.11.4	Human resources have the appropriate technical skills	No	No formal training in vaccinology
1.11.5	Training of the Secretariat team in related disciplines	No	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Partial	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	No	
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	Yes	Meetings and AEFI
1.12.3	Source of budget (if not covered by MOH)	WHO/Unicef	Training, monitoring
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	Yes	
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	
2.2.2	The criteria used for review and decision making	Yes	
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Yes	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Yes	
2.4.2.3	Results to present the findings per key outcome	Yes	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed.	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Dissent note by any member is documented	Not experienced	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	
3.1.4	The NITAG reports to a designated high-level official of the MOH who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	PCV, HPV, Influenza	
3.2.5	Any recommendation on existing vaccine schedule or campaign made by NITAG	No	
3.2.6	NITAG reviews the routine immunization program as part of the regular agenda	Yes	Started from 2019
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	Yes	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Partially	Limited circulation
3.3.4	The general population is aware of the NITAG's role	Yes	
3.4	**Collaboration with relevant partners based on interest**		

Sl no	Area/Topic	Status	Comments/Note
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Not formal	
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Not formal	
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	

6.3. DPR KOREA

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	■ Fully met	☐ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	☐ Fully met	■ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	■ Fully met	☐ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	■ Fully met	☐ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	■ Fully met	☐ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	■ Fully met	☐ Partially met	☐ Not met

6.3. DPR KOREA

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2012	NITAG
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2018	7 new members inducted
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Yes	
1.2.7	TOR for technical working groups	Yes	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	Yes	
1.3.4.5	Vaccine safety	No	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	Yes	
1.3.4.8	Any other, specify	Yes	Promote partnership
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	Same as TOR document
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.5	Mentions meeting rules	Yes	
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	Yes	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	Yes	
1.4.15	Mentions performance evaluation including process and outcome indicators	Yes	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	No	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	11	
1.5.2.1	Epidemiology	3	
1.5.2.2	Pediatrics	1	
1.5.2.3	Clinical medicine/Clinical research	0	
1.5.2.4	Infectious diseases	1	
1.5.2.5	Public health	0	
1.5.2.6	Vaccinology	0	
1.5.2.7	Immunology	2	
1.5.2.8	Microbiology (incl. Virology)	3	
1.5.2.9	Health systems and delivery	0	
1.5.2.10	Health economics	0	
1.5.2.11	Regulatory practice	1	
1.5.2.12	General practice	0	

Sl no	Area/Topic	Status	Comments/Note
1.5.2.13	Social science	0	
1.5.2.14	Ethics/Other disciplines	0	
1.5.2.15	NGOs/ Civil society/ Lay members	0	
1.5.2.16	Pharmaceutical industry	0	
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	Not fixed	Ex-officio
1.5.3.2	Tenure of membership for core members	Not fixed	
1.5.4	Ex-officio membership composition and expertise	3	
	Health Administration	1	
1.5.4.1	EPI	1	
	Public Health	0	
1.5.4.2	Maternal and child health	0	
1.5.4.3	Disease control	1	
1.5.4.4	NRA	0	
1.5.4.5	Finance and planning	0	
1.5.4.6	Procurement and supply	0	
1.5.4.7	Other related departments/Ministries	0	
1.5.4.8	University faculty/Hospital representatives	0	
1.5.5	Liaison membership	0	
1.5.5.1	Paediatric professional association	0	
1.5.5.2	Public health professional association	0	
1.5.5.3	Medical/Physician professional association	0	
1.5.5.4	Other professional association	0	
1.5.5.5	UN organisations (WHO, Unicef)	0	
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	Annually
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	Yes	Annually written and verbally before meetings
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.7.2	Independent Chairperson	No	
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	2-3	
1.8.2	No. of meetings held during reference period	10	
1.8.2.1	2016	2	
1.8.2.2	2017	2	
1.8.2.3	2018	3	
1.8.2.4	2019	3	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	Yes	Annual orientation
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	No	

Sl no	Area/Topic	Status	Comments/Note
1.11.2	MoH officially appoints NITAG secretariat	Yes	
1.11.3	Number of human resources in the Secretariat	2	
1.11.3.1	Fulltime members	2	
1.11.3.2	Part-time members	0	
1.11.4	Human resources have the appropriate technical skills	Yes	
1.11.5	Training of the Secretariat team in related disciplines	Yes	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Yes	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	Yes	
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	Yes	
1.12.3	Source of budget (if not covered by MOH)	MoHS	
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	Yes	SOP for evidence review and synthesis available
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	
2.2.2	The criteria used for review and decision making	Yes	
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional	Yes	

Sl no	Area/Topic	Status	Comments/Note
	and international considerations; socio-economic and social impact of the disease)		
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Yes	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Yes	
2.4.2.3	Results to present the findings per key outcome	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Yes	
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Dissent note by any member is documented	Not experienced	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	
3.1.4	The NITAG reports to a designated high-level official of the MOH, who is not a NITAG member	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	MR, IPV
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	Yes	NIP plan 2016-2019
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	Yes	DPT-Booster
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Partially	Limited circulation
3.3.4	The general population is aware of the NITAG's role	Not sure	

Sl no	Area/Topic	Status	Comments/Note
3.4	**Collaboration with relevant partners based on interest**		
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Not sure	No interview could be conducted
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Not sure	
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	

6.4. INDIA

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	■ Fully met	☐ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	☐ Fully met	■ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	☐ Fully met	■ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	■ Fully met	☐ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	■ Fully met	☐ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	■ Fully met	☐ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	☐ Fully met	■ Partially met	☐ Not met

6.4. INDIA

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2001	
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2013/2018	Reconstituted/ Partial rotation
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Yes	
1.2.7	TOR for technical working groups	Yes	STSC and WG
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	Yes	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	Yes	
1.3.4.8	Any other, specify	Yes	Research
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	Yes	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	Yes	
1.4.14	Mentions process for NITAG evaluation	No	
1.4.15	Mentions performance evaluation including process and outcome indicators	No	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	Yes	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	16	
1.5.2.1	Epidemiology	1	
1.5.2.2	Pediatrics	1	
1.5.2.3	Clinical medicine/Clinical research	3	
1.5.2.4	Infectious diseases	2	
1.5.2.5	Public health	1	
1.5.2.6	Vaccinology	1	
1.5.2.7	Immunology	0	
1.5.2.8	Microbiology (incl. Virology)	1	
1.5.2.9	Health systems and delivery	0	
1.5.2.10	Health economics	1	
1.5.2.11	Regulatory practice	1	
1.5.2.12	General practice	0	

Sl no	Area/Topic	Status	Comments/Note
1.5.2.13	Social science	1	
1.5.2.14	Ethics/Other disciplines	1	Biotechnology
1.5.2.15	NGOs/ Civil society/ Lay members	0	
1.5.2.16	Pharmaceutical industry	0	
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	Not fixed	Coterminous with position
1.5.3.2	Tenure of membership for core members	2/3 years	MOHFW Order 2013/ Code of practice 2015
1.5.4	Ex-officio membership composition and expertise	13	4 Ex-officio members listed as liaison members
1.5.4.1	Health administration	3	PS, AS & MD, DGHS
1.5.4.2	EPI	0	
1.5.4.3	Maternal and child health	0	
1.5.4.4	Biotechnology	1	
1.5.4.5	Health Research	1	
1.5.4.6	NRA	0	
1.5.4.7	Finance	0	
1.5.4.8	Procurement	0	
1.5.4.9	Other related departments/Ministries	7	
1.5.4.10	University/Institution faculty	1	THSTI
1.5.5	Liaison membership	9	
1.5.5.1	MCH/RCH- MoHFW	1	JS-RCH
1.5.5.2	EPI	2	
1.5.5.3	NRA	1	
1.5.5.4	Paediatric professional association	1	
1.5.5.5	Public health professional association	0	
1.5.5.6	Physician professional association	1	
1.5.5.7	Other professional association	0	
1.5.5.8	Professional Institution	1	President, PHFI
1.5.5.9	UN organisations	2	WHO, Unicef
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	Yes	
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	
1.7.2	Independent Chairperson	No	Secretary, MOHFW (Chair) Secretary, DBT (Co-Chair) Secretary, DHR (Co-Chair)
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	NTAGI - 2/1 STSC- 4	GoI order 2013/ Code of practice 2015
1.8.2	No. of meetings held during reference period		
1.8.2.1	2016	1	
1.8.2.2	2017	1	
1.8.2.3	2018	1	
1.8.2.4	2019	0	Postponed
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Not documented	STSC meetings held
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	Yes	
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	Yes	
1.11.2	MoH officially appoints NITAG secretariat	Yes	
1.11.3	Number of human resources in the Secretariat	3	
1.11.3.1	Fulltime members	3	
1.11.3.2	Part-time members	0	
1.11.4	Human resources have the appropriate technical skills	Yes	
1.11.5	Training of the Secretariat team in related disciplines	Yes	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Yes	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	Yes	
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	Yes	
1.12.3	Source of budget (if not covered by MOH)	NA	
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		

Sl no	Area/Topic	Status	Comments/Note
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	Yes	
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	
2.2.2	The criteria used for review and decision making	Yes	
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Yes	
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Yes	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the	Yes	

Sl no	Area/Topic	Status	Comments/Note
	inability to conclude on a given topic, if relevant)		
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Yes	
2.4.2.3	Results to present the findings per key outcome	Yes	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Yes	
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed.	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Dissent note by any member is documented	Yes	For internal records. Not mentioned in the minutes.
2.6	**Implementation of decision-making procedure as per SOP**		

Sl no	Area/Topic	Status	Comments/Note
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	
3.1.4	The NITAG reports to a designated high-level official of the MOH who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	HPV, PCV
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	No	
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	Yes	Td vaccine for all ages & PW; Rotavirus vaccine interchangeability

Sl no	Area/Topic	Status	Comments/Note
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	Yes	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	Yes	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Yes	
3.3.4	The general population is aware of the NITAG's role	Yes	Public comments received on NTAGI minutes/ decisions
3.4	**Collaboration with relevant partners based on interest**		
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Partial	AEFI Committee Chairperson member; NCCPE/NVC not member
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Partial	Secretary Health- Chairperson; AS & MD and JS RCH members
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	SAGE and RITAG members are part of NTAGI

6.5. INDONESIA

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	■ Fully met	☐ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	■ Fully met	☐ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	■ Fully met	☐ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	■ Fully met	☐ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	☐ Fully met	■ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	☐ Fully met	■ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	☐ Fully met	■ Partially met	☐ Not met

6.5. INDONESIA

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2007	
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2019	Reconstituted
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Yes	
1.2.7	TOR for technical working groups	Yes	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	No	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	Yes	
1.3.4.8	Any other, specify		
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	Yes	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	Yes	
1.4.14	Mentions process for NITAG evaluation	No	
1.4.15	Mentions performance evaluation including process and outcome indicators	No	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	Yes	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	17	
1.5.2.1	Epidemiology	1	
1.5.2.2	Pediatrics	7	
1.5.2.3	Clinical medicine/Clinical research	2	
1.5.2.4	Infectious diseases	2	Both paediatricians
1.5.2.5	Public health	1	
1.5.2.6	Vaccinology	0	
1.5.2.7	Immunology	0	
1.5.2.8	Microbiology (incl. Virology)	2	
1.5.2.9	Health systems and delivery	0	
1.5.2.10	Health economics	2	
1.5.2.11	Regulatory practice	0	

Sl no	Area/Topic	Status	Comments/Note
1.5.2.12	General practice	0	
1.5.2.13	Social science	0	2 social paediatrician members
1.5.2.14	Ethics/Other disciplines	0	
1.5.2.15	NGOs/ Civil society/ Lay members	0	
1.5.2.16	Pharmaceutical industry	0	
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	4 years	
1.5.3.2	Tenure of membership for core members	4 years	
1.5.4	Ex-officio membership composition and expertise	0	No specified ex-officio members
1.5.4.1	Health administration	0	
1.5.4.2	EPI	0	
1.5.4.3	Maternal and child health	0	
1.5.4.4	Biotechnology	0	
1.5.4.5	Health Research	0	
1.5.4.6	NRA	0	
1.5.4.7	Finance	0	
1.5.4.8	Procurement	0	
1.5.4.9	Other related departments/Ministries	0	
1.5.4.10	University/Institution faculty	0	
1.5.5	Liaison membership	0	No specified members
1.5.5.1	Paediatric professional association	0	
1.5.5.2	Public health professional association	0	
1.5.5.3	Physician professional association	0	
1.5.5.4	Other professional association	0	
1.5.5.5	UN organisations	0	
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	
1.6.5	All core members declare their CoI at the time of their appointment	Yes	Annually declare

Sl no	Area/Topic	Status	Comments/Note
1.6.6	All core members declare their CoI before every meeting or vote	Yes	Recently started
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	
1.7.2	Independent Chairperson	Yes	
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	3-4	
1.8.2	No. of meetings held during reference period		
1.8.2.1	2016	3/3	Plenary/WG
1.8.2.2	2017	2/4	Plenary/WG
1.8.2.3	2018	2/6	Plenary/WG
1.8.2.4	2019	3/5	Plenary/WG
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	1/-/2/2	2016/2017/ 2018/2019
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG,	Yes	

Sl no	Area/Topic	Status	Comments/Note
	professional agencies/experts, international partners)		
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	Yes	
1.11.2	MoH officially appoints NITAG secretariat	Yes	
1.11.3	Number of human resources in the Secretariat	2+1	
1.11.3.1	Fulltime members	2	
1.11.3.2	Part-time members	1	Executive Secretary
1.11.4	Human resources have the appropriate technical skills	Partially	Need further training
1.11.5	Training of the Secretariat team in related disciplines	No	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Yes	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	No	
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	Yes	
1.12.3	Source of budget (if not covered by MOH)	NA	
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	No	No framework is used
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.2.2	The criteria used for review and decision making		
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Yes	
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Yes	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Partially	
2.4.2.3	Results to present the findings per key outcome	Yes	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Partially	
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Dissent note by any member is documented	No	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.1.4	The NITAG reports to a designated high-level official of the MOH who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	Subject to the approvals from the religious and financial bodies
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	IPV, MR, HPV, JE, PCV
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	No	
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	No	
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	No	
3.3.4	The general population is aware of the NITAG's role	Not sure	
3.4	**Collaboration with relevant partners based on interest**		
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Limited	Committees brief annually and as per need
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Limited	Ex-officio attend meetings as per need as special invitees, not as members
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	

6.6. Maldives

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	☐ Fully met	■ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	☐ Fully met	■ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	☐ Fully met	■ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	☐ Fully met	■ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	■ Fully met	☐ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	☐ Fully met	■ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	☐ Fully met	■ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	☐ Fully met	■ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	■ Fully met	☐ Partially met	☐ Not met

6.6. MALDIVES

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2008/2013	NCIP/MTAGI
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2019	
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Partial	Structure not mentioned
1.2.7	TOR for technical working groups	Yes	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	No	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	No	
1.3.4.8	Any other, specify		
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	No	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	No	
1.4.15	Mentions performance evaluation including process and outcome indicators	No	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	No	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	Yes	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	7	
1.5.2.1	Epidemiology	1	From HPA
1.5.2.2	Pediatrics	3	
1.5.2.3	Clinical medicine/Clinical research	2	
1.5.2.4	Infectious diseases		
1.5.2.5	Public health	1	
1.5.2.6	Vaccinology		
1.5.2.7	Immunology		
1.5.2.8	Microbiology (incl. Virology)		
1.5.2.9	Health systems and delivery		
1.5.2.10	Health economics		
1.5.2.11	Regulatory practice		
1.5.2.12	General practice		

Sl no	Area/Topic	Status	Comments/Note
1.5.2.13	Social science		
1.5.2.14	Ethics/Other disciplines		
1.5.2.15	NGOs/ Civil society/ Lay members		
1.5.2.16	Pharmaceutical industry		
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	5 years	
1.5.3.2	Tenure of membership for core members	5 years	
1.5.4	Ex-officio membership composition and expertise	16	
1.5.4.1	EPI		Secretariat
1.5.4.2	Maternal and child health	1	
1.5.4.3	Disease control	1	
1.5.4.4	NRA	1	
1.5.4.5	Finance and planning	2	
1.5.4.6	Procurement and supply		
1.5.4.7	Other related departments/Ministries	4	
1.5.4.8	University faculty/Hospital representatives	7	
1.5.5	Liaison membership	4	
1.5.5.1	Paediatric professional association		
1.5.5.2	Public health professional association		
1.5.5.3	Medical/Physician professional association	1	
1.5.5.4	Other professional association	1	
1.5.5.5	UN organisations (WHO, Unicef)	2	
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	Mentions of annual CoI declaration
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Partially	
1.6.3	Declaration of interest forms are available for members to complete	Yes	Annual declaration
1.6.4	Routinely practices the CoI policy and keeps records of declarations	No	
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	No	
1.7	**Independence of the committee**		
1.7.1	The core members are independent	6/7	1 core member is ex-officio (HPA)
1.7.2	Independent Chairperson	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	3	
1.8.2	No. of meetings held during reference period	14	
1.8.2.1	2016	3	
1.8.2.2	2017	5	
1.8.2.3	2018	3	
1.8.2.4	2019	3	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	No	
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	Local data is scarce
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	No	EPI Team
1.11.2	MoH officially appoints NITAG secretariat	NA	

Sl no	Area/Topic	Status	Comments/Note
1.11.3	Number of human resources in the Secretariat	2	
1.11.3.1	Fulltime members	0	
1.11.3.2	Part-time members	2	EPI team members
1.11.4	Human resources have the appropriate technical skills	No	
1.11.5	Training of the Secretariat team in related disciplines	No	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Limited	Practically one person - shares time between several domains
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	No	WHO supports
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	Yes	
1.12.3	Source of budget (if not covered by MOH)	NA	
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	No	
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Partially	Local data is scarce
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	No	
2.2.2	The criteria used for review and decision making	No	

Sl no	Area/Topic	Status	Comments/Note
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Partially	
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Partially	
2.2.2.3	Value and preferences (population attitudes)	Partially	
2.2.2.4	Resource use (vaccine costs and resource use)	Partially	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Partially	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Partially	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Partially	Local data is scarce
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	No	Not started yet
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Partially	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Partially	

Sl no	Area/Topic	Status	Comments/Note
2.4.2.3	Results to present the findings per key outcome	Partially	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Partially	
2.4.2.5	Recommendation options including logical rationale	Partially	
2.4.2.6	References and the recommendation framework followed	Partially	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Descent note by any member is documented	Not experienced	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.1.4	The NITAG reports to a designated high-level official of the MOH, who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	EPI has limited capacity to implement the recommendations
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	HPV, pentavalent, IPV, HBV for HCW, Influenza for HR groups/ HCW
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	Yes	
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	Yes	DPT-Booster at 4 years
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Partially	Limited circulation
3.3.4	The general population is aware of the NITAG's role	No	No public dissemination of NITAG activities
3.4	**Collaboration with relevant partners based on interest**		
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Not formal	Some members are common
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Yes	Ex-officio members
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	Exposure for members other than Chair/Co-Chair is limited.

6.7. MYANMAR

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	■ Fully met	☐ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	☐ Fully met	■ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	■ Fully met	☐ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	☐ Fully met	■ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	☐ Fully met	■ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	☐ Fully met	■ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	☐ Fully met	■ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	☐ Fully met	■ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	☐ Fully met	■ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	■ Fully met	☐ Partially met	☐ Not met

6.7. MYANMAR

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2007/2017	NCIP/NITAG
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2017	
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Partial	Structure not mentioned
1.2.7	TOR for technical working groups	No	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	Yes	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	No	
1.3.4.8	Any other, specify	Yes	Emergency, outbreaks
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	No	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	No	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	No	
1.4.15	Mentions performance evaluation including process and outcome indicators	No	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	No	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	No	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	No	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	11	
1.5.2.1	Epidemiology	1	
1.5.2.2	Pediatrics	3	
1.5.2.3	Clinical medicine/Clinical research	1	
1.5.2.4	Infectious diseases		
1.5.2.5	Public health	1	
1.5.2.6	Vaccinology		
1.5.2.7	Immunology		
1.5.2.8	Microbiology (incl. Virology)	3	
1.5.2.9	Health systems and delivery	1	
1.5.2.10	Health economics		
1.5.2.11	Regulatory practice		
1.5.2.12	General practice		
1.5.2.13	Social science		

Sl no	Area/Topic	Status	Comments/Note
1.5.2.14	Ethics/Other disciplines	1	Medical council
1.5.2.15	NGOs/ Civil society/ Lay members		
1.5.2.16	Pharmaceutical industry		
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	4 years	
1.5.3.2	Tenure of membership for core members	4 years	
1.5.4	Ex-officio membership composition and expertise	33	
1.5.4.1	EPI	3	
1.5.4.2	Maternal and child health	2	
1.5.4.3	Disease control	2	
1.5.4.4	NRA	2	
1.5.4.5	Finance and planning	4	
1.5.4.6	Procurement and supply	1	
1.5.4.7	Other related departments/Ministries	19	
1.5.4.8	University faculty	3	
1.5.5	Liaison membership	2	
1.5.5.1	Paediatric professional association	1	
1.5.5.2	Public health professional association		
1.5.5.3	Medical/Physician professional association	1	
1.5.5.4	Other professional association		
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	Mentions of written CoI declaration
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Partially	
1.6.3	Declaration of interest forms are available for members to complete	No	Verbal declaration
1.6.4	Routinely practices the CoI policy and keeps records of declarations	No	Verbal declaration
1.6.5	All core members declare their CoI at the time of their appointment	No	Verbal declaration
1.6.6	All core members declare their CoI before every meeting or vote	No	Verbal declaration
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	
1.7.2	Independent Chairperson	Yes	
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	2	

Sl no	Area/Topic	Status	Comments/Note
1.8.2	No. of meetings held during reference period	12	
1.8.2.1	2016	NA	
1.8.2.2	2017	4	
1.8.2.3	2018	4	
1.8.2.4	2019	6	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	Yes	
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	No	EPI Team
1.11.2	MoH officially appoints NITAG secretariat	NA	
1.11.3	Number of human resources in the Secretariat	3	
1.11.3.1	Fulltime members	0	

Sl no	Area/Topic	Status	Comments/Note
1.11.3.2	Part-time members	3	EPI team members
1.11.4	Human resources have the appropriate technical skills	Yes	
1.11.5	Training of the Secretariat team in related disciplines	Yes	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Yes	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	Yes	WHO and Unicef support
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	No	
1.12.3	Source of budget (if not covered by MOH)	WHO	GAVI HSS fund
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	No	Not started yet
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	No	Not started yet
2.2.2	The criteria used for review and decision making	No	
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Partially	

Sl no	Area/Topic	Status	Comments/Note
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Partially	
2.2.2.3	Value and preferences (population attitudes)	Partially	
2.2.2.4	Resource use (vaccine costs and resource use)	Partially	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Partially	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Partially	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Partially	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	No	Not started yet
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Partially	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Partially	
2.4.2.3	Results to present the findings per key outcome	Partially	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Partially	

Sl no	Area/Topic	Status	Comments/Note
2.4.2.5	Recommendation options including logical rationale	Partially	
2.4.2.6	References and the recommendation framework followed	Partially	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Dissent note by any member is documented	Not experienced	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	First work plan prepared
3.1.4	The NITAG reports to a designated high-level official of the MOH, who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	PCV, HPV, RVV, JE
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	Yes	Annual EPI review
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	Yes	Pentavalent 4th dose
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Partially	Limited circulation
3.3.4	The general population is aware of the NITAG's role	Yes	
3.4	**Collaboration with relevant partners based on interest**		

Sl no	Area/Topic	Status	Comments/Note
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Not formal	
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Yes	Ex-officio members
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	

6.7. NEPAL

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	☐ Fully met	■ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	■ Fully met	☐ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	☐ Fully met	☐ Partially met	■ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	☐ Fully met	■ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	■ Fully met	☐ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	☐ Fully met	■ Partially met	☐ Not met

6.7. NEPAL

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2009	
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2018	
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Yes	
1.2.7	TOR for technical working groups	No	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	Lack of adequate local evidence
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	Yes	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	No	
1.3.4.8	Any other, specify		
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups	No	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	No	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	No	
1.4.15	Mentions performance evaluation including process and outcome indicators	No	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	No	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	4	
1.5.2.1	Epidemiology	0	
1.5.2.2	Pediatrics	3	
1.5.2.3	Clinical medicine/Clinical research	0	
1.5.2.4	Infectious diseases	0	
1.5.2.5	Public health	1	
1.5.2.6	Vaccinology	0	
1.5.2.7	Immunology	0	
1.5.2.8	Microbiology (incl. Virology)	0	
1.5.2.9	Health systems and delivery	0	
1.5.2.10	Health economics	0	
1.5.2.11	Regulatory practice	0	
1.5.2.12	General practice	0	
1.5.2.13	Social science	0	
1.5.2.14	Ethics/Other disciplines	0	
1.5.2.15	NGOs/ Civil society/ Lay members	0	

Sl no	Area/Topic	Status	Comments/Note
1.5.2.16	Pharmaceutical industry	0	
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	5 years	
1.5.3.2	Tenure of membership for core members	5 years	
1.5.4	Ex-officio membership composition and expertise	2	
1.5.4.1	EPI	1	
1.5.4.2	Maternal and child health	1	
1.5.4.3	NRA	0	
1.5.4.4	Finance	0	
1.5.4.5	Procurement	0	
1.5.4.6	Other related departments/Ministries	0	
1.5.4.7	University faculty	0	
1.5.5	Liaison membership	1	
1.5.5.1	Paediatric professional association	1	
1.5.5.2	Public health professional association	0	
1.5.5.3	Physician professional association	0	
1.5.5.4	Other professional association	0	
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	Recently started
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	Yes	Recently started
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	
1.7.2	Independent Chairperson	Yes	
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	3	
1.8.2	No. of meetings held during reference period		
1.8.2.1	2016	2	
1.8.2.2	2017	4	
1.8.2.3	2018	2	

Sl no	Area/Topic	Status	Comments/Note
1.8.2.4	2019	6	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	Yes	2019
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	No	CHD team
1.11.2	MoH officially appoints NITAG secretariat	No	
1.11.3	Number of human resources in the Secretariat	0	
1.11.3.1	Fulltime members	NA	
1.11.3.2	Part-time members	NA	
1.11.4	Human resources have the appropriate technical skills	NA	

Sl no	Area/Topic	Status	Comments/Note
1.11.5	Training of the Secretariat team in related disciplines	NA	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Yes	CHD team
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	No	
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	No	
1.12.3	Source of budget (if not covered by MOH)	WHO	
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	Yes	
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	
2.2.2	The criteria used for review and decision making	Yes	
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Yes	
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Yes	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Yes	
2.4.2.3	Results to present the findings per key outcome	Yes	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Yes	
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed.	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		

Sl no	Area/Topic	Status	Comments/Note
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Descent note by any member is documented	Not experienced	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	
3.1.4	The NITAG reports to a designated high-level official of the MOH who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	PCV, HPV, Rotavirus, fIPV
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	Yes	Recently started, a WG on missed opportunities
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	No	
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Partially	Limited circulation
3.3.4	The general population is aware of the NITAG's role	Yes	
3.4	**Collaboration with relevant partners based on interest**		
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Not formal	Adhoc and as needed
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Not formal	

Sl no	Area/Topic	Status	Comments/Note
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	

6.9. SRI LANKA

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (ToR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	■ Fully met	☐ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	☐ Fully met	■ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	■ Fully met	☐ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	■ Fully met	☐ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	■ Fully met	☐ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	■ Fully met	☐ Partially met	☐ Not met

6.9. SRI LANKA

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG (ACCD) formation year	1960	
1.1.2	Legal/administrative basis for formation	Yes	No official document available
1.1.3	Current NITAG reconstitution year	2019	
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	No	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Yes	CEU is the Secretariat
1.2.7	TOR for technical working groups	Partial	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	Yes	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	Yes	
1.3.4.8	Any other, specify	Yes	Research, ACCD covers all communicable diseases
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	Yes	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	No	
1.4.15	Mentions performance evaluation including process and outcome indicators	No	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	Not sure	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Partial	Lack of clarity in the list of members
1.5.2	Core membership composition and expertise	23	No clear differentiation between independent members and technical experts from different institutes as ex-officio
1.5.2.1	Epidemiology	0	
1.5.2.2	Pediatrics	8	
1.5.2.3	Clinical medicine/Clinical research	0	
1.5.2.4	Infectious diseases	0	
1.5.2.5	Public health	4	
1.5.2.6	Vaccinology	0	
1.5.2.7	Immunology	0	
1.5.2.8	Microbiology (incl. Virology)	8	
1.5.2.9	Health systems and delivery	0	
1.5.2.10	Health economics	0	
1.5.2.11	Regulatory practice	0	
1.5.2.12	General practice	0	

Sl no	Area/Topic	Status	Comments/Note
1.5.2.13	Social science	0	
1.5.2.14	Pharmacology	3	
1.5.2.15	Ethics/Other disciplines	0	
1.5.2.16	NGOs/ Civil society/ Lay members	0	
1.5.2.17	Pharmaceutical industry	0	
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	5 years	
1.5.3.2	Tenure of membership for core members	5 years	
1.5.4	Ex-officio membership composition and expertise	21	No clear differentiation between technical experts as independent/core members as ex-officio members
1.5.4.1	EPI	3	
1.5.4.2	Maternal and child health	1	
1.5.4.3	NRA	3	
1.5.4.4	Finance	0	
1.5.4.5	Procurement	1	
1.5.4.6	Other related departments/Ministries	13	
1.5.4.7	University faculty	0	
1.5.5	Liaison membership	9	
1.5.5.1	Paediatric professional association	1	
1.5.5.2	Public health professional association	1	
1.5.5.3	Physician professional association	5	
1.5.5.4	Other professional association	1	
1.5.5.5	Other (WHO)	1	
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	Yes	
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	Members are from academia
1.7.2	Independent Chairperson	No	
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		

Sl no	Area/Topic	Status	Comments/Note
1.8.1	No. of meetings mentioned in the SOP/ToR	4	
1.8.2	No. of meetings held during reference period		
1.8.2.1	2016	4	
1.8.2.2	2017	4	
1.8.2.3	2018	4	
1.8.2.4	2019	4	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	No	
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	No	CEU is the Secretariat
1.11.2	MoH officially appoints NITAG secretariat	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.11.3	Number of human resources in the Secretariat	3	
1.11.3.1	Fulltime members	3	
1.11.3.2	Part-time members	0	
1.11.4	Human resources have the appropriate technical skills	Yes	
1.11.5	Training of the Secretariat team in related disciplines	Yes	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Yes	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	Yes	
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	Yes	
1.12.3	Source of budget (if not covered by MOH)	NA	
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	Yes	
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	
2.2.2	The criteria used for review and decision making	Yes	
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Yes	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Yes	
2.4.2.3	Results to present the findings per key outcome	Yes	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed.	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Dissent note by any member is documented	Yes	In the record/ minutes.
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	
3.1.4	The NITAG reports to a designated high-level official of the MOH who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	HPV, fIPV, Influenza for PW
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	Yes	Annual EPI-VPD Review and conclave
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	No	
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Yes	
3.3.4	The general population is aware of the NITAG's role	Yes	
3.4	**Collaboration with relevant partners based on interest**		

Sl no	Area/Topic	Status	Comments/Note
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Partial	Common members, not as committee member(s)
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Yes	
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	

6.10 THAILAND

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	■ Fully met	☐ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	☐ Fully met	■ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	■ Fully met	☐ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	■ Fully met	☐ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	■ Fully met	☐ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	☐ Fully met	■ Partially met	☐ Not met

6.10. THAILAND

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	1970/2001/ 2019	
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2019	
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	No	
1.2.6	Role and organisational structure of secretariat	No	
1.2.7	TOR for technical working groups	No	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	No	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	No	
1.3.4.7	Vaccine development	No	
1.3.4.8	Any other, specify		
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	Yes	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	No	
1.4.15	Mentions performance evaluation including process and outcome indicators	No	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	Not sure	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	11	
1.5.2.1	Epidemiology	1	
1.5.2.2	Pediatrics	1	
1.5.2.3	Clinical medicine/Clinical research	2	
1.5.2.4	Infectious diseases	1	
1.5.2.5	Public health	1	
1.5.2.6	Vaccinology	1	
1.5.2.7	Immunology	1	
1.5.2.8	Microbiology (incl. Virology)	1	
1.5.2.9	Health systems and delivery		
1.5.2.10	Health economics	1	
1.5.2.11	Regulatory practice		
1.5.2.12	General practice		
1.5.2.13	Social science		
1.5.2.14	Ethics/Other disciplines	1 (nursing)	

Sl no	Area/Topic	Status	Comments/Note
1.5.2.15	NGOs/ Civil society/ Lay members		
1.5.2.16	Pharmaceutical industry		
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	4 years	
1.5.3.2	Tenure of membership for core members	4 years	
1.5.4	Ex-officio membership composition and expertise	13	
1.5.4.1	EPI	3	
1.5.4.2	Maternal and child health		
1.5.4.3	NRA	2	
1.5.4.4	Finance	4	
1.5.4.5	Procurement		
1.5.4.6	Other related departments/Ministries	4	
1.5.4.7	University faculty		
1.5.5	Liaison membership	6	
1.5.5.1	Paediatric professional association	3	
1.5.5.2	Public health professional association	1	
1.5.5.3	Physician professional association	1	
1.5.5.4	Other professional association	1	
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	Yes	
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	
1.7.2	Independent Chairperson	No	
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	3	
1.8.2	No. of meetings held during reference period		
1.8.2.1	2016	4	
1.8.2.2	2017	4	
1.8.2.3	2018	3	

Sl no	Area/Topic	Status	Comments/Note
1.8.2.4	2019	2	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	No	
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	Yes	
1.11.2	MoH officially appoints NITAG secretariat	Yes	
1.11.3	Number of human resources in the Secretariat	4	
1.11.3.1	Fulltime members	4	
1.11.3.2	Part-time members	0	
1.11.4	Human resources have the appropriate technical skills	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.11.5	Training of the Secretariat team in related disciplines	Yes	
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Yes	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	Yes	
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	Yes	
1.12.3	Source of budget (if not covered by MOH)	NA	
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	Yes	
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	
2.2.2	The criteria used for review and decision making	Yes	
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Yes	
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Yes	
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Yes	
2.4.2.3	Results to present the findings per key outcome	Yes	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Yes	
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed.	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		

Sl no	Area/Topic	Status	Comments/Note
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Dissent note by any member is documented	No	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	
3.1.4	The NITAG reports to a designated high-level official of the MOH who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	HPV, Rotavirus, Pentavalent
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	No	
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	No	
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	Yes	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	Yes	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Yes	
3.3.4	The general population is aware of the NITAG's role	Yes	
3.4	**Collaboration with relevant partners based on interest**		
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Limited, members represented	
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Limited	

Sl no	Area/Topic	Status	Comments/Note
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Limited	
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	

6.11. TIMOR-LESTE

COUNTRY NITAG EVALUATION
SUMMARY CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/ Topic	Evaluation status		
1	**Functionality of the NITAG**			
1.1	The NITAG is formally established	■ Fully met	☐ Partially met	☐ Not met
1.2	There are written terms of reference (TOR) for the NITAG	■ Fully met	☐ Partially met	☐ Not met
1.3	The NITAG is defined as an advisory body, and does not make policy	■ Fully met	☐ Partially met	☐ Not met
1.4	The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	■ Fully met	☐ Partially met	☐ Not met
1.5	The selection of members and rules for participation follow a transparent process	■ Fully met	☐ Partially met	☐ Not met
1.6	The NITAG follows a written policy on Conflict of Interest	■ Fully met	☐ Partially met	☐ Not met
1.7	The chairperson and core members are independent and serve in their own capacity	■ Fully met	☐ Partially met	☐ Not met
1.8	The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed	■ Fully met	☐ Partially met	☐ Not met
1.9	The NITAG annual work plan is aligned with NIP specific goals and targets	■ Fully met	☐ Partially met	☐ Not met
1.10	Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	■ Fully met	☐ Partially met	☐ Not met
1.11	The NITAG receives adequate support from the Secretariat for conducting activities	☐ Fully met	■ Partially met	☐ Not met
1.12	The NITAG activities are sustainable through secured adequate funding	☐ Fully met	■ Partially met	☐ Not met

Sl no	Area/ Topic	Evaluation status		
2	**Quality of work processes and outputs of the NITAG**			
2.1	The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	■ Fully met	☐ Partially met	☐ Not met
2.2	The NITAG follows a well-defined evidence based methodology to gather and evaluate evidence	■ Fully met	☐ Partially met	☐ Not met
2.3	Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	■ Fully met	☐ Partially met	☐ Not met
2.4	The NITAG secretariat and/or a technical Working Group develops a background document or similar materials for each policy question	■ Fully met	☐ Partially met	☐ Not met
2.5	There are minutes taken at each meeting and these are shared with all NITAG members within a defined period after a meeting	■ Fully met	☐ Partially met	☐ Not met
2.6	The decision-making procedure of the NITAG is implemented as defined in the SOP	■ Fully met	☐ Partially met	☐ Not met
3	**Integration of the NITAG into the policy process**			
3.1	The MOH consults the NITAG on immunization policy question	■ Fully met	☐ Partially met	☐ Not met
3.2	NITAG recommendations have a positive impact on immunization policy	■ Fully met	☐ Partially met	☐ Not met
3.3	The NITAG is well-recognized by stakeholder	■ Fully met	☐ Partially met	☐ Not met
3.4	NITAG members collaborate with relevant partners based on interest	■ Fully met	☐ Partially met	☐ Not met

6.11. TIMOR-LESTE

COUNTRY NITAG EVALUATION
DETAILED ASSESSMENT CHECKLIST
Period of assessment: 2016-2019

Sl no	Area/Topic	Status	Comments/Note
1	**Functionality of the NITAG**		
1.1	**Establishment of NITAG**		
1.1.1	NITAG formation year	2007/ 2015	NCIP/NITAG
1.1.2	Legal/administrative basis for formation	Yes	
1.1.3	Current NITAG reconstitution year	2019	Same committee tenure extended
1.2	**Terms of reference (TOR) for the NITAG**		
1.2.1	Objectives and mandates	Yes	
1.2.2	Size of the committee	Yes	
1.2.3	Membership composition/expertise	Yes	
1.2.4	Types and roles of members	Yes	
1.2.5	Tenure of membership/Extension/ Rotation	Yes	
1.2.6	Role and organisational structure of secretariat	Yes	
1.2.7	TOR for technical working groups	Yes	
1.2.8	TOR are updated as needed	Yes	
1.2.9	Up-to-date TOR are shared with all members	Yes	
1.3	**Roles of NITAG**		
1.3.1	To recommend evidence-based policies and strategies to the MOH	Yes	
1.3.2	To providing technical advice to the MOH in the form of recommendations	Yes	
1.3.3	NOT making policy for MOH	Yes	
1.3.4	Specific areas of technical advice		
1.3.4.1	New vaccines selection and introduction	Yes	
1.3.4.2	National immunization program	Yes	
1.3.4.3	Vaccine administration	Yes	
1.3.4.4	Surveillance of vaccine-preventable diseases	Yes	
1.3.4.5	Vaccine safety	Yes	
1.3.4.6	Vaccine policy	Yes	
1.3.4.7	Vaccine development	No	No NRA and manufacturer
1.3.4.8	Any other, specify		
1.4	**Standard Operating Procedures for NITAG**		
1.4.1	Availability of SOP/Internal operation manual	Yes	
1.4.2	Mentions membership selection/nomination process and membership rules	Yes	
1.4.3	Mentions Terms of Reference (ToR)	Yes	
1.4.4	Mentions mode of operations	Yes	
1.4.5	Mentions meeting rules	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.4.6	Mentions drafting, finalising and distributing meeting minutes, responsible person, timelines	Yes	
1.4.7	Mentions appointment of Working Groups (WG)	Yes	
1.4.8	Mentions ToR for the Technical WG including the process for establishment and operations	Yes	
1.4.9	Mentions preparation of recommendations and decision making	Yes	
1.4.10	Mentions submission of the approved recommendations to the national authorities	Yes	
1.4.11	Mentions policy on Conflict of Interest	Yes	
1.4.12	Mentions policy on confidentiality agreement	Yes	
1.4.13	Mentions training of members, involvement in NITAG network (regional or global)	No	
1.4.14	Mentions process for NITAG evaluation	Yes	
1.4.15	Mentions performance evaluation including process and outcome indicators	Yes	
1.4.16	Mentions about NITAG work plan and mode of preparation, responsible person and frequency	Yes	
1.4.17	Mentions financial particulars (annual budget and sources of funding)	Yes	
1.4.18	Mentions mode of sharing up-to-date SOP with members	Yes	
1.4.19	Specify the directives for representatives from the pharmaceutical industry	No	
1.5	**Composition of NITAG**		
1.5.1	Types of membership clearly defined (core, noncore, ex-officio, and liaison)	Yes	
1.5.2	Core membership composition and expertise	7	
1.5.2.1	Epidemiology	1	
1.5.2.2	Pediatrics	3	
1.5.2.3	Clinical medicine/Clinical research	2	
1.5.2.4	Infectious diseases	1	
1.5.2.5	Public health	0	
1.5.2.6	Vaccinology	0	
1.5.2.7	Immunology	0	
1.5.2.8	Microbiology (incl. Virology)	0	
1.5.2.9	Health systems and delivery	0	
1.5.2.10	Health economics	0	
1.5.2.11	Regulatory practice	0	
1.5.2.12	General practice	0	
1.5.2.13	Social science	0	

Sl no	Area/Topic	Status	Comments/Note
1.5.2.14	Ethics/Other disciplines	0	
1.5.2.15	NGOs/ Civil society/ Lay members	0	
1.5.2.16	Pharmaceutical industry	0	
1.5.3	Rules for core members clearly defined (attendance and participation expectations, term limits, rotation, termination, and staggering)	Yes	
1.5.3.1	Tenure of Chairperson	3 years	
1.5.3.2	Tenure of membership for core members	3 years	
1.5.4	Ex-officio membership composition and expertise	8	
	Health Administration	1	
1.5.4.1	EPI	1	
	Public Health	1	
1.5.4.2	Maternal and child health	1	
1.5.4.3	Disease control	1	
1.5.4.4	NRA	0	
1.5.4.5	Finance and planning	0	
1.5.4.6	Procurement and supply	0	
1.5.4.7	Other related departments/Ministries	1	
1.5.4.8	University faculty/Hospital representatives	2	
1.5.5	Liaison membership	5	
1.5.5.1	Paediatric professional association	0	
1.5.5.2	Public health professional association	0	
1.5.5.3	Medical/Physician professional association	0	
1.5.5.4	Other professional association	0	
1.5.5.5	UN organisations (WHO, Unicef)	5	WHO-3, Unicef-2
1.6	**Written policy on Conflict of Interest**		
1.6.1	Written policy on CoI exists and defines types of conflicts applicable	Yes	
1.6.2	CoI and management policy is comprehensive (declaring, assessing and managing CoI)	Yes	
1.6.3	Declaration of interest forms are available for members to complete	Yes	
1.6.4	Routinely practices the CoI policy and keeps records of declarations	Yes	
1.6.5	All core members declare their CoI at the time of their appointment	Yes	
1.6.6	All core members declare their CoI before every meeting or vote	Yes	
1.7	**Independence of the committee**		
1.7.1	The core members are independent	Yes	
1.7.2	Independent Chairperson	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.8	**Adherence to meeting frequency and timing as defined in the SOP**		
1.8.1	No. of meetings mentioned in the SOP/ToR	2/year	
1.8.2	No. of meetings held during reference period	8	
1.8.2.1	2016	2	
1.8.2.2	2017	2	
1.8.2.3	2018	2	
1.8.2.4	2019	2	
1.8.3	Secretariat schedules meetings in advance	Yes	
1.8.4	Agenda and background documents are circulated at least one week prior to the meeting	Yes	
1.8.5	Nature of meeting- Closed/ Open	Closed	
1.8.6	Additional ad-hoc meetings take place when needed	Yes	
1.9	**Strategic activity planning and execution**		
1.9.1	NITAG has an work plan (at least annual)	Yes	
1.9.2	The annual work plan defines the NITAG work based on the NIP needs	Yes	
1.9.3	The work plan represents a collaborative effort of the NITAG chair, Secretariat and members	Yes	
1.9.4	The work plan is composed of narrative, timeline and budget	Yes	
1.9.5	The work plan is validated by all core members	Yes	
1.9.6	Training/Orientation of members on NITAG function conducted during 2016-2019	Yes	
1.10	**Access to data and resources**		
1.10.1	NITAG has access to local and/or regional data	Yes	
1.10.2	Access to WHO position papers and other key global/regional documents	Yes	
1.10.3	Access to scientific databases and literature	Yes	
1.10.4	Obtains input from relevant governmental agencies via direct consultation or invitation	Yes	
1.10.5	Obtains input from stakeholders via direct consultation or invitation as liaison members	Yes	
1.10.6	National experts outside of the NITAG contribute to its work (through WG, professional agencies/experts, international partners)	Yes	
1.11	**Secretariat capacity and support to NITAG**		
1.11.1	Dedicated Secretariat for NITAG available	Yes	
1.11.2	MoH officially appoints NITAG secretariat	Yes	

Sl no	Area/Topic	Status	Comments/Note
1.11.3	Number of human resources in the Secretariat	1	
1.11.3.1	Fulltime members	1	Doctor
1.11.3.2	Part-time members	0	
1.11.4	Human resources have the appropriate technical skills	Partial	Capacity building is underway
1.11.5	Training of the Secretariat team in related disciplines	Partial	Capacity building is underway
1.11.6	Secretariat provides adequate administrative support to NITAG/WG	Yes	
1.11.7	Secretariat provides adequate technical support to NITAG/WG in evidence synthesis for decision making	Partial	WHO team supports
1.12	**Sustainability through secured adequate funding**		
1.12.1	Annual budget covers activities of the NITAG specified in the work plan and specifies the sources of funding	Yes	
1.12.2	Budget line for NITAG activities appears in the overall MOH budget	No	No separate budget for NITAG.
1.12.3	Source of budget (if not covered by MOH)	MoH and WHO	Meetings and manpower by MoH and capacity building by WHO
2	**Quality of work processes and outputs**		
2.1	**Adopts a well-defined evidence-based methodology to gather and evaluate evidence**		
2.1.1	Uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question	Yes	After the training by the Australia NCIRS/NITAG
2.1.2	Uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high functioning NITAGs	Yes	
2.1.3	For all other criteria uses local data as much as possible. If local data is not available, the NITAG uses regional or global data	Yes	
2.2	**NITAG adopts a generic set of criteria as a basis for decision-making**		
2.2.1	NITAG has defined and adopted a set of criteria for decision making	Yes	As suggested by Australia NCIRS
2.2.2	The criteria used for review and decision making	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.2.2.1	Problem (disease burden, clinical characteristics, costs of health care, regional and international considerations; socio-economic and social impact of the disease)	Yes	
2.2.2.2	Benefits and harms of the intervention/ vaccination (vaccine characteristics; safety; efficacy and effectiveness)	Yes	
2.2.2.3	Value and preferences (population attitudes)	Yes	
2.2.2.4	Resource use (vaccine costs and resource use)	Yes	
2.2.2.5	Equity (Impact of the vaccine on health inequities	Yes	
2.2.2.6	Acceptability of the vaccine to key stakeholders and population	Yes	
2.2.2.7	Feasibility (vaccine availability and delivery capacity, affordability, economic impact, cost effectiveness)	Yes	
2.3	**NITAG recommendations follow a consistent format**		
2.3.1	Recommendations refer to peer-reviewed published material and/or the background document	Yes	
2.3.2	Recommendations are supported by local evidence or contextual information	Partially	Limited local data and evidence
2.3.3	Recommendations are documented separately from the meeting minutes	Yes	
2.3.4	Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant)	Yes	
2.3.5	Recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices	Yes	
	Productivity		
2.4	**Background document or similar materials are prepared for NITAG for each policy question**		
2.4.1	The secretariat or a technical WG develops a background document, using a consistent format	Yes	
2.4.2	The document includes the following		
2.4.2.1	Introduction to present the policy question	Yes	
2.4.2.2	Methods to describe how evidence was searched for, reviewed and synthesized	Yes	

Sl no	Area/Topic	Status	Comments/Note
2.4.2.3	Results to present the findings per key outcome	Yes	
2.4.2.4	Discussion to synthesize the findings and consider the limitations	Yes	
2.4.2.5	Recommendation options including logical rationale	Yes	
2.4.2.6	References and the recommendation framework followed	Yes	
2.4.3	The members receive background documents prior to the meeting, leaving time to review	Yes	
2.5	**Meeting minutes and documentation**		
2.5.1	Minutes taken at each meeting and these are shared with all members within a defined time period	Yes	Minutes are very brief and details not mentioned
2.5.2	Designated person takes minutes during each meeting	Yes	
2.5.3	Meeting minutes include the attendance list and quorum	Yes	
2.5.4	Members receive meeting minutes within a defined time period after meeting for review before finalising	Yes	
2.5.5	Dissent note by any member is documented	Not experienced	
2.6	**Implementation of decision-making procedure as per SOP**		
2.6.1	NITAG discusses the evidence and recommendation options and then decides on whether to accept any of the options	Yes	
2.6.2	NITAG makes decisions by consensus or vote	Yes	
2.6.3	When making decisions, a quorum, as defined in the TOR, is present	Yes	
3	**Integration of the NITAG into the policy process**		
3.1	**MOH consults NITAG on immunization policy questions**		
3.1.1	There is a defined process for the MOH to officially request NITAG recommendations	Yes	
3.1.2	The MOH systematically consults the NITAG for immunization policy questions	Yes	
3.1.3	The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.1.4	The NITAG reports to a designated high-level official of the MOH, who is not a NITAG member	Yes	
3.1.5	The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications	Yes	
3.1.6	The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner	Yes	
3.2	**Impact of NITAG recommendations on immunization policy**		
3.2.1	The MOH considers NITAG recommendations for immunization related decisions	Yes	
3.2.2	The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair	Yes	
3.2.3	Recommendations accepted by the MOH are implemented in the country	Yes	
3.2.4	Any recommendation on new vaccine introduction made by NITAG	Yes	HPV, IPV, PCV, Rotavirus
3.2.5	NITAG reviews the routine immunization program as part of the regular agenda	Yes	Working group present
3.2.6	Any recommendation on existing vaccine schedule or campaign made by NITAG	Yes	DPT-Booster, MR
3.2.7	Any recommendation on vaccine/ immunization policy made by NITAG	No	
3.2.8	NITAG follows a dissemination process for their minutes of meetings (publicly available and accessible on a dedicated website)	No	
3.2.9	NITAG follows a dissemination process for their review and evidence synthesis documents (publicly available and accessible on a dedicated website)	No	
3.2.10	NITAG composition, ToR and SOP are available for public display and accessible	No	
3.3	**Recognition of NITAG by stakeholders**		
3.3.1	National immunization stakeholders and scientific community are aware of the NITAG role and activity	Yes	
3.3.2	National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG	Yes	

Sl no	Area/Topic	Status	Comments/Note
3.3.3	NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders	Partially	Limited circulation
3.3.4	The general population is aware of the NITAG's role	Not sure	
3.4	**Collaboration with relevant partners based on interest**		
3.4.1	Collaboration with the other immunization related committees in the country regularly (NCCPE, NVC, AEFI committees, etc.)	Yes	Members are common
3.4.2	Collaboration with the other health program stakeholders/committees for integration (maternal health, child health, nutrition, VPDs, etc.)	Yes	Ex-officio members
3.4.3	Collaboration with partners at country level on a voluntary basis (WHO, Unicef and other partners)	Yes	Members
3.4.4	Collaboration with partners and regional and/or international networks on a voluntary basis (other NITAGs, regional networks, international networks, Global NITAG Network)	Yes	SIVAC training, Twinning with Australia NITAG/NCIRS