Assessment tool for National Immunization Technical Advisory Groups (NITAG)

OVERVIEW

This document provides a tool for conducting an assessment of a National Immunization Technical Advisory Group (NITAG) based on the WHO guidance[1] and partners' field experience and inputs.

The tool is relevant for either a self-assessment or an externally conducted assessment. Countries may choose to use it at any point on the NITAG's life cycle to systematically assess how the committee functions and advises on immunization policy. A NITAG may choose to use the tool soon after its establishment so it can plan and document processes that will improve the capacity of the NITAG. In some cases, a NITAG may decide to use the tool annually or after recommendations have been made to assess the extent to which the NITAG's functionality, quality of work processes and integration facilitated or hampered the development of evidence-based recommendations. In this way, the assessment could serve as part of a quality improvement process. Another use of the tool could be prior to or as part of a larger immunization program review (e.g., EPI review, Gavi joint appraisal).

INSTRUCTIONS

1. Define the period of time of assessment
   Before using the tool, it is important to define the time period during which the assessment will apply. Suggested timeframes are the past 12 months, or the time period encompassing deliberation and development of recommendations on a particular vaccine. Defining a time period gives specificity to the exercise and allows comparison of assessments.

2. Gather key documents of the NITAG, including:
   - Ministerial decree/Legislation/Legal Instrument establishing the NITAG
   - Terms of Reference, Standard Operating Procedures, Policy on Conflict of Interest, NITAG work plan/ budget
   - NITAG evidence to recommendation framework, or similar document
   - NITAG meeting minutes, background documents or similar materials, recommendations made by the NITAG, communication documents between the NITAG and the MOH.

3. Conduct the assessment (pages 3-12)
   The assessment is divided into three modules: 1) Functionality of the NITAG; 2) Quality of work processes and outputs of the NITAG; and 3) Integration of the NITAG into the policy process.
   Within each module, there are a number of Recommendations. For each Recommendation:
   - Read the Recommendation and associated Description. Consider the extent to which the NITAG has fulfilled each criterion of the Description during the defined time period based on review of key documents and interviews/ discussions with informants, as needed.
   - In the Comments section, comment or highlight issues related to the Recommendation (e.g., convening stakeholders, developing written document, implementing the Recommendation)
   - In the Assessment section, select the option that best reflects the situation. For a Recommendation to be considered 'Fully met', assessors should be in consensus that all the items in the Description section have been met. If some, but not all of the items have been met, assessors should consider that item partially met.

4. Summarize the assessment selection on the Summary checklist (page 2)

5. Summarize the overall Strengths, Challenges and Proposed actions (page 13)

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[1] Duclos P. National Immunization Technical Advisory Groups (NITAGs): Guidance for their establishment and strengthening. Vaccine. 19 avr 2010;28, Supplement 1:A18‑25.

Summary checklist TO BE COMPLETED AFTER CONDUCTING THE ASSESSMENT PAGES 4-13
Time period during which assessment applies: _____[mm/yy] through _____[mm/yy]

1. Functionality of the NITAG			
Recommendation	**Assessment**		
The NITAG is formally established	☐ Fully met		☐ Not met
There are written terms of reference (TOR) for the NITAG	☐ Fully met	☐ Partially met	☐ Not met
The NITAG is defined as an advisory body, and does not make policy	☐ Fully met		☐ Not met
The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations	☐ Fully met	☐ Partially met	☐ Not met
The selection of members and rules for participation follow a transparent process	☐ Fully met	☐ Partially met	☐ Not met
The NITAG follows a written policy on Conflict of Interest	☐ Fully met	☐ Partially met	☐ Not met
The chairperson and core members are independent and serve in their own capacity	☐ Fully met	☐ Partially met	☐ Not met
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
The NITAG annual work plan is aligned with NIP specific goals and targets	☐ Fully met	☐ Partially met	☐ Not met
Multiple level data and stakeholder input are accessible and consulted if needed for making recommendations	☐ Fully met	☐ Partially met	☐ Not met
The NITAG receives adequate support from the Secretariat for conducting activities	☐ Fully met	☐ Partially met	☐ Not met
The NITAG activities are sustainable through secured adequate funding	☐ Fully met	☐ Partially met	☐ Not met

2. Quality of work processes and outputs of the NITAG			
Recommendation	**Assessment**		
The NITAG has defined and adopted a generic set of criteria as a basis for decision-making	☐ Fully met	☐ Partially met	☐ Not met
The NITAG follows a well-defined evidence-based methodology to gather and evaluate evidence	☐ Fully met	☐ Partially met	☐ Not met
Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation	☐ Fully met		☐ Not met
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
There are minutes taken at each meeting and these are shared with all NITAG members within a defined time period after a meeting	☐ Fully met	☐ Partially met	☐ Not met
The decision-making procedure of the NITAG is implemented as defined in the SOP	☐ Fully met		☐ Not met

3. Integration of the NITAG into the policy process			
Recommendation	**Assessment**		
The MOH consults the NITAG on immunization policy questions	☐ Fully met	☐ Partially met	☐ Not met
NITAG recommendations have a positive impact on immunization policy	☐ Fully met	☐ Partially met	☐ Not met
The NITAG is well-recognized by stakeholders	☐ Fully met	☐ Partially met	☐ Not met
NITAG members collaborate with relevant partners based on interest	☐ Fully met	☐ Partially met	☐ Not met

Assessment tool for NITAG

Time period during which the assessment applies: _____[mm/yy] through _____[mm/yy]

I.	Functionality of the NITAG

Legal or administrative basis

Recommendation	The NITAG is formally established	
Description	• The NITAG has a legal or administrative basis • An official document establishes the NITAG (e.g., Ministerial decree, Legislation, Legal Instrument)	
Comment		
Assessment	☐ **Fully met**	☐ **Not met**

Terms of Reference (TORs)

Recommendation	There are written terms of reference (TOR) for the NITAG		

Description	• TOR should specify:
	   o Objectives and mandates of the NITAG
	   o Membership composition: size, expertise represented, types and roles of members including ex-officio and liaison
	   o Role and organisational structure of NITAG secretariat
	   o TOR for technical working groups
	• TOR are updated as needed
	• Up-to-date TOR are shared with all members		

Comment			
Assessment	☐ **Fully met**	☐ **Partially met**	☐ **Not met**

Advisory role

Recommendation	The NITAG is defined as an advisory body, and does not make policy

Description	• The role of the NITAG is to recommend evidence based policies and strategies to the MOH
	• The NITAG's role is limited to providing technical advice to the MOH in the form of recommendations and does not make policy.
	• The technical advice provided by the NITAG may pertain to:
	   o Selection and Introduction of vaccines: generate evidence-based recommendations with regards to the introduction of new vaccines
	   o Vaccine administration: create standards for vaccination regimens, vaccine procurement and storage, routes of administration, dosing

	and contraindications
	o Vaccine safety: develop reporting standards for Adverse Events Following Immunization, for evaluating them and advising on health policy issues related to vaccine safety
	o Vaccine policy: review and improve policies of the National Immunization Program (NIP) including data collection, quality of the services provided and vaccination coverage
	o Surveillance of vaccine-preventable diseases: support the creation of standards for vaccine-preventable diseases surveillance and standard operating procedures and protocols for disease reporting and specimen collection
	o Vaccine development: advise on the progress in the development of new vaccines and other relevant technologies and the potential for their inclusion into the NIP
Comment	
Assessment	☐ **Fully met** ☐ **Not met**

NITAG functioning Standard Operating Procedures (SOP)

Recommendation	**The NITAG functioning SOP are clearly defined and include the rules and procedures for its operations**
Description	• SOP are formalized in a manual of procedures
	The manual of procedures covers the following aspects:
	• NITAG membership: selection/nomination process, and membership rules (e.g., attendance and participation expectations, duration of terms, rotation of membership for core members)
	• NITAG Terms of Reference (ToR)
	• Mode of operations:
	o Preparation of the NITAG work plan: consultation process, responsible person, circumstances for reviewing;
	NB: the annual work plan is developed in collaboration with the MOH, and includes the production of background documents, capacity-building activities and others as relevant. The work plan is monitored and adjusted accordingly
	o Meeting rules: frequency, timing of meetings, open versus closed, participation of industry and of observers, meeting agenda including the process for deciding on agenda items and input requested from the committee, process for setting up extraordinary meetings, meeting communication/ reports, process to review and share evidence with the committee, timelines for sharing meeting documents
	o Drafting, finalising and distributing meeting minutes: responsible person, timelines
	o Preparing recommendations and decision-making: appointment of working groups (WG), use of Population, Intervention, Comparator, Outcome (PICO) and specific recommendation framework, validation process of the questions and framework, development of background document, development of a recommendation, process of decision making including quorum, presence of chair, voting rules for approving

	different types of decisions
	o Submitting approved recommendations to the national authorities: responsible person, dissemination channel and timelines, follow-up system to receive feedback from national authorities
	o Process for NITAG evaluation
	o Policy on Conflict of interest
	o Policy on confidentiality agreement
	o Technical WG TOR including the process for establishment and their mode of operations
	• Training of members, involvement in NITAG network (regional or global)
	• Performance evaluation including process and outcome indicators used to evaluate the contribution and impact of the NITAG
	• Financial particulars:
	o Annual budget which includes the development of background documents and recommendations and other relevant activities
	o Sources of funding
	• Up-to-date SOP are shared with all members
Comment	*Comment on whether the SOPs are actually implemented*
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Selection process and Membership Rules

Recommendation	**The selection of members and rules for participation follow a transparent process**
Description	The process should:
	• Define types of membership, including core or voting, non-core or non-voting members (ex-officio, liaison) and their roles
	For core members:
	• Specify all areas of expertise to be represented among them: paediatrics, public health, infectious diseases, epidemiology, immunology, health economics, provision of health services, other
	NB: Core members represent a diverse range of expertise and are recognized experts in their country
	• Establish criteria and process for the identification, selection and official appointment of core members and the Chairperson by the MOH
	• Define rules for core members, including attendance and participation expectations, term limits, rotation, termination, and staggering of members' terms to allow for continuity
	For non-core members:
	NB: Ex-officio and liaison members do not take part in the decisions of the NITAG. As representatives of key organizations/ government agencies, they provide relevant input during discussions.
	• Establish criteria and process for their identification and selection
	• Define rules for non-core members, including attendance and participation expectations, rotation, and termination
	• Specify the directives applying to representatives from the pharmaceutical

	industry

Comment	

Assessment	☐ **Fully met**	☐ **Partially met**	☐ **Not met**

Recommendation	**The NITAG follows a written policy on Conflict of Interest**
Description	• A written policy on Conflict of Interest (CoI) exists, defining types of conflicts, importance and consequences of conflicts applicable to core members and to experts (not NITAG members) serving in working groups • The Conflict of Interest prevention and management policy comprehensively describes a process for declaring, assessing and managing CoI • Declaration of interest forms are available for members to complete • The NITAG routinely practices the COI policy and keeps records of declarations • All core members declare their interests at the time of their appointment and before every meeting or vote that involve decisions or recommendations on a vaccine product
Comment	

Assessment	☐ **Fully met**	☐ **Partially met**	☐ **Not met**

Independence

Recommendation	**The chairperson and core members are independent and serve in their own capacity**
Description	• NITAG core members are independent; they do not directly work for the NIP • Core members serve on the NITAG in their own capacity; they do not represent the organisation with which they are affiliated
Comment	

Assessment	☐ **Fully met**	☐ **Partially met**	☐ **Not met**

Meeting rules

Recommendation	**The NITAG adheres to meeting frequency and timing as defined in the SOP; and schedules additional ad-hoc meetings when needed**
Description	• The NITAG adheres to meeting frequency outlined in the TOR, suggested to be at least 1 meeting per year • The secretariat schedules meetings in advance • Additional ad-hoc meetings take place when needed

Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Strategic activity planning and execution

Recommendation	**The NITAG operates under an annual work plan**
Description	• The annual work plan defines the NITAG work based on the NIP needs • The work plan represents a collaborative effort of the NITAG chair, executive secretary and selected members • The work plan is composed of 3 sections: a narrative, a timeline and a budget • The work plan is validated by all NITAG core members
Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Resources

Recommendation	**Multiple level data and stakeholder[1] input are accessible and consulted if needed for making recommendations**
Description	• NITAG has access to local and/or regional data (e.g., national statistics, national surveillance data, national or regional studies) • NITAG has access to WHO position papers and other key global and regional documents • NITAG has access to scientific databases (i.e. Medline, Embase, Cochrane, CINAHL) • The NITAG obtains input from relevant governmental agencies (NIP, NRA, etc), via direct consultation or invitation as ex-officio members • The NITAG obtains input from stakeholders via direct consultation or invitation as liaison members • National experts outside of the NITAG contribute to its work (e.g., through WG) [1] Stakeholders may include governmental agencies, professional organisations, relevant CSOs, international partners
Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Recommendation	**The NITAG receives adequate support from the Secretariat for conducting activities**
Description	• The MoH officially appoints (Ministerial decree, Legislation, Legal Instrument) NITAG secretariat to support the NITAG • Human resources within the secretariat provide the support to administrative activities, e.g., schedule meetings (place, date, invitation), collect and share documents for review, share agenda, organize meeting logistics (room,

food/drink), create transparency on attendance and key decisions, develop agenda and documents, develop coherent meeting minutes, track follow-up on decisions taken
- Human resources have the appropriate technical skills to support NITAG by compiling evidence, obtaining support from experts in the field as needed, developing options for evidence-based recommendations

- If the policy question requires detailed consideration and/or substantial input from additional experts is needed, the NITAG chair convenes a WG to review and provide evidence-based information and prepare options for recommendations.
    - The WG has adequate staff capacity and expertise, and clear ToR (objectives, deliverables, timelines). A NITAG core member chairs the WG.

Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Recommendation	**The NITAG activities are sustainable through secured adequate funding**
Description	• The NITAG develops annual budget that covers activities of the NITAG specified in the work plan and specifies the sources of funding • A senior level MOH staff receives the annual budget • A budget line for NITAG activities appears in the overall MOH budget
Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

II. Quality of work processes and outputs of the NITAG

Quality of the analytical process

Recommendation	**The NITAG has defined and adopted a generic set of criteria as a basis for decision-making**

Description	• NITAG has defined a set of criteria, or types of evidence deemed necessary by the country to decide on vaccination policy. The criteria should include some or all of the following:
	   ○ Problem: Burden of disease; clinical characteristics of the disease; use and costs of health care; regional and international considerations; socio-economic and social impact of the disease;
	   ○ Benefits and harms of the intervention (vaccination): Vaccine characteristics; safety; efficacy and effectiveness
	   ○ Value and preferences: Attitudes of the target population on the vaccine
	   ○ Resource use: Vaccine related costs and resource use
	   ○ Equity: Impact of the vaccine on health inequities
	   ○ Acceptability of the vaccine to key stakeholders and of the target population

	o Feasibility: Vaccine availability and delivery capacity at national level; vaccine affordability; economic impact of intervention on immunization program as well as health sector; cost effectiveness; ability to evaluate
Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Recommendation	**The NITAG follows a well-defined evidence-based methodology to gather and evaluate evidence**
Description	For benefits and harms of the intervention (vaccination), the NITAG uses either of these methods: • NITAG uses a standardized and systematic method of searching for, reviewing and synthesizing relevant evidence based on a PICO-like framework for the policy question OR • NITAG uses existing systematic reviews and quality assessment of the evidence from SAGE, WHO, or other high-functioning NITAGs For all other criteria: • NITAG uses local data as much as possible. If local data is not available, NITAG uses regional or global data
Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Recommendation	**Recommendations of the NITAG follow a consistent format; with a summary of the evidence supporting the recommendation**
Description	• Recommendations make reference to peer-reviewed published material and/or the background document • Recommendations are supported by local evidence or contextual information • Recommendations are documented separately from the meeting minutes • Recommendations are clear and straightforward (including describing the inability to conclude on a given topic, if relevant) • The recommendations are submitted to the designated policy-makers in the form of a policy brief conforming to country practices
Comment	
Assessment	☐ **Fully met** ☐ **Not met**

Productivity

Recommendation	**A background document or similar materials are prepared for the NITAG for each policy question**
Description	• The secretariat or a technical WG develops a background document for the

NITAG, using a consistent format including
- o Introduction to present the policy question
- o Methods to describe how evidence was searched for, reviewed and synthesized
- o Results to present the findings per key outcome
- o Discussion to synthesize the findings and consider the limitations
- o Recommendation options including logical rationale
- o References and the recommendation framework followed.
- The NITAG members receive background documents prior to the meeting, leaving time to review them (e.g., at least one week).

Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Recommendation	**There are minutes taken at each meeting and these are shared with all NITAG members within a defined time period after a meeting**
Description	• A designated person takes minutes during each meeting based on the defined template • Meeting minutes include the attendance list and whether quorum was met • NITAG members receive meeting minutes within a defined time period (e.g., 5 working days) after each meeting, for their review before finalising
Comment	
Assessment	☐ **Fully met** ☐ **Partially met** ☐ **Not met**

Decision-making procedure

Recommendation	**The decision-making procedure of the NITAG is implemented as defined in the SOP**
Description	• After NITAG members receive the background document, the NITAG meets, discusses the evidence and recommendation options and then decides on whether to accept any of the options • Members make decisions by vote or consensus • When making decisions, a quorum of the NITAG, as defined in the TOR, is present
Comment	
Assessment	☐ **Fully met** ☐ **Not met**

III. Integration of the NITAG into the policy process

Integration of the NITAG into the government policy process

Recommendation	**The MOH consults the NITAG on immunization policy questions**

Description	• There is a defined process for the MOH to officially request NITAG recommendations
	• The MOH systematically consults the NITAG for immunization policy questions
	• The NITAG annual work plan is in accordance with MOH/NIP priorities and needs, and anticipates upcoming needs
	• The NITAG reports to a designated high level official of the MOH who is not a NITAG member
	• The NITAG and the MOH work in productive collaboration, engaging in responsive, well-coordinated, and formal communications
	• The NITAG addresses official requests for recommendations received from the MOH and/or the immunization program in a timely manner
Comment	
Assessment	☐ **Fully met**　　☐ **Partially met**　　☐ **Not met**

Recommendation	**NITAG recommendations have a positive impact on immunization policy**
Description	• The MOH considers NITAG recommendations for immunization-related decisions
	• The MOH accepts NITAG recommendations made by the NITAG, and if not, the MOH provides a clear reason to the NITAG chair
	• Recommendations accepted by the MOH are implemented in the country
	• NITAG follows a dissemination process for their documents that is appropriate within the country context, e.g., recommendations of the NITAG can be publicly available and easily accessible on a dedicated website
Comment	
Assessment	☐ **Fully met**　　☐ **Partially met**　　☐ **Not met**

Recognition of NITAG by stakeholders

Recommendation	**The NITAG is well-recognized by stakeholders**
Description	• National immunization stakeholders and scientific community (e.g., professional organisations) are aware of the NITAG role and activity
	• National immunization stakeholders and scientific community adopt or harmonize recommendations issued by the NITAG
	• NITAG recommendations are accessible by the scientific and professional organisations and immunization stakeholders
	• The general population is aware of the NITAG role
Comment	
Assessment	☐ **Fully met**　　☐ **Partially met**　　☐ **Not met**

Recommendation	**NITAG members collaborate with relevant partners based on interest**

Description	• NITAG collaborates with partners and regional and/or international networks on a voluntary basis (i.e.: other NITAGs, regional networks, international networks, Global NITAG Network)		
Comment			
Assessment	☐ **Fully met**	☐ **Partially met**	☐ **Not met**

COMPLETION OF ASSESSMENT

NITAG Chair [Name and Organisation Name]	NITAG members [Name and Organisation Name]	NITAG Secretariat [Name and Organisation Name]	Date of Assessment

SUMMARY OF STRENGTHS, CHALLENGES AND PROPOSED ACTIONS

	Strengths	Challenges	Proposed actions *(e.g., Update ToR to cover xxx; Develop standards for xxx)*
Functionality of the NITAG			
Quality of work processes and outputs of the NITAG			
Integration of the NITAG into the policy process			