Template: Terms of reference of the National Immunization Technical Advisory Group

Contents

Abbreviations

AEFI   adverse events following immunization
MoH   Ministry of Health
NITAG   National Immunization Technical Advisory Group
SAGE   Strategic Advisory Group of Experts on Immunization

Preface

Terms of reference of National Immunization Technical Advisory Groups (NITAGs) (sometimes also referred to as a "NITAG charter") indicate the objectives, mandate and duties of a NITAG. They describe the NITAG's structure, composition and functioning.

This template can be used by NITAGs to develop or revise their terms of reference. It draws on the experiences of long-functioning NITAGs (e.g. the United States Advisory Committee on Immunization Practices (ACIP); the German NITAG, STIKO; the United Kingdom's Joint Committee on Vaccination and Immunization (JCVI)) and the WHO Strategic Advisory Group of Experts on Immunization (SAGE). It is also based on WHO guidance for establishment and strengthening of NITAGs.

This document is indicative and should be adjusted based on the particular country context. Free spaces marked by a line ("_____") and followed by instructions in brackets ("[…]") indicate aspects for country adaptation. NITAGs may also change the text of this document based on a country's circumstances.

APPROVED
by order of the Ministry of Health

No. ___ dated _____ 20___

Terms of reference of the
National Immunization Technical Advisory Group
of _____ [*country*]

I. General provisions

These provisions on the National Immunization Technical Advisory Group (NITAG) have been developed on the basis of existing world experience and WHO recommendations.

The NITAG is guided in its activities by the laws and other regulatory legal acts of _____ [*country*], and orders of the Ministry of Health (MoH) of _____ [*country*], as well as this regulation.

The NITAG organizes its work in cooperation with other state authorities, local state administrations of _____ [*country*] and local governments, public associations, citizens and legal entities, as well as in cooperation with structural, subordinate and territorial divisions of the MoH.

[*Include if appropriate: "The NITAG is accountable to the MoH of _____ [country] in its activities."*] NITAG recommendations are advisory in nature and are used by the MoH to take evidence-informed decisions in the field of immunization.

The work performed by the NITAG members is voluntary and non-remunerated.

II. Mandate of the NITAG

The aims of NITAG activities are:
- to provide policy-makers, programme managers and state health-care structures with ongoing and timely medical, scientific and public health advice regarding the use of preventive vaccines and related agents in humans.
- to provide guidance to policy-makers and programme managers in making evidence-informed decisions on the control of vaccine-preventable diseases through immunization, on new vaccines and technologies, and on required adjustments to existing immunization programmes and schedules;
- to advise national authorities on the surveillance of vaccine-preventable diseases and the monitoring of the impact of immunization services, as well as on the monitoring of immunization and vaccine safety; advice on data collection needed for policy-making should be included;
- to guide, where appropriate, organizations, institutions or government agencies in the formulation of policies, plans and strategies for research and development of new vaccines and vaccine delivery technologies.

III. Roles and responsibilities of the NITAG

To implement the above activities, the NITAG is entrusted with the following tasks:

- development of evidence-based recommendations in the field of immunoprophylaxis, including on the introduction of currently or newly authorized vaccines in _____ [*country*] into the vaccination calendar and across the life-course, and the development of strategies and new directions in immunization policy in accordance with the principles of evidence-based medicine, including for mass immunization campaigns;
- development of recommendations on the monitoring of the immunization programme and surveillance of vaccine-preventable diseases in order to assess immunization programme performance and quantify the results of its impact;
- development of recommendations on monitoring of adverse events following immunization (AEFIs) and review of reported/identified AEFIs – including review of AEFI investigation reports and adjustment of recommendations in the light of review;
- review and revision of existing NITAG recommendations if new evidence becomes available;
- cooperation and exchange of information with independent expert committees on immunization of other countries and international NITAG networks, as well as national and international professional organizations and academic societies;
- cooperation with international organizations providing support to the immunization programme of _____ [*country*].

[*Include if appropriate: "The NITAG may also develop recommendations for administration of preventive or post-exposure immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available."*]

The NITAG is a technical advisory body and therefore does not perform functions related to the implementation, coordination or regulation of immunization.

III. Composition of the NITAG

NITAG members

The NITAG comprises three different categories of NITAG members:

1) Core NITAG members:
- are leading experts in the field of immunization practices and represent multidisciplinary expertise in public health and in the use of vaccines and prophylactic agents for the prevention of vaccine-preventable diseases;
- represent at least one of each of the following areas of expertise: _____ [*List the relevant disciplines considered within the country. WHO recommends that at least five disciplines/areas should be represented by core NITAG members. Countries should consider including experts from the following areas of expertise: clinical medicine (paediatrics and adolescent medicine, adult medicine, geriatrics), epidemiology, infectious diseases, microbiology, public health, immunology, vaccinology,*

immunization programme management, and health systems and delivery. Further areas of expertise may be represented];

- serve the NITAG as independent experts and do not oversee or report directly or indirectly to the immunization programme;
- are actively involved in the activities of the NITAG, including the study of key materials and the provision of necessary evidence, as well as in the work of the working groups;
- are expected to express their personal opinions as informed by their professional expertise and do not represent the interests of any group or stakeholder, including the organizations in which they work;
- are "voting" members of the NITAG (i.e. take part in _____ [*include the mode by which the NITAG makes decisions: "voting"/"reaching consensus"*] on the final NITAG recommendation);
- perform their duties on a voluntary basis; the MoH may reimburse NITAG members' travel expenses if these are necessary to allow participation in NITAG meetings;
- cannot be replaced in their function as core NITAG members by other experts.

2) Non-core NITAG members by virtue of their office (ex-officio members):
- are key employees of government agencies and organizations related to immunization, for example:
  - heads of relevant departments in the MoH, the Ministry of Finance or the Ministry of Education;
  - representatives of the national regulatory authority;
  - heads of relevant departments of the national public health agency;
- support the work of the NITAG by providing additional knowledge and expertise, by communicating the views of the department/agency/division they represent, and by communicating the NITAG's advice as permitted by _____ [*include the entity that permits communication on recommendations, e.g. the MoH*].

3) Non-core NITAG members due to their affiliation with a specific organization (liaison members):
- are representatives of nongovernmental organizations that play a role in the implementation of the immunization programme, for example:
  - medical and scientific associations;
  - civil society organizations;
  - international organizations (e.g. WHO, United Nations Children's Fund (UNICEF));
- contribute to the discussion and help provide background information or needed evidence;
- can serve on working groups and subcommittees.

Non-core NITAG members as described in (2) and (3):
- are appointed by the organizations/agencies/institutions they represent in the NITAG;
- are "non-voting" members of the NITAG (i.e. do not take part in _____ [*include the mode by which the NITAG makes decisions: "voting"/"reaching consensus"*] on the final NITAG recommendations); however, they have the right to provide information on the issues heard and participate in the discussion;
- terminate their NITAG membership when leaving the organization/agency they represent or their relevant position within these agencies;
- can assign an alternate of the same position, in case they are unable to attend a meeting.

The NITAG has _____ [*include number*] core members. The number of non-core members of the NITAG is not regulated but the numbers of core and non-core members should be balanced.

The composition of the NITAG is approved by order of the MoH.

NITAG Secretariat

The NITAG Secretariat is assigned by the MoH. The _____ [*include the institution which serves as NITAG Secretariat*] is appointed as the NITAG Secretariat.

The NITAG Secretariat performs the following functions [*adapt accordingly*]:
- develops together with the NITAG Chair the annual work plan of the NITAG;
- coordinates the establishment and work of NITAG working groups and participates in the work of NITAG working groups;
- facilitates interaction between the NITAG Chair and the MoH;
- organizes the NITAG meetings and together with the NITAG Chair develops the meeting agendas;
- prepares topics for NITAG deliberations – including collection, analysis and synthesis of evidence; these tasks should be implemented together with the respective working group, if a working group was established;
- prepares background documents and/or summaries of evidence and drafts the NITAG recommendations to facilitate the discussion at the NITAG meeting; these tasks should be implemented together with the respective working group, if a working group was established;
- sends the meeting agendas and if appropriate background documents/summaries of evidence and draft recommendations to the NITAG members at least _____ [*include number of weeks/days, e.g. 2 weeks*] before the meeting;
- provides additional information or clarifications at the request of NITAG members;
- prepares minutes of the NITAG meeting;
- prepares a policy brief for the MoH that summarizes the NITAG recommendation and its rationale.

NITAG Chair

The NITAG Chair:is responsible for ensuring the proper operation of the NITAG;
- establishes ongoing communication with the MoH through a designated focal point to identify, among other things, topics for which the MoH needs to receive NITAG recommendations;
- develops (together with the NITAG Secretariat) the annual NITAG work plan and NITAG meeting agenda;
- organizes the NITAG meetings and coordinates the discussions during the meeting allowing each opinion to be debated until the core members make a decision;
- ensures that NITAG decisions are made by _____ [*include the mode by which the NITAG makes decisions: "voting"/"reaching consensus"*];
- reviews and signs NITAG meeting reports and policy briefs to the MoH on NITAG recommendations;
- is responsible for official communication with government agencies [*include if appropriate: "and the public"*].

NITAG Vice-Chair

The NITAG Vice-Chair replaces the NITAG Chair and with this the Chair's duties, when the Chair is unavailable.

Appointment of NITAG members

Core NITAG members are selected based on _____ [*describe the selection process: e.g. open call for nominations*]. Core NITAG members are appointed based on their expertise by _____ [*include entity responsible for appointment of core NITAG members, e.g. the MoH*] in consultation with _____ [*include other entities involved in the appointment, e.g. the NITAG Secretariat*]. Appointments should allow a balanced committee in terms of gender, disciplines, geographic areas, points of view represented and the committee's function. Suggestions for membership will be sought from _____ [*include other entities involved in the appointment, e.g. the NITAG Secretariat*]. The NITAG Secretariat may maintain a list of potential nominees for NITAG membership. The candidate remains on the list until withdrawn or nominated to the committee.

The Chair of the NITAG is selected based on _____ [*describe the process of selection*]. The Chair of the NITAG is appointed by _____ [*include appointment procedure, e.g. assignment by the MoH or selection from among the core members of the NITAG*].
The Chair is a voting member.

The Vice-Chair of the NITAG is appointed by _____ [*include appointment procedure, e.g. selection from among the core members of the NITAG*].
The Vice-Chair is a voting member.

Non-core NITAG members are appointed by the agency they represent.

Declaration of interests

Prior to appointment, prospective core NITAG members are required to complete a declaration of interests, which requires detailed and specific information on any interests that may represent a potential (real or perceived) conflict. A conflict of interest is a conflict between a public duty and the private interests of a public figure, in which private interests may have an inappropriate effect on the performance of official duties.
Core NITAG members are required to submit _____ [*include term when declarations need to be renewed, e.g. annual*] declarations of interests to the NITAG Secretariat and update these when needed (e.g. when the situation changes). Core NITAG members should inform the NITAG Chair and Secretariat of any changes of situation that have a bearing on conflicts of interest.

The _____ [*include the entities that review the declarations of interests, e.g. the NITAG Chair and the NITAG Secretariat*] review the declarations of interests, determine whether or not there are potential conflicts of interest, and decide on the candidate's eligibility to become a member of the NITAG. Based on the declarations of interests provided, the NITAG Chair and NITAG Secretariat decide whether individual NITAG members need to be excluded from participating in discussions or voting on specific issues. _____ [*include information about the procedure of publishing declarations of interests, if relevant*].

Confidentiality note

To allow NITAG members to receive confidential/unpublished information and allow an open discussion among NITAG members, no information should be shared with the public, unless officially released. Therefore, NITAG members (core and non-core) must not discuss or divulge information obtained from the work of the NITAG, including matters discussed at meetings and recommendations, until the information has been officially released by _____ [*include institution, e.g. the MoH*] for public distribution.

All NITAG members (core and non-core) are required to sign confidentiality agreements upon their appointment/assignment.

Reports to respective associations by liaison members should be in general terms only and should be maintained in confidence by that member's organization. Draft NITAG recommendations should not be shared. In the event that it is deemed useful to share a draft recommendation with specific groups for feedback, the NITAG Chair should be consulted.

Duration of NITAG membership

Core NITAG members are appointed for a term of _____ [*include number of years of term duration*] years. The NITAG Chair, in agreement with the NITAG Secretariat, can extend the membership for _____ [*include length of term extension, e.g. a second term/xx years*]. [*Consider including: "To allow building of institutional memory within the NITAG/knowledge among NITAG members, only two thirds of core NITAG members should be replaced at a time". Comment: small countries should consider the availability of qualified experts who could potentially serve as core NITAG members when deciding on duration of NITAG membership.*]

Core NITAG members may resign at any time, but should declare their resignation in writing. If NITAG members neglect or breach their duties, they may be dismissed by the MoH.

IV. Organization of work of the NITAG

NITAG activities are carried out according to the NITAG's work plan. The work plan sets out the priorities to be discussed by NITAG members in line with the national immunization programme and the strategic plan of the MoH. Topics for the work plan can be proposed by the MoH, _____ [*include entities that may add topics, e.g. the NITAG Secretariat, other health organizations involved in the immunization service, as well as the Chair and the NITAG members*]. If a topic requires an ad-hoc recommendation/advice from the NITAG, ad-hoc meetings can be initiated or, if feasible, the topic can be included in the next scheduled NITAG meeting.

NITAG meetings

The NITAG should meet at least once every _____ [*insert frequency of meetings, e.g. six months*], but can meet more often, if necessary.

A NITAG meeting can be conducted if _____ [*insert minimum number/proportion of core members present to hold a meeting, e.g. half*] of its core members are present. Core NITAG members cannot be replaced by other experts. The absence of invited non-core NITAG members is not an obstacle to the

meeting proceeding, but non-core NITAG members can assign a representative to replace them in the meeting in case of absence.

The time and place of a NITAG meeting is determined by _____ [*include the entities that determine the meeting, e.g. the Chair and the NITAG Secretariat*].

NITAG meetings are _____ [*include how meetings are held: "open to the public"/"closed, meaning only NITAG members and people invited by the NITAG Secretariat in agreement with the Chair, as observers or invited experts, take part in them"*].

The meeting agenda and background material are sent to NITAG members at least _____ [*include latest time when the agenda can be sent, e.g. two weeks*] before the meeting. The meeting agenda should indicate which topics are for information and for which topics NITAG will make a decision.

For agenda topics on which the NITAG decides, the _____ [*include the entities assigned to prepare topics for NITAG deliberations, e.g. the Secretariat and/or NITAG working group*] collects, analyses and synthesizes evidence, prepares a summary document/background document and drafts the NITAG recommendation. Summary documents/background documents and drafted NITAG recommendations shall be sent to NITAG members _____ [*include time frame when documents must be sent, e.g. two weeks*] before the meeting to allow members to become familiar with the agenda topic.

At the NITAG meeting, members discuss the synthesis/background document and draft recommendation presented by _____ [*include the entity responsible for presenting, e.g. the NITAG Secretariat or the chair of the respective working group*]. As a result of the discussion, NITAG members may take one of the following actions:
1. Make a final decision on the topic discussed.
2. Request that the NITAG Secretariat or NITAG working group conducts additional analyses on collected data or collects and analyses additional evidence needed to make a final decision.

Making NITAG recommendations and quorum

NITAG decisions on recommendations are made by the core members [*include if appropriate "including the NITAG Chair"*] by _____ [*include how the NITAG decision is made: "open"/"closed"*] _____ [*include the mode by which the NITAG makes decisions: "voting"/"consensus building"*]. Decisions are made by _____ [*include how decisions are made: "majority vote with each core member having one vote"/"consensus"*]. [*If decisions are made by majority vote include the following: "A quorum of at least _____ [*include which quorum is required to authenticate a decision, e.g. two thirds*] of members is required to authenticate a decision"*].

An abstention will count as a neutral vote.

In case of an equal number of votes, _____ [*include how the decisive vote is cast, e.g. the Chair's vote is considered decisive*].

Meeting minutes

For each meeting, minutes will be prepared by the NITAG Secretariat within _____ [*indicate time frame, e.g. four weeks*], which summarize the discussion, conclusions drawn and, if suitable, the final recommendation on the respective topic.

Minutes will be reviewed by _____ [*include the entity that reviews the minutes, e.g. the NITAG Chair*] and will then be distributed to NITAG members (core and non-core) for comments within _____ [*indicate time frame, e.g. two weeks*] following the meeting. Once approved by all NITAG members, minutes can be shared with _____ [*indicate with whom minutes should be shared according to the procedure agreed with the MoH*], if appropriate or relevant.

Distribution of recommendations to the MoH

After the NITAG core members have decided on a final recommendation, the _____ [*include the entity that prepares the policy brief, e.g. NITAG Secretariat/working group*] prepares a policy brief including the final recommendation and its rational. After approval of the policy brief by _____ [*indicate the entity that approves the policy brief, e.g. the NITAG Chair*] the policy brief is submitted to the MoH/_____ [*include focal point in the MoH*] for acceptance.

If requested, the _____ [*indicate the entity that conducts meetings with the MoH, e.g. NITAG Chair and/or NITAG Secretariat*] will initiate a meeting to inform the MoH about the NITAG recommendation and its rational.

Within _____ [*indicate time frame*] after submission of the policy brief, the MoH shall inform the NITAG Chair and/or NITAG Secretariat about the acceptance of the NITAG recommendation and about the plans to implement it.

Publication of recommendations (if applicable)

After the acceptance of the recommendation by _____ [*indicate the entity that approves the NITAG recommendation, e.g. the MoH*], and if in line with the procedure agreed with the MoH, the NITAG recommendation may be published at _____ [*indicate location of publishing*] by _____ [*indicate publisher*].

Working groups

NITAG working groups are/can be established to provide technical support to the NITAG in the preparation of specific questions and can be time bound or long standing. NITAG working groups may be established if, for example:
- evidence collection and analysis require experts in areas not represented among the NITAG core members;
- the NITAG Secretariat is not in a position to prepare materials for the NITAG meeting on its own due to other priority commitments.

NITAG working groups are established by the _____ [*indicate the entity that establishes NITAG working groups, e.g. NITAG Secretariat*] in agreement with _____ [*indicate other entities included in working group establishment, e.g. the NITAG Chair*].
The NITAG working group shall include at least:
- one NITAG core member, who shall be appointed as the chair of the working group
- one representative of the NITAG Secretariat.

NITAG working groups may include:
- further core members

- experts in fields relevant to the issue under consideration
- non-core NITAG members.

The _____ [*include the entity that develops the NITAG working groups' terms of reference, e.g. NITAG Secretariat*] develops the terms of reference for the NITAG working group, which include the role, tasks and responsibilities of the working group, the declaration of interests, as well as its duration.

The working group collects, analyses and synthesizes evidence on the requested issue, prepares a summary of the evidence/background document and drafts the NITAG recommendation for further discussion at the NITAG meeting.

At the request of the NITAG Chair, the working group chair may periodically brief NITAG members on progress on the requested issue and provide a preliminary analysis of the data.

The NITAG working group reports only to the _____ [*include to whom the working group reports, e.g. NITAG Secretariat, NITAG Chair, NITAG; comment: NITAG working groups should not report to the MoH*].

Review of NITAG terms of reference

The terms of reference are reviewed regularly and revised if needed. Amendments or changes to the terms of reference need the approval of _____ [*include the entity that needs to approve the terms of reference, e.g. the MoH*]. NITAG members shall be informed about any changes or amendments at the next meeting.