

Improving evidence-based decision-making in immunization programmes

Regional Action Plan 2008–2010

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**World Health
Organization**

Regional Office for the Eastern Mediterranean

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Regional Action Plan

Background

Countries of the Eastern Mediterranean Region have made substantial progress towards the Millennium Development Goal 4 of reducing under-five mortality by two thirds between 1990 and 2015. For example, immunization currently averts an estimated 2.5 million deaths every year in all age groups; vaccination coverage with three doses of diphtheria-tetanus-pertussis (DTP3) has increased to about 82%; and immunization services are used increasingly to deliver other interventions, such as Vitamin A, bed nets, de-worming, etc. However, more people can be protected through introducing new vaccines and technologies, optimizing and expanding the benefits of current immunization programmes, and integrating and emphasizing the role of immunization in strengthening the overall health systems. Currently an estimated 2.8 million children do not receive the DTP3 vaccine, and nearly 25% of child deaths are attributed to vaccine preventable diseases.

In view of the current complexities and advancements in immunization, higher cost of new vaccine and technologies and the global interdependence and integration of health systems, managers of the Expanded Programme on Immunization (EPI) and national authorities face a plethora of priority decisions, varying from modification of immunization schedules, shift in disease elimination strategies to integration of services and introduction of new vaccines and technologies. These important decisions require the national authorities to have the information and capacity to evaluate their needs, establish public health priorities, and take actions without pressure or influence from industry or other sources. Thus evidence-based decision making is the cornerstone of successful immunization policy and strategy formulation and implementation, and accordingly the World Health Assembly (2000), Global Immunization Vision and Strategy (GIVS; 2006-2015) and the Regional Technical Advisory Group (2007 and 2008) have called for immunization programmes to improve their evidence-based decision-making process by establishing or strengthening National Immunization Technical Advisory Groups (NITAGs).

Introduction

An NITAG is a body of national experts empowering the Ministry of Health and advising on all technical and scientific topics related to vaccines and immunization. These technical groups are formally established by the Ministry of Health through issuing a decree or equivalent, and their recommendations are forwarded to high-level Ministry of Health officials for their consideration and prioritization. However, for credibility and public confidence and trust purposes, well-functioning NITAGs should be formal, technical and their decisions or recommendations evidenced-based and independent of political and industry influence. Therefore, it is highly recommended that the NITAG is

primarily composed of technical experts who do not *supervise* or *report to*, directly or indirectly, the immunization programme or (preferably) the Ministry of Health.

Moreover, the NITAG is different from the Regional Technical Advisory Groups (RTAG), the Inter-Agency Coordination Committee (ICC), the National Regulatory Authority (NRA), and disease-specific technical working group. The RTAG generally focuses on translating global recommendations into regional policies and strategies. The ICC primarily aims to support and coordinate funding, planning and implementation. The NRA has licensing, testing, inspecting, quality control and post marketing surveillance functions. Finally, disease-specific working groups, e.g. polio, measles, hepatitis, are tasked for limited time to deliver specific deliverable(s) for a particular disease. Furthermore, NITAGs do not *implement* activities or *supervise* immunization programmes, and instead provide technical advice on policy analysis and strategy formulation for all vaccine-preventable diseases, and guide the national authorities on identifying and monitoring important data and the latest scientific recommendations and advancements.

Situation Analysis

A global level survey was conducted in the spring of 2008 to gather information and better understand the current decision making processes and structures of Member States. The survey contained both qualitative and quantitative questions, and was divided into two main sections: 1) for all countries, collected information on vaccine policy development procedures and 2) for countries with NITAGs, focused on their characteristics and functions. Globally, 140 of the 193 Member States of the World Health Organization responded, 19 of which were from the Eastern Mediterranean Region. Of the 19 respondents, 12 claimed to have a functioning NITAG, with only 7 of those with NITAGs having written terms of reference. The main functions of NITAGs reported by the countries included: a) assisting government in establishing immunization policies and strategies; b) informing government on the public health needs for vaccine preventable diseases; and c) Assisting government to address issues of vaccine quality and safety. The main types of expertise (professions) represented on the NITAGs were clinicians, paediatricians and epidemiologists; and five and six countries mentioned that their NITAGs included ex-officio and liaison members, respectively. Most important factors when NITAGs were making recommendations included disease burden and vaccine safety, and the most important sources of information used to inform the decisions were WHO recommendations. Countries of the Region cited increase of expertise in their NITAGs, participation in and frequency of meetings, technical capacity and clear terms of reference as elements of functioning which needed strengthening. Finally, 63% and 37% of countries requested technical support from EMRO and advice on best practices, respectively.

Regional Plan of Action

This Regional Plan of Action, including the supplementary guide, tools and templates, take into account fact that Member States vary in terms of their human and financial resources, which inevitably impact the formulation, sustainability and performance of the NITAGs. Member States may also differ in term of their legal procedures and frameworks, which again may affect the membership or composition of a NITAG, and its establishment. Encapsulating the unique differences among the Member States is complicated; nevertheless, there are several elements which are independent of regional and national differences. For example, the purpose, functions, modes of functioning and performance of NITAGs are a few of the variables which may not be as greatly affected by the size or human and economic resources of a particular country. Accordingly, this Plan of Action intends to provide broad regional direction in improving evidence-based decision making and proposes strategies and practical steps in ensuring well-functioning NITAGs which reflect and respect the unique characteristics of the countries.

Goal

- Improve the evidence-based decision making process of immunization programmes

Objective

- By June 2010, Member States possess *well-functioning* NITAGs
- Target:
 - 100% of Member States meet the 7 required criteria specified for well-functioning NITAGs

Strategies

- Standardization
- Information sharing and technical support
- Advocacy and partnership

Below is a breakdown of the 2008–2010 Regional Plan of Action:

Strategy	Output	Cost	Status
Standardization	Action plan	N/A	Completed
	Regional guide	N/A	Completed
	Tools and templates	N/A	Completed
	Progress chart and checklist	N/A	Completed
Information sharing and technical support	In-country technical support	40,000	Ongoing
	Inaugural NITAG chairpersons briefing	50,000	Completed
	NITAG members training (ACIP and AMP)	35,000	In progress
	Video conferences and presentations	N/A	Ongoing
	Web page: http://www.emro.who.int/vpi/nitag/	N/A	Ongoing
Advocacy and partnership	In-country advocacy meetings	N/A	Ongoing
	Regional Director's circulars	N/A	Ongoing
	Agence de Médecine Préventive / SIVAC initiative	N/A	In progress

The progress chart below was developed to track the progress of Regional Office and Member States towards achieving the abovementioned objectives. Data for the progress chart were gathered through surveys, checklists and face-to-face meetings. First, a summary of definitions:

- **Well-functioning NITAGs:** Those technical groups meeting the 7 required criteria specified below.
- **Required criteria:** These 7 criteria reflect the three key characteristics of a NITAG – *formal*, *independent* and *technical*. The Regional Office requests written proof of following items and existing conditions:
 - 1) Ministerial Decree or equivalent issued
 - 2) Terms of reference and 3) standard operating procedures developed
 - 4) Declaration of Interest signed by all members
 - 5) Chairperson neither *supervises* nor *reports to*, directly or indirectly, the immunization programme or (preferably) the Ministry of Health
 - 6) NITAG has only technical advisory role
 - 7) NITAG composed of multi-disciplinary expertise.
- **Process:** Those measures intended to ensure transparency and accountability between the Regional Office and Member States.

NITAG 2008-2010 Progress Chart
WHO Eastern Mediterranean Region
 (Last updated December 2009)

Countries	At a glance		REQUIRED criteria							Process		
	WELL - FUNCTIONING NITAG	Meet 100% REQUIRED criteria	Formal			Independent		Technical		NITAG according to 2008 survey	2009 Checklist completed by Member States	EMRO Technical Assistance
			Ministerial decree	Terms of reference	Standard operating procedures	Declaration of interest	Independent Chairperson	Sole Technical advisory role	Multi- disciplinary Expertise			
Afghanistan	In progress	No	No	No	No	No	No	No	No	No	Yes	Yes/ Action Plan developed
Bahrain	In progress	No	Yes	Yes	No	Yes (to be verified)	No	Yes	?	No	Yes (old version)	Planned
Djibouti	?	No	?	?	?	?	?	?	?	No	No	Planned
Egypt	In progress	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes/ Action Plan developed
Iran	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes/ Action Plan developed
Iraq	In progress	No	?	?	?	?	No	?	?	Yes	No (only email communication)	Planned
Jordan	In progress	No	Yes (under revision)	Yes (under revision)	No	No	No	No	Yes	Yes	Yes (and email update on 7 July)	Yes/ Action Plan developed
Kuwait	?	No	No	No	No	No	No	No	No	No	No	Planned
Lebanon	In progress	No	Yes	Yes (to be verified)	Yes (to be verified)	No	No	No	No	Yes	Yes	Yes/ SIVAC
Libya	In progress	No	Yes (to be verified)	Yes (to be verified)	No	No	Yes (to be verified)	Yes (to be verified)	No	Yes	Yes	Planned
Morocco	In progress	No	Yes (to be approved)	Yes (to be approved)	No	No	No	Yes (to be approved)	Yes (under revision)	Yes	Yes	Yes/ Action Plan developed
Oman	In progress	No	Yes	Yes (to be fully adopted in August Meeting)	Yes (to be fully adopted in August Meeting)	No	Yes	Yes (to be fully adopted in August Meeting)	Yes	Yes	Yes (and email update on 8 July)	Yes/ Action Plan developed
Pakistan	In progress	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes/ Action Plan developed
Palestine	?	No	?	?	?	?	?	?	?	No	No	Planned
Qatar	?	No	?	?	?	?	?	?	?	Yes	No	Planned
Saudi Arabia	In progress	No	Yes	Yes	No	No	No	?	Yes	Yes	No (only email communication)	Planned
Somalia (Puntland)	In progress	No	Yes	Yes	No	No	No	Yes	No	No	No (only email communication)	Planned
Sudan	In progress	No	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes/ Action Plan developed
Sudan(s)	?	No	No	No	No	No	No	No	No	No	No	Planned
Syria	In progress	No	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes/ Action Plan developed
Tunisia	In progress	No	No	No	No	No	Yes	No	No	Yes	Yes	Yes/ Action Plan developed
UAE	?	No	No	No	No	No	No	No	No	No	No	Planned
Yemen	In progress	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Planned

Tools and templates

The remainder of this document includes guide, tools and templates intended to assist the Member States in establishing or strengthening their NITAGs. All Member States are encouraged to utilize the tools and sample content as a starting point, *adapting* them as needed to reflect their special requirements or circumstances.

Appendix A: Regional Guide

General

This Guide provides a practical overview of establishing or strengthening National Immunization Technical Advisory Groups or NITAGs. The NITAG is a body of national experts empowering the Ministry of Health and advising on all technical and scientific topics related to Vaccines and Immunization. These technical groups are formally established by the Ministry of Health through issuing a decree or equivalent, and their recommendations are forwarded to high-level Ministry of Health officials for their consideration and prioritization. However, for credibility and public confidence and trust purposes, the NITAG should be formal and technical, and its decisions or recommendations independent of political and industry influence. Therefore, it is highly recommended that NITAGs be primarily composed of technical experts who neither *supervise* nor *report*, directly or indirectly, to the immunization programme or (preferably) to the Ministry of Health.

Terms of Reference

The purpose of a NITAG is to empower and advise the national government, Ministry of Health, Immunization Programme, and/or other relevant institutions and organizations on all technical and scientific topics related to vaccines and immunization. The terms of reference of a NITAG are to **advise** on:

- Latest scientific advancements and recommendations
- Situation analysis and assessment
- Policy analysis and strategy formulation.

Key note

A NITAG should have a **technical advisory** role for **all** vaccine preventable diseases and should not serve as an implementing, supervisory, coordinating or regulatory body.

Therefore, a NITAG neither implements activities, which is the role of the immunization programme, nor supervises the immunization programme, which is the role of the Ministry of Health. Moreover, a NITAG should be distinguished from the Inter-agency coordination committee (ICC), which aims to coordinate and support funding, planning, implementation, advocacy; the National Regulatory Authority (NRA), which has licensing, testing, inspecting, quality control and post marketing surveillance functions; and from disease-specific technical advisory groups, such as polio, measles, hepatitis, which are formulated to focus on one disease for a specified time period and deliverable(s). It is, however,

important to note that disease-specific technical advisory groups should be created under the auspices of a NITAG.

Composition

Type

Each NITAG should be composed of two types of members: core and non-core. Core members should be experts, credible and serve in their capacity and not represent the interests of a particular group, stakeholder, private industry or government entity. Moreover, core members should neither directly/indirectly *supervise*, nor *report* to the immunization programme, and preferably to the Ministry of Health. Core members should participate in advising and deciding on the final set of recommendations which are to be forwarded to high level Ministry of Health officials for their consideration and prioritization.

Non-core members represent either government (*ex-officio*) or non-government (*liaison*) entities. *Ex-Officio* refers to government entities such as the Ministries of Health, Planning, Education, Finance, or Defense/ Police; or National Regulatory Authority. *Liaison* refers to professional societies or associations (medical, paediatrics) or key technical partners (WHO, UNICEF, nongovernmental organizations). Both *ex-officio* and *liaison* members can contribute to the discussion and help provide background information or needed evidence; however, they should not be directly involved in deciding on the final set of recommendations.

Key note

Any individual can only serve in one capacity. For example, a core member cannot serve both as a technical expert and representative of an entity.

Size

Groups should function with 10 to 15 core members, the majority of whom should neither directly/indirectly *supervise*, nor *report* to the immunization programme, and preferably, to the Ministry of Health. NITAGs should also consist of around 5 to 10 non-core members.

Expertise

Technical advisory groups should be **multidisciplinary** with sufficient depth and breadth of expertise. When feasible (i.e. depending on the size and capacity of country), it is recommended that countries consider including 1 or 2 experts from each of the following disciplines/areas:

- Paediatrics
- Infectious diseases
- (Clinical) research
- Adult medicine
- Public health
- Health systems and delivery
- Epidemiology
- Immunology
- Health economics

Membership

Nomination

Core members should be nominated and appointed formally by senior level government officials through a well-defined process. In addition to technical expertise, other considerations for nomination may include geographic diversity, gender balance, representation of special population groups, and public/civil society. Prior to appointment, all core members should complete a **Declaration of Interest** (See Appendix I); and *all* members (i.e. core and non-core) and special invitees should sign a Confidentiality Agreement (See Appendix J). These documents should be updated as needed. Finally, the **chairperson** should be a senior and widely respected core member nominated by core member peers (See Appendix L).

Rotation

Core members, including the Chairperson, should be appointed for specified number of terms (e.g. 2 terms) and years (e.g. 3 years). Core members who have served their maximum terms and years can be reappointed after absence from the group for a specified number of years (e.g. 2 years).

Termination

Possible reasons for termination include: failure to attend a specified number of consecutive meetings (e.g. 2 meetings); change in affiliation resulting in a conflict of interests; and lack of professionalism involving, for example, a breach of confidentiality.

Modes of Functioning

Formal recognition and general support

The Ministry of Health should issue a **Decree** or equivalent which articulates a formal and well-defined relationship between the NITAG and the Ministry. The decree should clarify the *terms of references* and *reporting requirements* of the NITAG, and specify the role of immunization programme as the Secretariat, and the immunization programme manager or equivalent as the Executive Secretary (See Appendix G). Furthermore, the Ministry of Health should provide adequate administrative support, including line item budget if needed. The Secretariat should prepare **Standard Operating Procedures** for the NITAG *composition, membership and modes of functioning* and orient the members accordingly (See Appendix E).

Key note

The Executive Secretary is considered a non-core member who can contribute to the discussion and help provide background information or needed evidence; however, they should not be directly involved in deciding on the final set of recommendations.

Agenda preparation and frequency of meetings

The Secretariat is responsible for preparing and circulating an updated agenda and background materials at least 3 months in advance of meetings. Moreover, it can seek the support of scientific/research institutions or societies to prepare the agenda and background materials. While remaining flexible to include ad hoc and urgent agenda topics (e.g. H1N1) as needed, the Secretariat and technical group should agree on some agenda topics with 1 to 2 year- horizon (e.g. introduction of new vaccines). The Secretariat and technical group should also agree on at least 2 fixed meetings, once every 6 months, while remaining flexible to call a meeting at any point to discuss important decisions or urgent matters.

Recording, reporting and dissemination

The Secretariat should take minutes of the meeting, and share them with the NITAG members within 2 weeks after the meeting. Once the core members endorse the recommendations, the Secretariat should forward them to a high level Ministry of Health official who is not a member of the group. Public dissemination of the minutes including the recommendations, if/when appropriate, is encouraged.

Decision-making and recommendations

The Secretariat should clearly delineate the forum and process of making decisions on the final set of recommendations. Some important variables to consider include: Open versus closed meeting; Participation of industry; Decision by vote or consensus; Process to review and share evidence with the group; Basis for decision making (e.g. vaccine effectiveness and safety, disease burden including age specific burden, public health/epidemiology, actions in other countries, cost-effectiveness and affordability); and recording and adequate communication of any potential conflict of interest declared by members.

Working groups

Working Groups are established as resources for NITAGs to review and provide evidence-based information and options for recommendations (*See Appendix K*).

Performance

To be recognized as a well-functioning NITAG, the secretariat must ensure that all 7 required criteria specified by the WHO Regional Office are met (*See Appendix B*). In addition, the Secretariat should develop process and intermediate outcome measures to demonstrate the contributions of the NITAG to the overall improvement of the immunization programme. Measures can be considered in terms of processes (e.g. number of meetings, composition, etc) and/or intermediate outcome measures (e.g. number of recommendations implemented).

Appendix B: Seven Required Criteria for Well-functioning NITAGs

This tool summarizes the 7 required criteria for a well-functioning NITAG. Immunization managers may use this tool to monitor the progress and status of a well-functioning NITAG. All criteria require written documents to demonstrate their implementation.

Required Criteria for Well-Functioning NITAGs (written document/ proof is requested for each required criterion)	Status (Yes/No)	If NO , provide comment:
Formal		
<u>Ministerial decree</u> or equivalent for establishing the NITAG issued?		
<u>Terms of reference</u> of the NITAG developed?		
<u>Standard operating procedures</u> for NITAG composition, membership and modes of functioning developed?		
Independent		
<u>Declaration of Interest</u> developed and signed by all core members?		
<u>Chairperson</u> is a core member who neither <i>supervises</i> nor <i>reports to</i> , directly or indirectly, the immunization programme or (preferably) to the Ministry of Health?		
Technical		
NITAG Terms of Reference specify only a <u>technical</u> advisory role, and NOT supervisory, implementation, coordination or regulatory?		
At least two thirds (6 out of 9) of the specified <u>technical disciplines</u> (e.g. paediatrics, adult medicine, health economist, etc) reflected in the composition of NITAG Core Members?		

Appendix C: NITAG Checklist

This checklist is a summary of key variables and questions that immunization managers should consider as they establish or revise/strengthen the NITAGs. The checklist reflects the NITAG Guide (Appendix A) and complements the required criteria in Appendix B.

Guide Checklist	Status (Yes/No)	If NO , provide comment:
Terms of Reference		
Disease-specific technical advisory groups, such as polio and measles, are under the auspices of the NITAG?		
Composition		
NITAG is composed of 10 to 15 core members?		
75% of core members neither <i>supervise</i> nor <i>report to</i> , directly or indirectly, the immunization programme or (preferably) the Ministry of Health?		
NITAG is composed of 5 to 10 non-core members (i.e. Ex-Officio and Liaison)?		
Membership		
Confidentiality Agreement signed by all members (core and non-core) and special invitees? <i>(please provide written example)</i>		
Core members, including the Chairperson, are appointed for a limited number of terms and years?		
Possible reasons for membership termination are clearly defined?		
Modes of functioning		
Immunization programme serves as Secretariat?		
Immunization programme manager or equivalent serves as Executive Secretary?		
NITAG meetings and activities reflected in the Ministry of Health annual budget plan?		

Guide Checklist (continued)	Status (Yes/No)	If NO, provide comment:
Agenda and background materials circulated at least 3 months in advance of meetings?		
Agreement on 1 to 2 year horizon agenda topics?		
At least 2 fixed meetings, once every 6 months, scheduled annually?		
Minutes of the meeting shared with the NITAG members within 2 weeks of the meeting?		
Recommendations forwarded to a high level Ministry of Health official who is not a member of the group?		
Forum and process of making decisions on the final set of recommendations clearly delineated?		
Guide for establishing working groups is developed?		
Process and intermediate outcome measures developed to assess contribution or impact of group? <i>(please provide written documentation)</i>		

Appendix D: Steps for establishing or strengthening an NITAG

Immunization managers and/or Ministry of Health officials may use this tool to establish or revise/strengthen a NITAG. This tool contains sequential practical steps; however, may be applied in parallel.

1. Review the regional guide and the WHO headquarters guidelines
2. Develop a working group
3. Assess the existing structures (disease specific groups, ICC, etc)
4. Specify terms of reference (*Appendix E*)
5. Develop standard operating procedures for the composition, membership and modes of functioning (*Appendix E*)
6. Identify and nominate the technical experts as core members
7. Identify the ex-officio and liaison entities as non-core members
8. Calculate the annual cost (related to travel, per diem, etc)
9. Prepare an introductory letter to a Ministry of Health high official specifying the terms of reference of the NITAG and nomination of NITAG members (*Appendix F*)
10. Obtain an official ministerial decree or equivalent (*Appendix G*)
11. Send a letter of invitation to appointed technical experts
12. Send a letter of invitation to the ex-officio and liaison entities requesting the nomination of a non-core member (*Appendix H*)
13. Call for a first meeting/circulate an agenda
 - a) Introductions and orientation (terms of reference and standard operating procedures)
 - b) Signing of Declaration of Interest (*Appendix I*)
 - c) Signing of Confidentiality Agreement (*Appendix J*)
 - d) Discussions on priority issues or agenda setting

Appendix E: Terms of Reference and Standard Operating Procedures

Immunization managers may use this template to prepare the terms of reference and standard operating procedures for a NITAG. All countries are encouraged to utilize the sample content as a starting point; however, adapt as needed to reflect their special requirements or circumstances. The final product should be endorsed by the supervisory division (Communicable Disease Control; Primary Health Care; etc).

Terms of Reference

The purpose of a National Immunization Technical Advisory Group (NITAG) is to empower and advise the national government, Ministry of Health, Immunization Programme, and/or other relevant institutions and organizations on all technical and scientific topics related to Vaccines and Immunization. The **terms of reference** of a NITAG are to **advise** on:

- Latest scientific advancements and recommendations
- Situation analysis and assessment
- Policy analysis and strategy formulation

The NITAG will have only a **technical advisory** role for **all** vaccine preventable diseases. Accordingly, disease-specific technical advisory groups, such as polio, measles, hepatitis, will function under the auspices of the NITAG.

Standard operating procedures

Composition

Type

- NITAG is composed of two of types of members: core and non-core.
- Core members are experts, credible and serve in their capacity and not represent the interests of a particular group, stakeholder, private industry or government entity.
- The majority of core members neither supervise nor report to, directly or indirectly, the immunization programme or (preferably) the Ministry of Health.
- Core members advise and decide on the final set of recommendations.
- Non-core members represent either government (ex-officio) or non-government (liaison) entities.

- Non-core members can contribute to the discussion and help provide background information or needed evidence; however, they will not directly decide on the final set of recommendations.
- A core or non-core member can only serve in one capacity.

Size

- NITAG functions with 10 to 15 core members and 5 to 10 non-core members.

Expertise

- NITAG is composed of 1 to 2 experts from each of the following disciplines: *paediatrics, adult medicine, epidemiology, infectious diseases, public health, immunology, clinical research, health systems and delivery, and health economics.*

Membership

Nomination

- Core members are identified through a formal procedure (newspaper, magazine, internet, etc) or informal networks of medical and public health professionals.
- Core members are recognized and active in their respective areas of expertise.
- Non-core members are nominated by the participating entities.
- The chairperson is a senior and widely respected core member nominated by the core member peers.
- All core members must complete a Declaration of Interest at the beginning of their appointment.
- All members and special invitees must sign a Confidentiality Agreement at the beginning of their appointment or if invited on special basis.
- The group can seek the help of suitable competent experts or bodies to carry out its functions.

Rotation

- The chair rotates after (#) years and (#) terms.
- The core members is appointed for (#) of years for maximum of (#) terms. A core member who has served their maximum years and terms can be reappointed after absence from the group for a (#) of years.

Termination

- Membership is terminated if members:
 - Fail to attend (#) of consecutive unchanged scheduled meetings;
 - Change affiliation resulting in a conflict of interests;
 - Breach the confidentiality agreement.
- Modes of functioning

Formal recognition and general support

- A ministerial decree or equivalent is issued.

- Immunization programme serves as the secretariat.
- Immunization programme manager or equivalent serves as the executive secretary as a non-core member.
- NITAG members serve as volunteers; however, administrative and travel cost associated with the meetings are reflected in the annual plan.
- Secretariat orients all members through briefing sessions and/ or informational packages.

Agenda preparation and frequency of meetings

- Secretariat is responsible for preparing and circulating an updated agenda, along with proper background documents, articles, etc, at least 3 months in advance of meetings.
- Secretariat and members can agree on some agenda topics with 1 to 2 year horizon.
- NITAG meets at least once every 6 months, and whenever necessary or upon the request of Chair or Secretariat.
- Members can excuse themselves prior to and before the start of the meeting if there is conflict of interest with regards to a particular agenda item.

Reporting, recording and dissemination

- Secretariat records and shares the meeting minutes, including the recommendations, with NITAG members within 2 weeks after the meeting.
- Members will have 2 weeks to respond, clarify and/or endorse.
- Endorsed minutes and recommendations are forwarded directly to *(name and title; high level ministry of health official who is not a member of the group)*.
- If the minutes and recommendations do not contain sensitive information *(based on the decision of the high level official)*, they can be disseminated via the list serves, or posted on the official web site within 6 weeks of the meeting.

Decision-making and recommendations

- Meetings are closed and by invitation only.
- Participation of the industries is through invitation only.
- Decisions and recommendations are made through consensus. If consensus is not reached on a particular recommendation, the Chair can make a decision on the final recommendation noting in the minutes that there was no consensus reached on the issue at hand.
- Decisions are based on vaccine effectiveness and safety, disease burden including age specific burden, public health/epidemiology, actions in other countries, and cost-effectiveness and affordability.

Working Group

- Working groups are established as resources to review and provide evidence-based information and options for recommendations.
- Each working group operates under specific terms of reference, which should be defined within 30 days of the NITAG meeting leading to the establishment of the working group.

- These working groups are established on a time limited basis in exceptional situations to help address specific questions identified by NITAG when the issue is particularly complicated and can not be addressed by existing disease-specific working groups.
- One existing NITAG member will serve as the Chair of the working group.
- Terms of reference and proposed related expertise to serve on the working group are developed jointly by the NITAG member serving as Working group Chair and the Secretariat.

Performance

- Performance of the NITAG will be determined by:
 - Meeting the WHO EMRO specified 7 required criteria for a well-functioning NITAG
 - Percent of NITAG recommendations generated from the last 5 meetings which are being implemented by the ministry of health
 - *Insert other measures?*

Appendix F: Introductory Letter

Immunization managers may use this template to prepare a letter for high-level Ministry of Health officials which communicates and promotes the establishment or revision of a NITAG. It should highlight the terms of reference, issuance of a decree and propose an initial or revised list of nominees as members. All countries are encouraged to utilize the sample content as a starting point; however, adapt as needed to reflect their special requirements or circumstances. The final letter should be endorsed by the supervisory division (Communicable Disease Control; Primary Health Care; etc).

Your Excellency,

Referencing XXXXXXX letter dated XXXX and attached Guide from the World Health Organization, Regional Office for the Eastern Mediterranean, we are pleased to propose the **(establishment or revision?)** of the National Immunization Technical Advisory Group. This group serves as a technical advisory body for the Immunization Programme, Ministry of Health and the Government, with the following terms of reference:

Advise on the:

- Latest Scientific Advancements and Recommendations
- Situation Analysis and Assessment
- Policy Analysis and Strategy Formulation
- **Additional and more specific functions?**

Below are the nominees to serve **(or replace?)** as core and non-core members:

Core members

- Select 1 or 2 Paediatricians
- Select 1 or 2 Adult Medicine Specialists
- Select 1 or 2 Epidemiologists
- Select 1 or 2 Infectious Diseases Specialists
- Select 1 or 2 Public health Advisors/specialists
- Select 1 or 2 Immunologists
- Select 1 or 2 (Clinical) Research Advisers
- Select 1 or 2 Health Systems and Delivery Advisers
- Select 1 or 2 Health Economists
- ***Select others?***

Non-core members: Ex-officio

- Ministry of Finance
- Ministry of Health
- Ministry of Education
- Ministry of Planning
- **Select others?**

Non-core members: Liaison

- Medical or Public Health Association/Society
- Paediatrics Association/Society
- National Regulatory Authority
- WHO
- UNICEF
- **Select others?**

All NITAG members will serve as volunteers; however, the administrative and travel cost associated with the meetings are estimated at XXXX.

We propose that the immunization programme serves as the Secretariat and the immunization programme manager as the Executive Secretary. The Chair will be nominated from the core members, and will neither report to nor supervise, directly or indirectly, the immunization programme.

The Secretariat will seek the support of scientific or research institutions or associations to prepare agenda topics and background materials. Furthermore, the technical group and Secretariat may set up working groups, under specific terms of reference and limited time basis, as resources to review and provide evidence-based information and options for recommendations.

Your kind approval of the terms of reference and appointment of nominees, as well as the issuance (**or revision**) of a ministerial decree are highly appreciated.

Name and title

Appendix G: Ministerial Decree

High-level Ministry of Health official may use this template to prepare a Ministerial decree or equivalent to formalize the establishment or revision of a NITAG. All countries are encouraged to utilize the sample content as a starting point; however, adapt as needed to reflect their special requirements or circumstances.

No () for the year 20XX

National Immunization Technical Advisory Group

The undersigned is directed to communicate that *(name and title)* -----, Ministry of Health, Government of ----- is pleased to constitute **(or revise?)** the “National Immunization Technical Advisory Group or NITAG” as per the attached WHO Guide with immediate effect.

In this respect it is denoted that within its overall terms of reference, the National Immunization Technical Advisory Group will be a technical advisory body for the Immunization Programme, Ministry of Health and the Government of ----- . Ministry of Health reviews, prioritizes and makes the final decisions on all recommendations provided by technical advisory group.

The NITAG will compose of core and non-core members, with Secretariat support from the immunization programme. The immunization programme manager or equivalent will serve as Executive Secretary. The NITAG shall meet at least once in 6 months and whenever necessary or upon the request of the chair.

All core members will complete a Declaration of Interest at the beginning of their appointment. Membership will be deemed terminated if members: Change affiliation resulting in a conflict of interests; Breach the confidentiality agreement; Fail to attend **(#)** of consecutive unchanged scheduled meetings; **Others?**

Issued this day ----- at ----- by Secretary, Ministry of Health, Government of

Appendix H: Invitation letter

Immunization managers may use this template to prepare an invitation letter for ex-officio and liaison entities. All countries are encouraged to utilize the sample content as a starting point; however, adapt as needed to reflect their special requirements or circumstances. The final letter should be endorsed by the supervisory division (Communicable Disease Control; Primary Health Care; etc).

Dear,

His/Her Excellency, XXXXX, Minister of Health, Government of XXXXX, has issued a decree on (date) to establish **(or revise?)** the National Immunization Technical Advisory Group. This group will be a technical advisory body for the Immunization Programme, Ministry of Health and the Government, with the following terms of reference:

Advise on the:

- Latest Scientific Advancements and Recommendations
- Situation Analysis and Assessment
- Policy Analysis and Strategy Formulation
- **Additional and more specific functions?**

We invite you to propose a nominee to participate and represent your agency as a non-core member. The role of non-core members is to contribute to the discussion and help provide background information or needed evidence. All NITAG members will serve as volunteers. Attached please find standard operating procedures for this technical group.

Sincerely yours,

Name and title

Appendix I: Declaration of Interest

Immunization managers may use this template to prepare a country-specific Declaration of Interest document, which has to be completed by all core members prior to their appointments to avoid conflict of interest. This sample is copied from the Joint Committee on Vaccination and Immunization (UK) website (<http://www.advisorybodies.doh.gov.uk/jcvi/code.htm#app2>). All countries are encouraged to utilize the sample content as a starting point; however, adapt as needed to reflect their special requirements or circumstances.

ADVISORY COMMITTEES

DECLARATION OF INTERESTS IN INDUSTRY IN ACCORDANCE WITH THE CODE OF PRACTICE

ANNUAL JCVI DECLARATIONS OF INTEREST

NAME:

PROFESSION/TITLE:

PERSONAL INTERESTS (Specific)

(for definition please see paragraphs 4(a), (b) and (c) of the Code of Practice)

Consultancies:

Fee-Paid Work:

Shareholdings:

Other (please specify):

PERSONAL INTERESTS (Non-Specific)

(for definition please see paragraphs 4(a), (b) and (c) of the Code of Practice)

Consultancies:

Fee-Paid Work:

Shareholdings:

Other (please specify):

NON-PERSONAL INTERESTS (Specific)

(for definition, please see paragraphs 5 (a) and (b) of the Code of Practice)

Fellowships:

Industrial Support:

Other (please specify):

NON-PERSONAL INTERESTS (Non- Specific)

(for definition, please see paragraphs 5 (a) and (b) of the Code of Practice)

Fellowships:

Industrial support:

Other (please specify):

Name

Date

INTRODUCTION

1. This code of practice guides the Chairman and the members of the Joint Committee on Vaccination and Immunisation (JCVI, the Committee) as to the circumstances in which they should declare an interest in the pharmaceutical products (or other) industries.
2. In this code, "industry" means:
 - a) companies, partnerships or individuals who are involved with the manufacture, sale, promotion or supply of medicinal products;
 - b) trade associations representing companies involved with such products;
 - c) companies, partnerships or individuals who are directly concerned with the research, development or marketing of a medicinal product which is being considered by the Committee.

References to "the industry" include cases involving a single company.

In this code, "the Department" means the Department of Health, and references to "member(s)" include the Chairman.

DIFFERENT TYPES OF INTEREST

3. The following is intended as a guide to the kinds of interests which should be declared. Where members are uncertain as to whether an interest should be declared, they should seek guidance from the Chairman or the Secretariat or, where it may concern a particular product which is to be considered at a meeting of the Committee, from the Chairman at that meeting. **If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them.** However, members are not under an obligation to search

out links between one company and another, for example where a company with which a member is connected has an interest in another company of which the member is not aware and could not reasonably be expected to be aware.

Personal Interests

4. A personal interest involves payment to a member personally. The main examples are:
 - a) Consultancies -- any consultancy, directorship, position in or work for the industry which attracts regular or occasional payments in cash or kind.
 - b) Fee-paid work -- any work commissioned by the industry for which the member is paid in cash or kind.
 - c) Shareholdings -- any shareholding in or other beneficial interest in shares of the industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management.

Non-Personal Interests

5. A non-personal interest involves payment which benefits a department for which a member is responsible, but is not received by the member personally. The main examples are:
 - a) Fellowships -- the holding of a fellowship endowed by the industry.
 - b) Support by the industry -- any payment, other support or sponsorship by the industry which does not convey any pecuniary or material benefit to the member personally but which does benefit their position or department; for example:
 - I. a grant from a company for the running of a unit or department for which the member is responsible:
 - II. a grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the member is responsible. This does not include financial assistance for students;
 - III. the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.

Members are under no obligation to seek out knowledge of work done for or on behalf of the industry within departments for which they are responsible if they would not normally expect to be informed.

DECLARATION OF INTERESTS

Declaration of Interests to the Department

6. Members of the Committee should inform the Department in writing when they are appointed of their current personal and non-personal interests. Only the name of the company and the nature of the interest is required; the amount of any salary, fee, shareholding, grant, etc. need not be disclosed to the Department. An interest is current if the member has an on-going financial involvement with the industry, for example if they hold shares in a relevant company, if they have

a consultancy contract with the industry, or if they or the department for which they are responsible is in the process of carrying out work for the industry. Members are asked to inform the Department, through the Secretariat, at the time of any change in their personal interests. Changes in non-personal interests can be reported annually. (Non-personal interests involving less than £1000 from a particular company in the previous year need not be declared.)

Declaration of Interests at Meetings

7. Members are required to declare relevant interests at Committee meetings. They must state whether the interests are personal or non-personal and whether they are specific or non-specific to the matter or product under consideration. Interests are considered relevant if they occurred within the last 12 months for new members and existing members.
 - a) An existing member must declare a personal specific interest if they have in the last year worked on the matter or product under consideration and have received personal payment for that work, in any form, from the industry.
 - b) An existing member must declare a personal non-specific interest if they have in the last year a current personal interest in the company concerned which does not relate specifically to the matter or product under discussion.
 - c) An existing member must declare a non-personal specific interest if they are aware that in the last year the department for which they are responsible has received payment for work on the matter or product but the member has not personally received payment in any form from the industry for the work done.
 - d) A member must declare a non-personal non-specific interest if they are aware that in the last year the department for which they are responsible has received payment from the company concerned which does not relate specifically to the matter or product under discussion.
8. The examples of "personal", "non-personal", and "current" interests given in the previous paragraph should be read in the context of paragraphs 3, 4 and 5. A member who is in any doubt as to whether they have an interest which should be declared, or whether they should take part in the proceedings, should ask the Chairman for guidance.

The Secretary of State and/or the Committee has the power to determine whether or not a member with an interest shall take part in the proceedings. The usual procedure for Committee meetings is as follows:

Members with a personal specific interest will be asked to leave the room for the discussion and decision-making.

Members with a personal non-specific interest will be able to participate in discussions but not take part in the decision-making.

Members with non-personal specific interests will be able to answer direct questions from the chair but not take part in the decision making.

Members with non-personal non-specific interests will be able to take participate in the discussion and the decision-making.

9. If a member is aware that a product under consideration is or may become a competitor of a product manufactured, sold or supplied by a company in which the member has a current personal interest, they should declare their interest in the company marketing the rival product.
10. Members of the Committee are required to declare any direct interests relating to salaried employment or consultancies, or those of close family members in matters under discussion at each meeting. Having fully explained the nature of their interests the Chairman will, having consulted the secretariat and other members present, decide whether and to what extent the member should participate in the discussion and determination of the issue. If it is decided that the members should leave the meeting, the chairman may first allow them to make a statement on the item under discussion.
11. If a member present at the JCVI meeting has a current personal specific interest then they should be asked to leave the room.
12. If a member present at the JCVI meeting has a current personal non- specific interest then they may take part in the proceedings unless, exceptionally, the chair rules otherwise.
13. If a member present at the JCVI meeting has a current non-personal specific interest then they should be asked to leave the room when they have personal knowledge of the intervention or matter either through their own work, or through direct supervision of other people's work. In either of these cases, they should declare this interest and should not take part in the proceedings except to answer questions.
14. If a member present at the JCVI meeting has a current non-personal non-specific interest then they may take part in the proceedings unless, exceptionally, the chair rules otherwise.
15. JCVI Sub-groups provide advice to main JCVI. JCVI sub-group members are required to declare their interests. In general a JCVI subgroup member with a current personal specific interest should not be invited to participate. However in exceptional circumstances where they have particular expertise they could be invited to attend the meeting but may not take part in any decision making subject to their own declaration of interests. All other members of a JCVI sub-group can participate in the discussion and the decision-making. The Chair of a JCVI sub-group should not have personal specific interests in any item under discussion.

RECORD OF INTERESTS

16. A record is kept in the Department of the names of members who have declared interests to it, and the nature of those interests. This information will normally remain confidential to the Department unless it is required to be disclosed in Parliament.

Appendix J: Confidentiality Agreement

Immunization managers may use this template to prepare a country-specific Confidentiality Agreement document, which has to be completed by all members prior to their appointments, or if invited on special basis, to ensure confidentiality of proprietary information. This sample is copied from the Strategic Advisory Group of Experts (SAGE) website

(http://www.who.int/immunization/sage/SAGE_TORs_Full_21_11_08.pdf). All countries are encouraged to utilize the sample content as a starting point; however, adapt as needed to reflect their special requirements or circumstances.

1. Commercial, academic and other research institutions and individual scientists often submit or present for discussion by committees or groups of the WHO Department of Immunization, Vaccines and Biological on research, products and processes (hereafter referred to as "Information") which the institutions and individuals consider proprietary. To help ensure the appropriate use by WHO of such Information whilst protecting the institutions' or individual's proprietary rights, WHO undertakes to release such Information only to persons who have signed this agreement.
2. Information submitted by such institutions or individuals through WHO to committees or groups for review, discussion or comment, whether at meetings, on internet-based collaborative workspaces, during telephone conferences or otherwise, shall be regarded by the Undersigned as confidential, unless clearly stated otherwise, by the institution, individual concerned and/or the WHO Secretariat.
3. The Undersigned undertakes to treat such confidential Information as proprietary information and agrees not to make copies of it, nor to disclose or use the same in whole or in part.
4. If requested to do so, the Undersigned agrees to return to WHO any and all Information identified as confidential.
5. The Undersigned shall not be bound by confidentiality if he/she is able to demonstrate that the Information:
 - a) was known to him/her prior to any disclosure to him/her by the institution or
 - b) individual or WHO;
 - c) was in the public domain at the time of disclosure by the institution or individual;
 - d) becomes part of the public domain through no fault of the Undersigned; or
 - e) becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality to the institution, individual or WHO.

6. This Confidentiality Undertaking is valid during the entire time the Undersigned participates in the work of the committee or group, in whatever capacity, and for a period of ten (10) years thereafter.

Signed:

Signature.....

Name.....

(print or type)

CONFIDENTIALITY1.

Version: 21 November 2008 5



Appendix K: Working Groups

*Immunization managers may use this template to develop terms of reference and modes of functioning for NITAG working groups. This sample is copied from the Strategic Advisory Group of Experts (SAGE) website (http://www.who.int/immunization/sage/SAGE_TORs_Full_21_11_08.pdf). All countries are encouraged to utilize the sample content as a starting point, **adapting** it as needed to reflect their special requirements or circumstances.*

Purpose, structure and functioning of the Strategic Advisory Group of Experts on Immunization (SAGE) Working Groups

Working Group purpose and decision to establish SAGE Working Groups

SAGE Working Groups are established as resources intended to increase the effectiveness of SAGE deliberations by reviewing and providing evidence based information and options for recommendations together with implications of the various options to be discussed by the full SAGE in an open public forum.

These Working Groups are established on a time limited basis in exceptional situations to help address specific questions identified by SAGE when the issue is particularly complicated and could not be addressed by existing standing WHO advisory committees. The need and charge for a working group is discussed and agreed during SAGE meetings.

Terms of reference of the Working Groups and identification of needed expertise to serve on the working group

Each Working Group operates under specific terms of reference (TORs). These TORs need to be defined within 30 days of the SAGE meeting leading to the establishment of the working group.

TORs and proposed related expertise to serve on the Working Group are developed jointly by the SAGE member serving as Working Group Chair and the lead WHO technical staff. Final decision is taken jointly by the SAGE Chair and the Director of the Department of Immunization, Vaccines and Biologicals.

Working Group composition and selection of membership

Each Working Group should include two SAGE members (one of whom functions as chair), WHO staff (one of whom functions as the Working Group technical lead), and additional subject matter experts serving in their own individual capacity and with a view to meet the identified needed expertise for the group. This may include organizations representatives, and members of regional technical consultative groups SAGE members and other experts who have identified conflicts of interest cannot serve on the Working Groups charged with responsibility in the identified areas of conflict. The size of the Working Groups should not exceed 10 members and will be adjusted based on the need for expertise and representation.

A public call for nomination of working group members will be posted on the SAGE website together with the relevant terms of reference of the Working Group and indication of the desirable expertise. SAGE members, regional offices, WHO staff and key partner organization will also be approached for potential nominations. From the pool of nominees, the Working Group Chair and Lead WHO staff will propose a Working Group composition for endorsement by the SAGE Chair and the Director of the Department of Immunization, Vaccines and Biologicals. The proposed list should also identify other names and rationale for proposed selection.

Individuals other than SAGE members and organization representatives may participate in SAGE Working Groups meetings only by secretarial invitation in consultation with either Chairs of SAGE or of the Working Group. Occasionally the Working Group Chair, in consultation with the Lead WHO staff and the SAGE Chair, may request the participation of additional disease / vaccine experts who are not members of the working group. These may include SAGE members, organization representatives, industry representatives/experts, public health officials and faculty of academic institutions. Other experts, including representatives of vaccine manufacturers may be asked to provide information to the Working Groups on an ad hoc basis and as needed.

WHO staff perform, coordinate, or identify scientific studies and outbreak investigations to address questions that arise regarding appropriate vaccine policy decisions; conduct analysis of data addressing efficacy, effectiveness, safety, feasibility, and economic aspects of immunization policy.

Modus Operandi

SAGE Working Groups are not allowed to render consensus advice or recommendations directly to the WHO DG. SAGE Working Group Chairs, other Working Group representatives, or the Working Groups *per se* are not empowered to speak on behalf of SAGE. Rather, they are utilized by the SAGE to gather and organize information upon which the SAGE can deliberate and act. Thus, while SAGE Working Groups can and should examine an area in detail and define the issues, including development of options for recommendations, the actual processes of group deliberation terminating in development of group consensus and recommendations must occur in the open public forum of SAGE meetings.

Working Group process

Effective communication and a strong working collaboration between the Working Group Chair and the Lead WHO staff are significant determinants of the effectiveness of a Working Group. The development of a brief (1–2 pages) summary of each Working Group meeting by one of these people will facilitate the function of the Working Group. Summaries should be provided to the SAGE Executive secretary so that IVB senior staff, immunization Regional Advisers and SAGE members can be informed in real time of progress and issues.

With the Lead WHO Staff, the Chair of the Working Group develops a plan for routine operations of the Group. Working Groups accomplish most of their work through teleconferences. A set day and time for routine monthly teleconferences may be established, in order to allow standing teleconferences to be arranged and Working Group members to anticipate and reserve time for these

teleconferences. The frequency of Working Group teleconferences may be changed depending on the urgency of issues being considered by the group and the amount of preparatory work needed prior to a topic being brought up for plenary discussion and decision making at SAGE. Some Working Groups may more effectively achieve their purpose through exchange of e-mail communications with intermittent teleconferences.

In-person meetings of Working Groups may facilitate progress. If possible, they should be scheduled in association with SAGE meetings and should be anticipated at least 2 months in advance of the SAGE meeting. WHO routinely supports travel costs for the duration of SAGE meetings for SAGE members, chairs of regional technical advisory groups, WHO Regional Advisers and any experts invited to present at SAGE. WHO may support travel for additional persons: requests should be brought to the SAGE Executive Secretary for consideration on a case by case basis, with justification for the increased costs.

As issues mature, proposals for presentation to the SAGE should be submitted to the SAGE Executive secretary at least 10 weeks ahead of each SAGE meeting for circulation to SAGE members and to WHO staff. At this stage, formal interaction between the SAGE Working Group Chair, lead WHO staff, SAGE Executive secretary and the SAGE Chair should occur allowing for a briefing on the issue at hand and ensuring that areas of potential conflict are recognized prior to the meeting itself. Decisions to proceed with tabling the issue at the next SAGE meeting will then be taken jointly by the Chair of SAGE and IVB Director after consideration of issues raised during the consultative process.

Management of Conflict of Interest/Undue Influence

When a SAGE Working Group is formed, and at the start of each Working Group meeting, participants should respond to a request to report conflicts of interest relevant to the focus of the Working Group. This is done using the eDOI. SAGE members, organization representatives or WHO staff who have conflicts of interest may not participate in the Working Group. Persons who serve as consultants, may participate in the Working Group despite conflicts of interest if, in the judgment of the SAGE Chair, SAGE Executive Secretary, Working Group Chair and lead WHO staff they bring specific expertise that is essential to the efforts of the Working Group. However, conflicts, both personal and those of their liaison organization (in the case of liaison representatives), must be declared and recorded at the beginning of each Working Group meeting. Participation of all persons with declared conflicts will be restricted by the Working Group Chair and lead WHO staff to that necessary for the Working Group to benefit from the expertise provided by the consultant. No person with an identified conflict of interest should participate in drafting policy options or policy recommendations.

All consultants participate in Working Groups at the discretion of the Working Group Chair and lead WHO staff. The value and impact of SAGE recommendations and WHO policies and recommendations are critically dependent upon public trust in the integrity of the process. Thus, participation of any consultant may be curtailed, even in the absence of a declared conflict of interest, if in the judgment of the Working Group Chair and the lead WHO staff a potential for the appearance of undue influence exists.

Appendix L: NITAG Chairperson

The secretariat and NITAG core members may use this template to consider nomination of the Chairperson. The expected quality and responsibilities are adapted from the Strategic Advisory Group of Experts (SAGE) website. All countries are encouraged to utilize the sample content as a starting point; however, adapt as needed to reflect their special requirements or circumstances.

NITAG Chairperson: Expected Qualities and Responsibilities

Qualities

The Chair should possess all qualities required from NITAG members. In addition, the Chair should:

- Have at least one year of experience serving on NITAG (exceptions are permitted especially if the group has been recently established);
- Have demonstrated the ability both to lead and work effectively and collegially with similar bodies;
- Possess a broad knowledge of national and global immunization related issues;
- Have a reputation that extends beyond their region of origin and be widely respected by the national immunization community;
- Have leadership and management skills to facilitate and direct discussion at meetings. This includes the ability to foster open and collegial discussion among members and to lead to conclusive consensus while maintaining focus on the issues at hand and keeping on time with agendas;
- Have respect for committee members from diverse backgrounds, perspectives and sources of expertise;
- Promote the contribution of all members of the committee;
- Be able to promote a culture of respect among committee members and key stakeholders;
- Be able to function in a team, often under stressful circumstances;
- To lead on behalf of NITAG in circumstances of challenge that may come from stakeholders, working groups, or others but remaining sensitive to the issues or views that have been raised.
- Be able to dedicate up to **(xx?)** days of work each year for travel, meetings and preparation and review of documents.

Responsibilities

- Play a leadership role in the further strengthening and building the credibility of the group
- Ensure that the committee receives appropriate and sufficient administrative support, meeting space and resources to function efficiently, and report deficiencies
- Ensure that any potential conflict of interest reported by members is appropriately dealt with
- Assist the secretariat to prepare the agenda before meetings

- Ensure that decisions are sufficiently evidence based and informed but reflect the view of the committee and are not unduly influenced by interested parties
- Oversee the development and work of working groups
- Approve on behalf of the group the final set of NITAG conclusions and recommendations
- Report to the Minister or the designated person on the outcome of each meeting (if necessary)
- As requested by the secretariat and pending availability represent the group at various meetings as required
- Participate in and chair the membership selection panel