



# **OPERATIONAL GUIDE** FOR NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUPS

**PAHO**



Pan American  
Health  
Organization



World Health  
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Americas

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## 1. PURPOSE OF NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUPS

The currently available vaccines for priority diseases offer substantial health benefits. The relative value of these vaccines depends on the burden of disease, the cost of the vaccine, and the available resources for the introduction of the vaccine into the national immunization program (NIP). Since population characteristics, burden of disease, and available resources vary between subregions and countries, the decision to introduce new and relatively expensive vaccines requires a set of evidence that reflects a country's conditions. This also applies to policy changes affecting vaccines already included in national immunization schedules.

A National Immunization Technical Advisory Group (NITAG) is a technical resource that provides evidence-based advice to national authorities on immunization. A multidisciplinary and informed group with a variety of expertise will give impartial recommendations on vaccines and vaccine-related issues aimed at improving population health. This technical resource is particularly important in view of the vast and complex body of knowledge on immunization and will help counter the pressure from external interest groups.



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“A NITAG’s  
independence is  
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for creating  
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NITAGs are specifically mandated to use evidence-based decision-making to: make policy recommendations that take into account the local epidemiological and social context; make recommendations on prioritized VPD-related public health issues; advise on the implementation of national programs; and advise on the monitoring of the impact of technical immunization recommendations.

In some countries, these technical responsibilities belong to other committees or subcommittees of the same NITAG. Likewise, this guide will serve as a basis for recommendations for all committees that function in an advisory role to NIPs.

Smaller countries with limited resources may collaboratively explore a subregional or intercountry mechanism to provide independent and expert technical assistance instead of creating individual NITAGs. This has been the case for countries of the Caribbean, which in 2018 created the Caribbean Immunization Technical Advisory Group for 20 English- and Dutch-speaking countries and territories.

A NITAG's independence is the cornerstone for creating credibility and trust. Autonomy and impartiality are achieved in different ways in the NITAGs of the Americas, but in order to ensure a respected and effective committee that functions well, the following should be taken into consideration:

- 1) Establishment of the NITAG through a formal mechanism such as a ministerial decree or other appropriate means;

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- 2) Formulation in writing of its terms of reference, affiliation/selection criteria, and standard operating procedures (SOPs);

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- 3) Commitment of high-level officials to the NITAG, with formal reporting to a senior official of the ministry of health;

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- 4) No affiliation as NITAG core members to government workers. As a minimum, no affiliation as core members to direct reports to the NIP;

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- 5) NITAG members who declare interests according to a written policy, including the process used to review and minimize conflicts of interest;

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- 6) Guaranteed financing for the NITAG's operations;

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- 7) Sufficient technical and administrative support from the NITAG Secretariat.

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## 2. FUNCTIONS

NITAG functions vary among countries and depend on the needs and technical expertise in each country. NITAGs have an advisory function and should not be responsible for the implementation, coordination, or regulation of immunization-related activities.

The functions below are general in nature and may overlap with the activities of other professional existing groups. Each country will have to adapt these functions to its situation.

Technical assistance from the NITAG should include:



### ***Introduction of new vaccines and updates to existing vaccination schedules***

Generate evidence-based recommendations on the introduction of new vaccines and update of existing vaccination schedules, considering national public health priorities as well as technical, programmatic, logistical, financial, and social criteria.

Additionally, NITAG support may include any of the following:



### ***Vaccine administration***

Create standards for vaccination schedules, vaccine procurement and storage, routes of administration, dosing, and contraindications,



### ***Vaccine safety***

Develop standards for reporting events supposedly attributable to vaccination or immunization (ESAVI); evaluate ESAVI; and advise on health policy issues related to vaccine safety,



### ***Vaccine policy***

Review and provide recommendations to improve NIP policies, including data collection, quality of services provided, and vaccination coverage,



### ***VPD surveillance***

Support the creation of standards for surveillance of VPDs, and standard operating procedures and protocols for disease reporting and specimen collection,

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### ***Vaccine impact***

Advise on the monitoring of the impact of technical recommendations including vaccine effectiveness and impact,

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### ***Anticipation of the program's needs***

Monitor trends in VPDs, identify research gaps and guide the NIP in leveraging existing resources or creating partnerships to address the identified needs. Review the progress in the development of new vaccines and the potential for their inclusion into the NIP,

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### ***VPD elimination***

Support an independent process to document and verify evidence during the stages of VPD elimination, e.g., measles, rubella, congenital rubella syndrome.

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In several countries of the Americas, NITAGs have reported having other functions, such as advocacy before instances outside the health sector (presidency, national congress, cooperation agencies etc.), periodic evaluation of the NIP's performance (examining vaccine coverage, VPD surveillance, procurement, ESAVIs surveillance, etc.) and formulation of recommendations to strengthen the program, serving as spokespersons in special situations (vaccine promotion and communication before the media, communication during outbreaks, pandemics, crises related to ESAVIs, anti-vaccine statements, etc.).

## a. Develop a Strategic Vision Document

NITAGs should prepare a formal Strategic Vision Document. The objective of this document is to have a clear, explicit, and formal vision and strategic plan for the NITAG. It should reflect consensus and be supported by its members. This document often serves as the official basis for the NITAG and for a ministerial decree that institutionalizes the group.

This document should be a living instrument, created once but then modified in light of new evidence and the availability of new vaccines and technologies, or new country needs and challenges.

The document should contain the following basic elements:

<b>i. Vision</b>	<b>ii. Mission</b>	<b>iii. Goals and targets</b>	<b>iv. Strategies and activities</b>
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The Document of Strategic Vision should be approved by the core members of the NITAG and presented to senior health authorities.

The document should be reviewed on an annual basis or when new information or new health interventions that are relevant for the NITAG's support to the NIP are available. Its strategies should be modified when necessary to ensure the achievement of the proposed objectives.



### **i. Vision**

Vision implies a mental image of a desirable future state. In the case of a NITAG, this is related to the state of population health with respect to VPDs.

The strategic vision should have the following characteristics:

- attractive (desirable, motivational)
- attainable (realistic objectives)
- flexible (general enough to allow the experts to use their criteria in decision-making)

An example of vision would be: "A country free of illness and deaths from vaccine-preventable diseases."



## ii. Mission

While vision reflects the desired future, the mission indicates how this future state can be reached. The mission involves the general purpose of a NITAG and justifies its existence.

An example of a mission would be: “Protect the health of the country’s population through recommendations that have the greatest impact on vaccine-preventable diseases.”



## iii. Goals and objectives

Goals and targets should be focused on achieving the mission. Goals should be general and include more specific target objectives.

Targets should include when it is expected that they will be achieved:

**Target objective 1:** “By the end of 2020, provide a recommendation on the expansion of influenza vaccination programs to include pregnant women as a target group.”

**Target objective 2:** “By the end of 2021, provide a recommendation on monitoring Hepatitis A vaccine impact post-introduction.”

Goals and objectives may be proposed for up to a five-year period and then updated periodically.



## iv. Strategies and activities

NITAGs should clearly outline the generic criteria for decision-making and the corresponding process in writing in its SOPs. These criteria can be refined depending on the exact topic under consideration.

Strategies are the specific lines of work developed to meet each objective. These should be frequently reviewed and monitored to ensure progress and compliance.

Example of a strategy: “Guide the national research agenda to develop a recommendation on co-administration of two vaccines in the national schedule.”

Example of a strategy: “Guide the cost-effectiveness analysis of the HPV vaccine to develop a recommendation on the inclusion of this vaccine in the national schedule.”



### 3. AFFILIATION

#### a. Composition

The composition of the NITAG encompasses the size of the group, types of affiliation, and expertise of members. It is essential that all core members act independently and do not represent an interest group. Members should be free from conflicts of interest and be recognized in their field of expertise. Other factors may be considered when selecting members such as gender distribution, geographical diversity, and representation of special populations, among others.

##### i. Size

Many successful committees function with 10-15 independent expert members who represent a broad range of disciplines that encompass many aspects of immunization. For smaller countries, 7-10 independent experts may be considered. These individuals should not be working for or accountable to the NIP or the ministry of health.

##### ii. Type of affiliation

Governments may decide to have several types of NITAG members. Affiliation can be grouped into three categories:



“Core members are independent experts that issue evidence-based recommendations without conflicts of interest or bias toward the government”

1. Core members are the key component. These are independent experts without conflicts of interest or bias toward the NIP. They contribute in their own expert capacity, and do not represent any institution or entity. These are the members who generate the NITAG's recommendations.
2. The core NITAG may be expanded to include associate members representing government agencies involved in immunization (e.g., regulatory agencies), professional associations, other national advisory committees, and other technical partners, such as WHO and UNICEF. These members enrich discussions by bringing in the perspectives of the entities they represent, but cannot vote on final recommendations. Typically these members consult the group they represent prior to the meeting to share their position on specific agenda items.

3. Members of the Secretariat support the preparation of the technical dossier, coordinate and participate in meetings, and prepare meeting minutes. These members represent the health authorities, often the NIP, and do not speak from personal perspective. They can express an opinion but do not vote on recommendations.

The Chair of the NITAG should be a senior-level expert, recognized and respected by peers. The Chair must be an effective leader and efficient moderator able to guide the NITAG's deliberations. He/she should not supervise nor report to the NIP. The Chair may be appointed through an external process or be selected from among the core members. The Chair must run the meetings according to SOPs.

### **iii. Expertise**

Technical advisory groups such as NITAGs should be multidisciplinary, with core members covering a broad range of expertise. These members may be experts in the disease, vaccine, methods, or programmatic aspects. When feasible, countries should consider including experts from the following disciplines/areas:

- ⇒ Pediatrics

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- ⇒ Internal medicine (adult)

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- ⇒ Epidemiology (focusing on infectious diseases)

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- ⇒ Public health

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- ⇒ Immunology

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- ⇒ Microbiology

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- ⇒ Vaccinology

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- ⇒ Clinical trials of vaccines

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- ⇒ Health systems and care delivery

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- ⇒ Health economics

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- ⇒ Obstetrics/gynecology

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- ⇒ Others (such as social sciences, ethics)

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In addition to these core experts, national governments may wish to include individuals from the following groups as associate members or as part of the Secretariat:

- NIP manager or coordinator

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- Coordinator of epidemiological surveillance

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- Representative of the national regulatory authority or the drug/vaccine licensing entity

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- Representative of the national laboratory of reference for VPDs

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- Representative of the national association of pediatrics, geriatrics, medicine, nurses, gynecology/obstetrics, chronic diseases, among others

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- WHO representative or other technical partner

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- Representative of civil society

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- Representative of the national health technology assessment entity where applicable

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## **b. Selection of members**

The members should be selected and formally appointed by high-level government officials through a well-defined, transparent process. Acceptance of public appointments can increase the NITAG's credibility. A certain number of fixed positions may be reserved for associate members and for members of the Secretariat. Before being appointed, it is important that core members declare any conflict of interest and that all members sign a confidentiality agreement.

## **c. Term limits**

It is essential to have a process for rotated affiliation with limited periods of service. Core members should be appointed for a fixed number of years with the possibility of renewal. A three to four year term with a maximum of two additional terms is common practice. In order to maintain continuity in the group, it is important to ensure that the terms of all members do not expire at the same time.

#### **d. Voting**

Only core members should have the power to vote on the NITAG's decisions. Associate members, members of the Secretariat, and observers or invited experts can provide additional information and contribute to discussions, but should not participate in the development of recommendations or voting.

#### **e. Termination**

It is important to have written SOPs that specify the process for terminating a member's service. These should specify who has the authority to initiate the process and what method the group will use to decide whether to terminate a membership. Possible reasons for termination include: not attending a specified number of consecutive meetings; a change in the member's affiliation that results in a conflict of interest; a breach of confidentiality; or a lack of professionalism.

#### **f. Responsibilities of the members**

Core members must act professionally. This includes attending general meetings and meetings of subcommittees, adequate preparation before meetings, and rigorous and impartial participation in decision-making. Core members are not expected to discuss issues with the government or make comments independently, but rather through an agreed upon process.

#### **g. Financial support**

The countries may consider remunerating core members with travel allowances or a per diem that covers the time spent in meetings. Generally, NITAG members in this Region provide their services *ad honorem*. The secretariat typically covers meeting expenses and the corresponding travel expenses.

## 4. MEETINGS AND OPERATIONAL PROCEDURES

The subjects addressed below should be specified in the NITAG's operational procedures:



### a. Frequency of meetings

NITAGs generally meet regularly at least twice, but usually not more than four times a year. The Chair or a ministry of health employee may convene additional special meetings to address important subjects or emergencies. Sometimes meetings may be conducted remotely, especially special *ad hoc* meetings to address specific topics.

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### b. Preparing meetings

NITAGs need a formal process to prepare their agenda. Consider allowing the following people to bring subjects to the NITAG's attention: the ministry of health/the NITAG chair; all NITAG members; subcommittees; and working groups. The meeting agenda and all relevant information on the agenda items should be provided to all members in a timely fashion prior to the meeting.

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### c. Managing meetings

The commission that creates the NITAG should specify the operational procedures to be followed at meetings. The Chair of the NITAG should direct the meeting. The NIP manager often serves as NITAG secretary.

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### d. Decision by vote or consensus

Only core members should have a say in selecting the NITAG's recommendations. The NITAG needs to decide if it will make decisions by majority vote or by consensus, and how many members need to be present (quorum) to formulate recommendations. It is important to reflect these rules in the NITAG's operating procedures.



### **e. Open and closed meetings**

Countries may decide to publish the minutes of meetings (for example, at the NITAG or NIP website) or to open meetings to the public. This increases transparency for the decision-making process and builds confidence in the NITAG, but it may reveal information that the country/NITAG would prefer to keep confidential. It is important to note that opening NITAG meetings to the public, as is done in the United States, means preparing a great deal of communications material.

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### **f. Proceedings/reports of meetings**

The minutes of meetings should be shared with members for approval after the meeting, ideally within a month. Publishing the minutes will build confidence in the NITAG's recommendations. Some NITAGs periodically publish reports on their recommendations or post them on a website.

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### **g. Technical and administrative support**

Sufficient and receptive administrative support will facilitate obstacle-free operations. The ministry of health often lends this support to NITAGs. Administrative responsibilities may include compiling agenda items, disseminating reference materials, logistics of the meetings, arrangements for trips, and support for the preparation and distribution of reports. Moreover, the Secretariat technical support is crucial for the adequate preparation of a dossier. The Secretariat typically compiles national data, conducts literature reviews, and synthesizes information systematically in standardized formats, such as the "evidence-to-recommendation" framework.



## **h. Subcommittees and working groups**

Countries can decide to create:

- Subcommittees to evaluate specific subjects such as a one-time activity
- Working groups that systematically review specific vaccine-related subjects and provide summarized evidence to the NITAG.

The Chair may assign members to these groups or the NITAG may use a self-appointment process. Like the NITAG as a whole, these smaller groups have to follow specified operational procedures. Subcommittees and working groups can invite national or international experts when necessary. These smaller groups will focus on matters specific to each country and may address, for example, vaccine development, vaccine safety, public participation, performance of vaccination campaigns, financing of vaccines, or immunization of adolescents.



## **i. Managing conflicts of interest**

NITAGs should develop a policy to manage conflicts of interests. This involves compiling the members' interests and limiting or eliminating the potential influence that these interests could have on the preparation of recommendations. The policy establishes the process and measures adopted to ensure that there are no conflicts of interest in the work of the NITAG. This is achieved by requiring that the members declare their interests. Then, for each subject discussed in the NITAG, an evaluation is made of whether (and to what extent) a member's interests involve a conflict of interest. If so, the member's contribution on that specific subject could be set aside or limited. Individuals should fully declare their interests without deciding themselves whether or not they constitute

a conflict. It is the members' responsibility to declare their interests; evaluating whether these constitute a conflict of interest could be the role of the NITAG Chair, of the Secretariat, of both, or of a group/individual delegated by the Chair/Secretariat depending on the country's SOPs. A policy to manage conflicts of interest protects the credibility of the NITAG, its members, and the NIP. The following will need to be taken into account:

- the frequency and nature of professional relations between the experts and academia, partners in technical agencies, the ministry of health, the private sector, etc.;
- the terms of reference and/or legal foundation of the NITAG;
- existing legislation on the management of conflicts of interest in the country;

If the government has a structure for legal advisory services, it is appropriate to refer to it.



#### **j. Participation from the pharmaceutical industry**

Vaccine manufacturers should not attend NITAG meetings as participants. They may occasionally attend, solely to provide specific information about their products when requested by the NITAG. Then they must leave the discussion.

Vaccine manufacturers could also present or participate in a working group meeting/call, but would also have to leave the discussion.



## 5. DECISION-MAKING

### a. Decision-making criteria

NITAGs need to use clearly defined and transparent criteria when formulating recommendations. The types of criteria may vary with the subject, covering different areas of knowledge. This explains the need for experts from various disciplines in a NITAG.

When decisions are made concerning the introduction of new vaccines, three types of criteria should be taken into account: technical, programmatic/operational, and social.

#### - Technical criteria

- i. Vaccine safety and efficacy
- ii. Burden of disease (age-specific burden of disease, morbidity, and mortality)
- iii. Cost-effectiveness

#### - Programmatic operational criteria

- iv. Vaccine supply (sustainability)
- v. Logistic issues (infrastructure, personnel, cold chain)
- vi. Financing strategies (mandates for national procurement, associations)

#### - Social criteria

- vii. Perception of risk of suffering from diseases
- viii. Equity (impact on marginalized groups)

PAHO's ProVac initiative has developed standardized and widely tested tools that aim to facilitate a comprehensive analysis of new vaccine introductions, and minimize biases related to experts opinions, a weak evidence base, or the pressure of groups of interest. All ProVac material can be found at: <https://www.paho.org/es/temas/inmunizacion>

When there is insufficient information, the NITAG may request additional studies to obtain the necessary data. Countries may also consider using regional data or data from other countries, depending on the resources available in the country. Recommendations on subjects other than the introduction of new vaccines may consider criteria depending on the policy question to the NITAG is helping answer.

## **b. Recommendations**

NITAGs formulate recommendations (not resolutions) for national governments on matters related to their strategic vision. The manual of operational procedures should specify the method by which the NITAG shares recommendations with the ministry of health and, if appropriate, with the public. Recommendations can be shared through meetings with key ministry of health staff or in written reports.

Written reports should be summarized into policy briefs or position papers that should be disseminated to decision-makers as agreed in the NITAG's SOPs. Since the NITAG's recommendations are by definition non-binding for the NIP, it is important to provide periodic feedback to the NITAG on their consideration, implementation, and impact in order to preserve their valuable engagement.

## **c. Collaboration with other groups**

NITAGs benefit from a close collaboration with other national, regional, and international organizations involved in immunization, such as national regulatory bodies, NITAGs in neighboring countries, and PAHO/WHO technical groups. These organizations can provide functional guidance and technical assistance to NITAGs.

In 2017, the Global NITAG Network (GNN) was created. This network is an effective platform to share information and experiences, promote connections between different committees, participate in peer-to-peer learning initiatives, share resources, simplify activities, and foster NITAG participation in regional and global meetings on vaccination. The GNN was created through a global initiative by a number of NITAGs, with a secretariat located in WHO and a steering committee made up of rotating NITAG members in the six WHO regions. Among the benefits offered is a monthly electronic bulletin board system on new developments in NITAGs, information on annual meetings in the network, and related materials. Also, recently formed NITAGs can seek technical assistance from more established ones, and participate in peer-to-peer exchanges and access tools and useful resources. It is encouraged that all NITAGs in the Americas Region be active members in GNN. <http://www.nitag-resource.org/>

## 6. CONCLUSION

Evidence-based decision-making at the national level is increasingly important as the options for immunization policies increase. Robust structures and transparent decision-making processes are essential to make the best possible decisions on immunization. NITAGs offer credibility and ownership to NIPs, while protecting these programs and contributing to their sustainability. In order to have a functional and credible NITAG, it is important to have a legislative/administrative basis or formal process for its establishment, a transparent selection process, written operating procedures, confidentiality agreements and a policy for the management of conflicts of interest, as well as a strong technical secretariat. A NITAG's impartial recommendations, based on a robust review of the best available evidence, are essential to fulfill its valuable mission.

## APPENDIX A

### Checklist for establishing or strengthening a NITAG

Please use this list to quickly identify opportunities to improve your NITAG. It may also be useful for countries in the process of establishing a NITAG. A more complete tool for evaluating NITAGs will be available in English, Spanish, and French from:

<https://www.paho.org/es/temas/inmunizacion>  
or <https://www.nitag-resource.org/>

General (establishment and support)		
	Yes/No	If no, please specify
Was an official mechanism used to establish the NITAG? (e.g., a ministerial decree)		
Are the recommendations issued non-binding?		
Does the NITAG have sufficient funding to fulfill its terms of reference? (budget allocation or other resources)		
Does the NITAG have adequate technical and administrative support?		
Does it formally report to the ministry of health?		
Does it have a manual on SOPs?		

Functions		
	Yes/No	If no, please specify
Do the NITAG's terms of reference reflect only an advisory function?		
<b>In which topics is the NITAG involved? (select all that are relevant)</b>		
- Selection and introduction of vaccines		
- Vaccine administration (vaccination schedules, vaccine procurement, storage, administration)		
- Vaccine safety (surveillance and evaluation of ESAVIs)		
- Vaccination policy (review and improvement of NIP policies and strategies)		
- VPD surveillance (protocols for surveillance and case definition)		
- Vaccine impact		
- Anticipation of the NIP needs (future vaccines/ technologies, research gaps etc.)		

**NITAG Membership (size, expertise, and type)**

	Yes/No	If no, please specify
Does the group consist of 7-10 individual core experts?		
Are the majority independent core members? (independent means they do not directly work for or report to the NIP)		
Do the members bring broad and varied expertise to the group? (e.g., pediatrics, epidemiology, public health, immunology, vaccine studies, health economy, health services delivery, etc.)		
Does the NITAG have a written policy for managing conflicts of interest?		
Have all members completed a written declaration of interests?		
Are there associate members and a Secretariat? (specify affiliation and role)		

**Affiliation (appointment, rotation, termination)**

	Yes/No	If no, please specify
Are there standardized procedures for the appointment of members?		
Are the selection and appointment processes transparent?		
Is the NITAG Chair independent of the ministry of health?		
Have all core members signed a confidentiality agreement?		
Are all members appointed for limited terms?		
Are there SOPs for termination of members' services?		

## Meetings and Operational Procedures

	Yes/No	If no, please specify
Does the NITAG meet at least twice a year?		
Is an agenda prepared and circulated to NITAG members at least two weeks before meetings?		
Are there SOPs for holding/organizing/managing meetings?		
Are voting procedures specified (i.e. voting or consensus)?		
Are core members the only members allowed to vote on recommendations?		
Are meeting minutes available for review by core members within a month after the meetings?		
Are there rules for participation from the pharmaceutical industry?		
Does the NIP manager or his/her equivalent serve as the executive secretary of the NITAG?		
Is the Secretariat in charge of the technical preparation of a dossier?		
Are subcommittees or working groups formed to address specific subjects?		



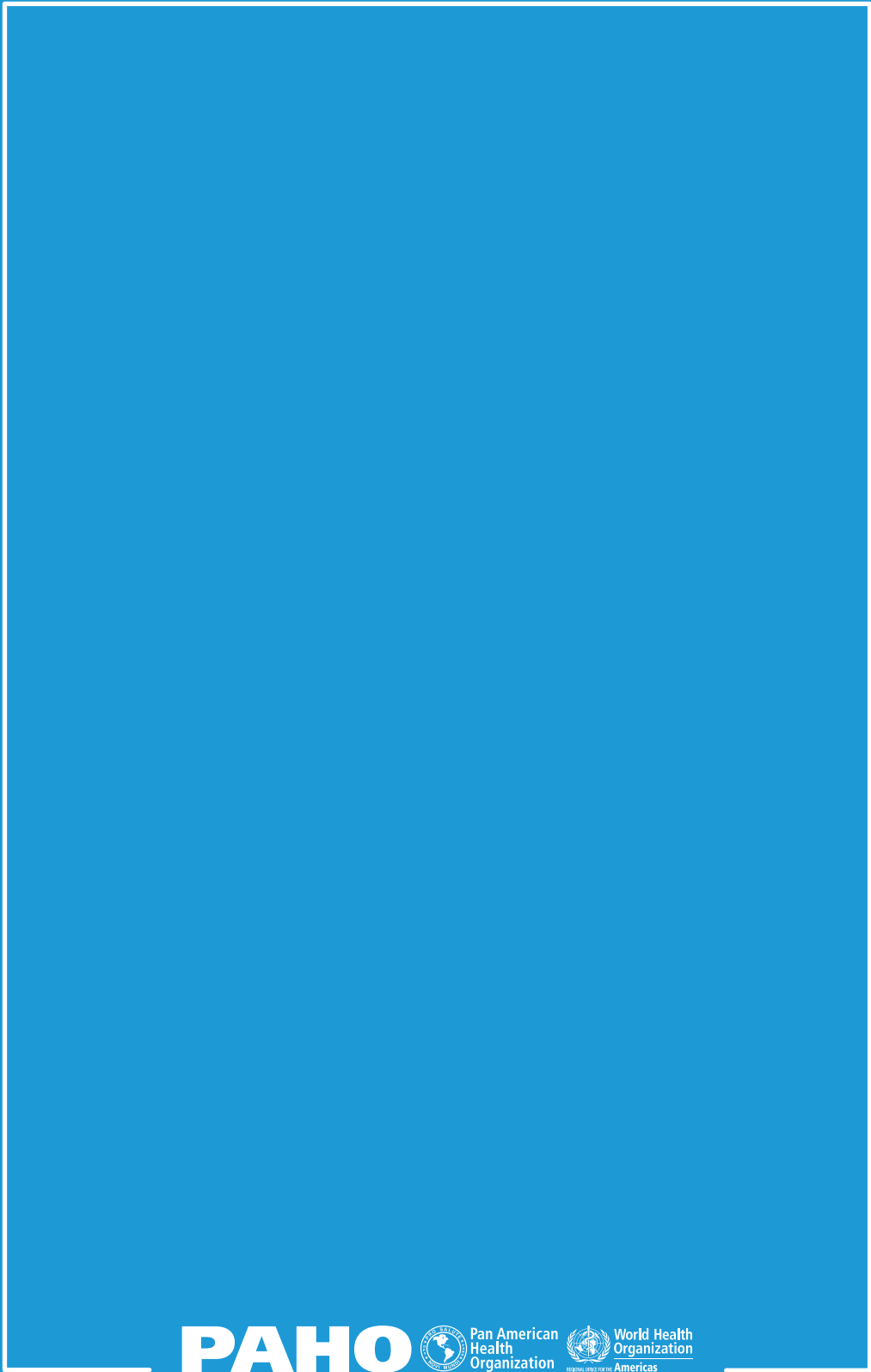


## NITAG Performance

	Yes/No	If no, please specify
Are process and outcome indicators used to evaluate the contribution or impact of the NITAG?		
Of the recommendations made by the NITAG in its last five meetings, what percentage are actually being implemented by the ministry of health?		
In the past 12 months, has the ministry of health consulted the NITAG before implementing a policy relevant to the NIP?		

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