

## Review

## Supporting countries in establishing and strengthening NITAGs: Lessons learned from 5 years of the SIVAC initiative



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## ABSTRACT

To empower governments to formulate rational policies without pressure from any group, and to increase the use of evidence-based decision-making to adapt global recommendations on immunization to their local context, the WHO has recommended on multiple occasions that countries should establish National Immunization Technical Advisory Groups (NITAGs). The World Health Assembly (WHA) reinforced those recommendations in 2012 when Member States endorsed the Decade of Vaccines Global Vaccine Action Plan (GVAP). NITAGs are multidisciplinary groups of national experts responsible for providing independent, evidence-informed advice to health authorities on all policy-related issues for all vaccines across all populations. In 2012, according to the WHO–UNICEF Joint Reporting Form, among 57 countries eligible for immunization program financial support from the GAVI Alliance, only 9 reported having a functional NITAG. Since 2008, the Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative (at the Agence de Médecine Préventive or AMP) in close collaboration with the WHO and other partners has been working to accelerate and systematize the establishment of NITAGs in low- and middle-income countries. In addition to providing direct support to countries to establish advisory groups, the initiative also supports existing NITAGs to strengthen their capacity in the use of evidence-based processes for decision-making aligned with international standards. After 5 years of implementation and based on lessons learned, we recommend that future efforts should target both expanding new NITAGs and strengthening existing NITAGs in individual countries, along three strategic lines: (i) reinforce NITAG institutional integration to promote sustainability and credibility, (ii) build technical capacity within NITAG secretariats and evaluate NITAG performance, and (iii) increase networking and regional collaborations. These should be done through the development and dissemination of tools and guidelines, and information through a variety of adapted mechanisms.

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**Abbreviations:** AMP, Agence de Médecine Préventive; ECOWAS, Economic Community of West African States; GAVI, Global Alliance for Vaccines and Immunization; IVI, International Vaccine Institute; JRF, Joint Reporting Form; MoH, Ministry of Health; NITAG, National Immunization Technical Advisory Group; NUVI, New and Under-Utilized Vaccine Introduction; PAHO, Pan-American Health Organization; SIVAC, Supporting Independent Immunization and Vaccine Advisory Committees; WAHO, West African Health Organization; WHA, World Health Assembly; WHO, World Health Organization.

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### 1. Introduction

Following the launch of the Expanded Program on Immunization (EPI) by WHO 40 years ago, most low and middle-income countries began their immunization programs with six antigens: diphtheria-tetanus-whole cell pertussis (DTwP), measles, oral poliovirus (OPV) and bacillus Calmette-Guerin (BCG). Some countries subsequently introduced up to ten further antigens, including hepatitis B, *Haemophilus influenzae* type b (Hib) conjugate, pneumococcal conjugate (PCV), meningococcal conjugate (MCV), yellow fever virus, rotavirus, influenza and human papillomavirus (HPV) [1]. Moreover, several vaccines containing additional antigens are in the development pipeline (and are likely to become available in the next decade), such as those containing

malaria, dengue, group B streptococcus, tuberculosis, human immunodeficiency virus and respiratory syncytial virus vaccines.

The immunization arena is also becoming progressively complex for a variety of reasons, including the extension of immunization activities beyond childhood; the growing number of vaccine manufacturers; the multitude of vaccine presentations; and pricing that varies according to supply and demand and (above all) the ability to pay.

In addition, national health authorities in many developing countries still lack the methodology for evaluating scientific data that is increasingly voluminous and complex. Finally, countries with limited financial resources are facing even more difficult choices when prioritizing recommended public health interventions.

NITAGs are multidisciplinary groups of national experts responsible for providing independent, evidence-informed advice to health authorities on policy-related issues for the entire range of vaccines across all populations. The role of NITAGs is to collect, review, assess and organize scientific evidence on specific vaccine-related topics in the form of recommendations to national health authorities.

WHO has repeatedly recommended that countries should establish NITAGs for two reasons: first, to empower governments to devise logical policies without pressure from any particular outside group; and, secondly, to increase the use of evidence-based decision-making for adapting global recommendations on immunization to local contexts. The World Health Assembly (WHA) bolstered these recommendations in 2012 when member states endorsed the Decade of Vaccines – Global Vaccine Action Plan (GVAP) [2], a worldwide strategy that aims to prevent millions of deaths by 2020 via more equitable access to existing vaccines for people in all communities. GVAP includes a specific objective on NITAGs, namely: “All countries should have a functional NITAG by 2020”.

WHO initially defined six basic indicators for characterizing functional NITAGs: formal written terms of reference; a legislative or administrative status; a minimum of five main areas of expertise in the core membership; a meeting at least once a year; a secretariat for distributing the agenda and background material prior to meetings; and a declaration of interests policy for all members [3]. A more comprehensive set of indicators for assessing NITAG functionality, performance, outcomes and outputs was developed in 2013 by WHO, SIVAC and other partners [4]. The progress made on this and other objectives will be monitored over the next 10 years, with an annual report being presented for discussion at the WHA [2].

NITAGs in developed countries have been instrumental in providing independent and scientifically sound advice to governments for many years. The importance of such NITAGs is illustrated by the role of the Joint Committee on Vaccination and Immunization (JCVI) in the UK, the Advisory Committee on Immunization Practices (ACIP) in the US, the Vaccine Technical Committee (CTV)

in France, the Standing Committee on Vaccination (STIKO) in Germany, the Australian Technical Advisory Group on Immunizations (ATAGI) and the Korea Advisory Committee on Immunization Practices (KACIP) in South Korea. Other NITAGs from middle-income countries (such as the Vaccine Technical Committee (CTV) in Tunisia and the Indonesian Technical Advisory Group on Immunization (ITAGI)) have also reached satisfying operational and performance levels [5].

According to the WHO-UNICEF JRF, 99 countries worldwide (52%) in 2012 reported the existence of a NITAG with a formal (legislative or administrative) basis (with a high of 86% in the Eastern Mediterranean Region). Among the 63 countries (33%) that reported having a functional NITAG, only 38 were developing countries; out of the 57 countries eligible for immunization program financial support from Gavi, the Vaccine Alliance, only nine reported a functional NITAG [6].

AMP and IVI established the SIVAC Initiative in 2008 in close collaboration with WHO and backed by funding from the Bill & Melinda Gates Foundation. SIVAC aims to accelerate and systematize the establishment of NITAGs in low and middle-income countries [7]. In addition to providing direct support to countries for setting up advisory groups, the initiative also helps existing NITAGs strengthen their capacities to use evidence-based processes for decision-making with international standards.

As part of AMP's WHO Collaborating Center on evidence-informed immunization policy-making, SIVAC is one of the key actors supporting WHO-HQ and their regional offices to establish and strengthen NITAGs, alongside the US Centers for Diseases Control and Prevention (US CDC). This group of organizations is heavily coordinated by WHO-HQ and includes, in particular, the NITAG focal points from WHO regional offices, the US CDC and WHO IVB.

This paper is devoted to analyzing and discussing SIVAC's contribution to the WHO and global community objectives on NITAGs. We review the lessons learned from the first 5 years of the project and report on the expansion of NITAGs based on SIVAC's experience and perspective. We then present a strategic overview of NITAG development for the next 5 years.

## 2. Background

Together with WHO and partners, the SIVAC initiative has assisted nine countries in setting up NITAGs since its inception, and is currently working to achieve the same goal in an additional eight countries. The initiative has also helped seven countries to strengthen their pre-existing NITAGs, and agreement for support has been reached with a further 14 countries over the next 2 years (See Table 1 and Map 1). The criteria for country selection has been discussed elsewhere [7,8], as have the methodologies and processes for establishing NITAGs.

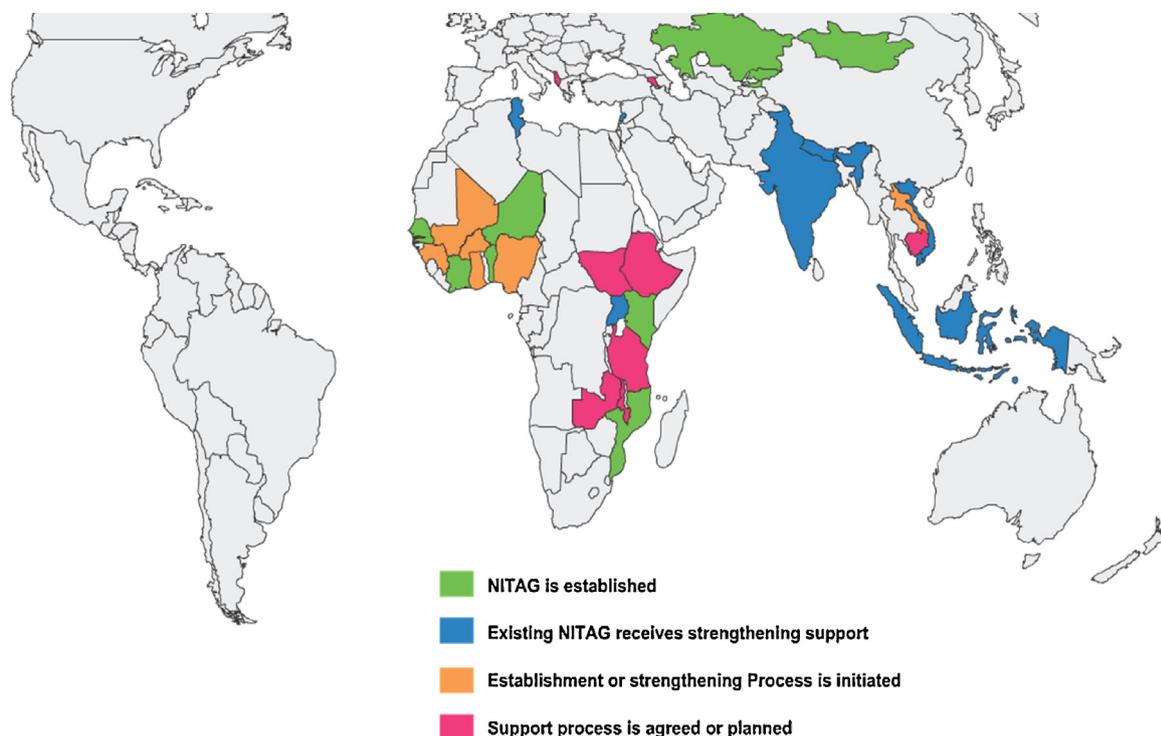
In addition to offering direct assistance to individual NITAGs, one of SIVAC's objectives has been to provide global technical

**Table 1**  
Countries where SIVAC support was provided or is ongoing/initiated/planned.

NITAG is established	Existing NITAG receives strengthening support	Establishment or strengthening process is initiated	Support process is agreed or planned
Benin	India	Burkina Faso	Albania
Côte d'Ivoire	Indonesia	Ghana	Armenia
Kazakhstan	Lebanon <sup>a</sup>	Guinea	Cambodia
Kenya	Nepal	Lao DPR	Ethiopia
Kyrgyzstan	Tunisia	Mali	Malawi
Mongolia	Uganda	Nigeria	South Sudan
Mozambique <sup>b</sup>	Vietnam	The Gambia	Tanzania
Niger			Zambia
Senegal			

<sup>a</sup> Process reinitiated after a suspension.

<sup>b</sup> Support period completed.



Map 1. Countries where SIVAC support was provided or is ongoing/initiated/planned.

support to all countries, including those not directly helped by the initiative. This includes developing a number of guidelines on establishing and operating NITAGs, drawn up in collaboration with WHO and other partners (such as US Centers for Disease Control and Prevention and existing NITAGs). This guidance, which can be adapted to any country's health system, provides a framework for the legal establishment of NITAGs and the preparation of terms of reference (ToR) and standard operating procedures (SOPs). The India NITAG secretariat, for example, used the guidelines to address issues such as managing conflicts of interest, limiting external influence from groups, and defining the roles and responsibilities of the committee's members. The guidelines include information on the mode of operation, the number of members, and the duration and number of terms served, as well as the organization of working groups, interactions with other technical committees such as National Regulatory Authorities (NRAs) [9], and the ideal mix of expertise.

### 3. Lessons learned

Amongst the lessons learned, we first present the challenges faced in establishing and strengthening NITAGs since 2008. We then set out the perceived benefits that have been reported, together with concrete examples from various countries. We discuss *all* the lessons learned in order to provide the most comprehensive context possible.

#### 3.1. Challenges

##### 3.1.1. National authorities need to better understand the role of NITAGs

Despite WHO's multiple recommendations (both globally and regionally) about setting up NITAGs, knowledge about the advisory groups remains poor among senior immunization health officers at country level. In GAVI-eligible countries, the existence of an Inter-Agency Coordination Committee (ICC) is an official requirement for

accessing GAVI support. ICCs, which are chaired by the MoH and comprise the majority of in-country technical partners (e.g. WHO and UNICEF), focus on implementing EPI decisions made by the ministry and their operational aspects. NITAGs, on the other hand, have an advisory role and do not have a mandate to address and supervise implementation and operations; nor do they concentrate exclusively on EPI. As a result, the function of the NITAGs does not overlap or interfere with that of the ICC. In other words, the two committees should work in complementary fashion.

Lack of knowledge about NITAGs often leads to misconceptions on the part of national authorities, with the independence of NITAGs being a key concern. In some instances the MoH has perceived the autonomy of a NITAG as a threat. Ministers and senior MoH officials in one particular eastern European country, for example, were afraid that the NITAG might issue recommendations that would undermine their authority and challenge their prerogatives. These apprehensions have tended to disappear, however, once the national authorities have been given further information about the NITAG's role as an advisory committee, and have been reminded that the minister of health appoints NITAG members, assigns the secretariat, contributes to the agenda and is the ultimate decision-maker. Concern was also eased when the authorities were shown examples of NITAGs from other countries.

The secretariat oversees the NITAG agenda in a comprehensive exercise that involves not only the MoH but also other national immunization stakeholders and NITAG members. This approach ensures that NITAG agendas represent all perspectives [10]. The independence of recommendations is ensured (i) by obliging voting members to declare any conflict of interest and (ii) by using systematic evidence assessment to develop the recommendations.

##### 3.1.2. Technical agencies need to better understand the role of NITAGs in order to facilitate their establishment

It is somewhat surprising that in certain countries and regions it is the staff of international technical partners, rather than the national authorities, who have expressed reluctance about

establishing NITAGs. There have been concerns that decisions about new vaccines could be delayed if it were necessary to consult NITAGs in advance. Questions have also been asked about the availability and ability of national experts to make recommendations when countries have relied heavily on WHO and UNICEF for the last 4 decades. These concerns result from a lack of understanding about the role of a NITAG in the decision-making process. While consulting a NITAG may indeed delay the decision process, it can reasonably be assumed that NITAGs can have strong positive outcomes over the long run.

Many international partners and technical institutions now support the establishment of NITAGs, and recognize their important role at country level. All WHO Regional Committees have recommended that their members create NITAGs. Furthermore, one of GAVI Alliance's criteria for applications for new vaccine introduction is whether a country's NITAG (where applicable) has issued a recommendation on the relevant vaccine.

### 3.1.3. *Conflicting priorities and mistrust impede the establishment of NITAGs*

The establishment of a NITAG may be hindered by competing priorities or mistrust, whether real or perceived. In one east African country, the process of setting up a NITAG (which began with the submission of a letter of intent by senior MoH officers) stalled prior to the restructuring of the country's political system in 2010, which resulted in the creation of two Ministries of Health: a Ministry for Public Health and a Ministry for Medical Services. The creation of the NITAG was subsequently complicated by overlapping portfolios and competition between the leadership of the two ministries. In addition, the NITAG was not considered to be as high a priority as other issues the country was facing.

The government of a certain country in the eastern Mediterranean had previously established an advisory group through a selection process that was perceived as biased by other stakeholders. Despite the prominent role played by private immunization practitioners, the group did not include any representatives from the private medical sector. Attempts to reorganize the committee were hindered by a lack of trust between the experts from the private sector and the MoH rooted in two factors: an absence of cooperation stretching back several decades, and the MoH's perception that the private sector representatives had strong conflicts of interest with vaccine manufacturers.

### 3.1.4. *Scarcity of human resources in secretariats and lack of training hamper optimal NITAG functioning*

The NITAG's executive secretariat coordinates NITAG activities in compliance with their ToR and SOPs. Secretariats are responsible for coordinating the technical background documents for review by the committee prior to issuing recommendations. However, the scarcity of trained human resources in many low and middle-income countries hinders the creation of sufficiently robust secretariats (as is the case for the health sector in general).

Individual countries have adopted different approaches to staffing NITAG secretariats with varying degrees of success. In one middle-income African country, the MoH appointed the national EPI manager to take on the role of NITAG secretary in addition to the manager's routine duties and without providing further (financial or human) resources. By contrast, the NITAG executive secretariat in one European country is based at the national Center for Immunoprophylaxis. As well as its public health, training and research activities, the center is also responsible for all the country's immunization-related work and reports directly to the MoH. The entire staff of the center provides support to the NITAG. A different approach was taken by a country in south-east Asia: the WHO country office initially served as secretariat for the existing

NITAG for several months before responsibility was transferred to the Child Health Division in the MoH.

It is vitally important that secretariats are fully equipped and available (under the supervision of the NITAG chair) to conduct proper assessments of immunization situations, reach consensus, prioritize agendas items, form working groups and develop communication strategies (targeting government and populations as required). A visible and physical NITAG secretariat office is important, together with an email address and other logistical equipment (such as printers and scanners at the very least).

Based on what has worked well in NITAGs in developed countries, an executive secretariat would ideally be housed in a national research institution with a dedicated and experienced immunization professional (preferably a public health physician); he or she would be assisted by at least one full-time junior member with a public health (or related) master's degree. The institution would have perfect communication channels with the EPI program manager and the authority to call on any academic personnel as required.

It is a given that all NITAG secretariats eventually reach limits in terms of their expertise and overall staffing, and that this can hinder adequate preparation for meetings, such as drawing up background technical materials and distributing documents in advance. Several NITAGs have overcome these limitations through the extensive use of technical working groups, which typically include one or two NITAG members, the NITAG executive secretariat, and national experts (external to the NITAG) who assemble scientific content prior to full NITAG meetings. The value of such groups has been illustrated in numerous countries: in Tunisia, for example, a specific working group on pneumococcal conjugate vaccine was established to gather international evidence and, more importantly, to explore the availability of local, unpublished data. After the group's findings were presented, NITAG members requested that further data be collected focusing on the potential economic implications of reduced hospitalizations due to vaccination. The replicability of this model requires access to local experts and strong coordination skills.

A critical need emerged, whilst helping countries to create or improve their NITAGs, for capacity building in setting up committees. During the training on roles and responsibilities in some Asian and African secretariats, SIVAC identified the imperative to strengthen the following areas: preparing background material, coordinating working groups, using recognized methodologies to assess the quality of evidence, and developing structured recommendations. SIVAC and its international partners are now drawing on these early experiences to provide similar training to secretariats in several countries where the NITAGs are considering IPV introduction in Europe and Africa.

### 3.1.5. *Lack of national experts impedes the establishment and functioning of NITAGs*

WHO recommends that NITAG core members should represent at least five different areas of expertise [3], and the availability of local experts is one of the most important factors considered by SIVAC when analyzing a country situation. Established training institutions (recognized universities), hospitals (mostly university hospitals) or research bodies (e.g. Pasteur Institutes) have existed for several years in all the countries where NITAGs have been set up or strengthened. As well as providing a source of expertise, these establishments enhance the credibility of the recommendations issued by a NITAG.

A mapping exercise should be carried out as soon as a NITAG is created to identify national researchers and experts by specialty, field of research, etc. The secretariat should then plan an information strategy on the NITAG's role and mission together with an outline of the type of support it may require. A mechanism

for ensuring efficient cooperation and collaboration should also be introduced. National experts are usually more than willing to offer their support provided that requests are clearly formulated with reasonable timelines.

With their greater NITAG managerial and operational expertise, international and national agencies play a pivotal role, as do technical partners. They help to ensure that NITAG recommendations take into account the realities of a country on the ground, such as government priorities or the requirements of funders. Moreover, their participation in NITAG meetings avoids the perceived split between academics and “implementers”. This combination of skills and roles within a NITAG has been viewed very positively by countries and is to be encouraged.

### 3.1.6. *The absence of a proper management of conflicts of interest threatens the independence of recommendations*

One of the challenges in almost all SIVAC-supported countries has been to convey that NITAG recommendations must be independent of all external influences: not just from vaccine manufacturers but also from the MoH and WHO. One way to achieve this goal is by managing potential conflicts of interest in a transparent manner.

A conflict of interest involves a clash between an official's public duty and private-capacity interests, in which the latter could improperly influence the performance of his or her functions and responsibilities [6]. NITAG members who have a conflict of interest with vaccine producers are either requested to leave the room during discussions in which they have a declared interest or are asked to withhold from voting. An additional concern has been that members might be influenced by external groups even when no conflict of interest currently exists. Where this has been the case, NITAGs have consulted with peers from developed countries on an individual basis. There is, however, no generic way of handling such situations.

As liaison and ex-officio members, WHO and MoH representatives do not normally vote.

Despite initial worries, the systematic use of conflict of interest forms in SIVAC-supported countries has been accepted and has led to improved trust between stakeholders.

### 3.1.7. *Lack of solid institutional integration threatens financial sustainability and resistance to political turmoil*

Although the financial requirements for operating NITAGs on an on-going basis are limited (logistics for meetings, occasional consultancy fees and domestic travel for members), the early years require substantial resources, mainly for building technical capacity. MoH reserves are finite, and plans are not always in place to ensure that committees continue functioning when initial funding comes to an end. In two countries, the recognition of NITAGs as formal advisory committees by the MoH (and other stakeholders) has proved vital for securing domestic funding. Two other NITAGs in Asia and Eastern Europe secured government funding only once SIVAC financial support ceased; NITAG activities were then included in the MoH annual work plan.

However, MoH recognition does not guarantee funding. For example, two African and Asian countries are yet to obtain on-going financing for their activities. As a result, the 2 years of financial and technical support initially planned by SIVAC have been extended to prepare for long-term sustainability, mainly by helping the MoH to include an additional line in the regular budget.

There was also an unfortunate situation in one African country, where the per diem received by NITAG members was too high (in spite of SIVAC's strong opposition to such practices), and the NITAG failed to secure government financing when SIVAC support came to an end. In addition, although resources for NITAG operations were integrated into the Health System Strengthening (HSS)

application submitted to GAVI in 2012, the proposal was rejected. Consequently, the NITAG failed to carry out any activities in 2013.

NITAGs that have been fully integrated into the immunization system are able to continue functioning when external factors, such as political turmoil, intervene. Revolutions or civil wars broke out in several countries during the NITAG implementation phase (Kyrgyzstan (2010), Tunisia (2011) and Côte d'Ivoire (2012)). As a result, the planned NITAGs could not be implemented, and existing NITAGs suffered interruptions to their activities.

However, in countries where NITAGs were properly integrated into the national public health system, they withstood the upheaval. In Côte d'Ivoire, for example, the newly-formed NITAG ceased operating during the political crisis that followed the presidential elections, but was able to resume very rapidly owing to the high motivation of NITAG core members. While not yet optimal in every aspect, the Côte d'Ivoire committee is active and has issued recommendations. An equally positive example was seen in Tunisia during the 2011 turbulence, when the NITAG continued to meet regularly despite the rapid turnover of senior health officials. The legislative laws that created the NITAGs in Tunisia and Côte d'Ivoire facilitated their sustainability in a time of great crisis.

## 3.2. *Opportunities and successes*

### 3.2.1. *New NITAGs have impacted on recent vaccine decisions*

A vivid example of a NITAG influencing a vaccine decision was seen in 2012, when the MoH in a certain African country was preparing to apply for GAVI Alliance funding for rotavirus vaccine (through the Immunization Coordination Committee (ICC)). Following the MoH's decision, the NITAG reviewed the proposal and found that the local epidemiological data used to justify the choice of vaccine was incomplete. The NITAG then requested the analysis of additional data that had been collected over several years by national research institutes. The MoH took heed of the NITAG's advice, delayed the submission of the application and requested that the NITAG examine the supplementary data. Based on a combination of the evidence reviewed as part of the initial application (epidemiological, economic, logistical, etc.) and the additional data, the country decided to introduce a different rotavirus vaccine.

NITAGs include a number of new but important stakeholders in the immunization decision-making process that are not involved in ICCs, such as academics and health care professionals, scientific societies and NGOs, and representatives from civil society. It is not surprising, therefore, that NITAGs can be perceived as a disruptive influence. However, the slight delays that may result from NITAG involvement are counterbalanced by the benefits of more robust, evidence-based decisions that are tailored to local specificities. Furthermore, as all national immunization stakeholders are (ideally) represented on NITAGs, their recommendations are more likely to be accepted – and implemented – by MoH, especially if there is an effective NITAG communication strategy. Finally, the involvement of NITAGs in the decision-making process ensures that recommendations are widely disseminated.

There is no disputing that the intervention of independent committees in high-income countries may result in short delays in vaccine introduction. However, it is hoped that by pooling the efforts of all partners, NITAGs in low and middle-income countries may attain similar levels of trust and credibility. Secretariats should remember that, as the scope of a NITAG is not restricted to new vaccines, their agendas should be wide-ranging and include (for example) routine immunization, vaccine hesitancy and surveillance alerts. In short, NITAG recommendations should focus on immunization systems in their entirety when making recommendations.

### 3.2.2. Experience sharing with other NITAGs provides good learning opportunities

Orientation and training sessions are held shortly after the establishment of a new NITAG to help secretariat members understand their roles and the functioning of the NITAG. SIVAC has offered support to secretariats for attending the meetings of efficient, long-existing NITAGs. For example, the chair and secretary of the Nepal NITAG has visited the Australian NITAG (ATAGI), and two representatives from the Côte d'Ivoire and Lebanon committees paid a visit to the French NITAG (CTV). In both cases, the visiting NITAG members valued the opportunity to discuss their experiences in person with other NITAGs and to observe meetings.

The impact of such experience sharing has been particularly noticeable in Tunisia and Mongolia. Following a visit to the Quebec state committee, the Tunisian NITAG conducted an in-depth reorganization of its processes and technical activities (i.e. preparation of background materials, use of working groups, and development of meeting agendas). Similarly, after two officials from Mongolia attended the New Zealand Immunization Technical Forum (an advisory body to the New Zealand MoH), the Mongolian government issued a decree altering the NITAG membership structure (adding ex-officio and liaison members); started using working groups to prepare materials for NITAG meetings; and initiated a discussion on financial sustainability. Finally, after delegates from an eastern European country attended the European Technical Advisory Group of Experts (ETAGE) in 2012, its NITAG membership was revised, and the chairperson – an MoH official – stepped down, to be replaced by an independent chair from academia.

### 3.2.3. Partnering with local and regional organizations has been a success

Strategic collaborations have been instrumental in promoting the creation of NITAGs, particularly in the Asian and West African regions. ECOWAS ministers issued two recommendations to member states in 2012 and 2013 to set up NITAGs [11], which saw NITAGs being established in Benin, Senegal and Niger, as well as preliminary steps in more than ten West African countries, including Nigeria, Liberia, Gambia, Mali, Guinea, Togo and Burkina Faso [12]. WAHO regional support played a key role in introducing these countries to the process of creating a NITAG [12].

### 3.2.4. Global availability of technical resources facilitates NITAG functioning

A wide-ranging consultation in 2009 among national stakeholders and technical partners at country and global level concluded that relevant information should be made available to all countries wishing to establish or strengthen a NITAG. It was recommended that an extensive, multilingual, online database for NITAG members and secretariats be set up. This online tool, which was launched 2009, includes [5]:

A NITAG observatory for providing technical guidelines on the creation and functioning of NITAGs, and information on more than 50 NITAGs around the world, including examples of their recommendations.

A digital library.

A Center of Expertise, which features vaccinology courses and trainings.

NITAG members from Tunisia and Mozambique reviewed the online tool with partners in an independent evaluation in December 2012. The resources were rated as being highly effective, especially the observatory and online library. However, according to the tracking tools, some of the Center of Expertise modules (the e-learning component in particular) could be improved by adding

more documentation on NITAGs and vaccines. As a consequence, the e-learning component will be revised and a new tool launched in 2014.

### 3.2.5. A step-by-step, country-driven approach to establishing and/or strengthening NITAGs is indispensable

While the aim is to implement best practice guidelines for all SIVAC countries, the approach to establishing or strengthening a NITAG is unique to each setting. Local contexts and specificities make it impossible to employ the same processes everywhere and at every step, such as:

Obtaining initial ministry support.

Analyzing the country's immunization context and adapting guidelines to the specific situation.

Supporting the development of a NITAG concept paper and the drafting of a ministerial decree.

Conducting training for committee members on their roles and responsibilities.

Providing technical training to the secretariat.

In some countries the existence of other immunization committees, a strong private sector or two MoH have made it impossible to employ the same mechanisms. For the approach to be country-driven, it is crucial to have the support of the MoH: where a ministry has been convinced of the added value of a NITAG, it has been established successfully. In short, by using a step-by-step, country-driven approach, most obstacles can be overcome.

### 3.2.6. Developed countries reported a positive impact from SIVAC activities

A number of developed countries have reported changing some NITAG features based on SIVAC's experience of establishing NITAGs, with Israel offering the following concrete example.

The Israeli Advisory Committee on Infectious Diseases and Immunizations (established 40 years ago) has 15 core members, nine ex-officio members and six observers, all appointed by the Director of Public Health Services in the MoH. The committee was reformed after examining the April 2010 *Vaccine* supplement [3] describing the structure and functions of a NITAG. The 2012 reform was approved by the MoH and impacted the committee in the following areas:

Term of office: previously unlimited, this is now restricted to 5 years (possible to add further terms).

Membership categories: now includes three groups – core members, ex-officio members and observers.

Voting rights: the *Vaccine* articles generated debate about the voting rights of ex-officio members, who ultimately retained their right to vote.

Terms of reference: a more detailed document is now in place.

Conflict of interest policy: a policy was adopted and new forms developed.

Types of expertise: an economist and legal adviser were appointed as observers.

The functioning of the committee has improved with the reform, and a self-assessment of its effectiveness (based on WHO indicators) is planned for 2014 [4].

#### 4. Implications and recommendations for creating and strengthening future NITAGs

##### 4.1. Reinforce institutional integration to promote sustainability and credibility

NITAGs that are fully integrated into a country's health system benefit from sustainability and credibility, with two decisive factors being: the careful positioning of the NITAG in the decision-making process; and a legal (ministerial or legislative) establishment document. Institutional integration can also be facilitated by addressing misconceptions and misunderstandings about the role and responsibility of NITAGs. This requires open communication from all partners at country-level in order to avoid sending confusing messages to health authorities.

Institutional integration may also involve coordination with other disease-specific advisory committees. NITAGs are expected to provide technical advice on all immunization-related aspects (including new vaccines and routine immunization) and to recommend ways to improve the overall operation of the immunization system. Accordingly, their interactions with existing vaccine-specific committees and routine immunization programs require clarification. Many GAVI-eligible and middle-income countries with well-functioning, disease-specific committees (such as polio, measles or hepatitis committees) increasingly support the establishment or strengthening of NITAGs.

Future efforts should include activities aimed at integrating disease-specific advisory committees into NITAGs; reinforcing institutional positioning; and increasing compliance with WHO-recognized practices in terms of technical methodologies for collecting and assessing evidence for generating recommendations.

As we have seen, institutional integration allows NITAGs to withstand political turmoil, facilitates financial security and enhances credibility. It bears repeating that, in all SIVAC-supported countries that have experienced political upheaval, NITAG activities resumed thanks to the legal standing of the committee and the NITAG's solid integration into a pre-existing institution. Furthermore, it is easier for NITAGs with institutional integration (and which, therefore, benefit from broad acceptance) to secure funding and ensure sustainability after external support has ended. Adequate funding is, of course, of paramount importance: NITAGs must develop plans that focus on the most sustainable sources of finance (although government backing remains the ideal source).

##### 4.2. Build technical capacity within NITAG secretariats and evaluate performance

A study of the 2012 WHO–UNICEF JRFs found that NITAGs need to comply with international standards. Out of 63 countries that reported having a NITAG, only 33% met the six process indicators of an efficient NITAG [6], whereas the GVAP objective for 2020 is that all countries should have fully-functional NITAGs. These results reveal the need to strengthen both new and existing NITAGs. Future efforts should focus on building the technical capacities of NITAG executive secretariats so that they have adequate resources to carry out their responsibilities; this is the key to optimal functioning for all NITAGs and especially for those that have recently been created.

The need to provide organizational support and capacity building for NITAG secretariats and members (including clear ToR and SOPs) is widely accepted. Additionally, technical partners may play a fundamental role in ensuring that nascent NITAG secretariats collate appropriate evidence and follow standard procedures. Technical support requires the development of normative documents by WHO and relevant partners (e.g. guidelines for issuing evidence-based recommendations, including methodologies for the critical assessment of evidence and compiling recommendation briefs).

It also calls for in-person training on important topics such as mapping immunization stakeholders, the functioning of working groups, the use of accepted methodologies to assess scientific evidence, and methodologies for writing policy briefs.

A significant milestone for established and newly-created NITAGs alike is the assessment of their outputs and outcomes. This assessment can be performed by the MoH itself or an external consultant using the 17 output and outcome indicators defined by WHO [4]. SIVAC and partners used these criteria to develop a full evaluation protocol, including guidance for the desk review of NITAG documents, and an analysis plan. The protocol, which was piloted recently in Mongolia, Côte d'Ivoire, Nepal and Indonesia, is currently being revised and finalized; it will be made publicly available on the NITAG Resource Center. For existing NITAGs, the assessment should be conducted prior to developing the work plan in order to identify weaknesses regarding functionality and performance indicators, and to allow for a plan to be drawn up in accordance with the requirements that are identified. Findings from these evaluations will be presented in a future joint publication on NITAG production, impact and performance.

##### 4.3. Increase networking and regional collaboration

Executive secretariats should develop ties with other NITAGs to ensure their continued development. For example, as described above, interaction with strong NITAGs can have a rapid impact on nascent NITAG functioning and performance.

Networks can be established based on WHO regions or other similarities, such as language. For instance, in the Eastern Mediterranean Region, the Tunisian NITAG could help form a regional network with Sudan, Morocco, Iran and Egypt in collaboration with the WHO Regional Office. In sub-Saharan Africa, one network could bring together French-speaking NITAGs, and another their English-speaking equivalents, with a third for Portuguese-speaking Angola, Mozambique, Cape Verde and Guinea Bissau. Other potential regional networks could include Vietnam, Lao DPR, Cambodia and the Philippines in the Western Pacific region, as well as the countries of eastern European.

## 5. Conclusions

A number of immunization initiatives, including SIVAC, have contributed to the increased use of evidence-informed decision-making on immunization at country level over recent years. Low and middle-income nations have relied heavily on external authorities for policy advice, yet vaccine recommendations need to be adapted to local contexts. Despite interest in evidence-informed decision-making in many countries, technical assistance is still required to promote a sustainable and independent body that can advise governments on the local application of global vaccine recommendations. International and national technical agencies should also play a more active role in NITAGs as liaison members. This combination of skills and roles has proved highly successful and helped NITAGs to avoid issuing recommendations that are "unrealistic" or "too theoretical".

Based on the lessons learned over the last 5 years, advocacy will be required from all immunization partners to help raise awareness about the importance of evidence-based policies using NITAGs. By adopting the GVAP, all countries are committed to setting up NITAGs, meaning that many states will need to establish or strengthen their NITAGs. The process of setting up a NITAG should be more straightforward in these countries, given the methodology and resources now accessible to all regions in need.

Efforts should concentrate on expanding new NITAGs and strengthening existing ones in individual countries as well as developing a regional approach (where relevant); devising and disseminating tools and guidelines; and sharing information through a variety of channels. Significant time, effort and money need to be invested in strengthening NITAG secretariats, particularly as some NITAGs may not have the experience and institutional stability to continue in the absence of additional technical support.

While solutions to some of these problems already exist, countries still need to take an active role in establishing and maintaining NITAGs. Although WHO will continue to function as the lead technical organization, its leadership should not impede NITAG independence provided that the following conditions are met: the ToR, positioning and funding are clear; there is a solid and well-equipped secretariat; the processes are rigorous; and members have strong technical capacities.

As part of the WHO Collaborating Center for evidence-informed policy-making in immunization, SIVAC will continue to work in collaboration with WHO to support NITAG development and strengthening. GAVI Alliance, for its part, could require a plan for NITAG development for HSS funding and support its implementation. Countries should also investigate innovative mechanisms to sustain funding for NITAGs. Without an accelerated and joint effort, the GVAP objective of “all countries having a functional NITAG by 2020” will not be achieved.

#### Conflict of interest statement

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