SAGE APRIL 2017
NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUPS
Background Paper

Contents

1. Acronyms

AMP-HPID	Agence de Médecine Préventive-Health Policy and Institutional Development Unit, WHO collaborating center for evidence informed immunization policy-making
AFRO	WHO African Regional Office
AMRO	WHO American Regional Office
CDC	US Centers for Disease Control and Prevention
ECDC	European Center for Disease Prevention and Control
EMRO	WHO Eastern Mediterranean Regional Office
EPI	Expanded Programme on Immunization
EURO	the WHO European Regional Office
GNN	Global NITAG Network
HSIS	Health Systems and Immunization Strengthening
HSS	Health Systems Strengthening
HTA	Health Technology Assessment
ICC	Inter-agency Coordinating Committees
IVI	International Vaccine Institute
JA	Joint Appraisal
MIC	Middle Income Country
NITAG	National Immunization Technical Advisory Group
PAHO	Pan American Health Organization
PIVI	Partnership for Influenza Vaccine Introduction
ProVac	Promoting [of] evidence-based decisions about Vaccine introductions Initiative
RAVIN	Rotavirus Accelerated Vaccine Introduction Network
RITAG	Regional Immunization Technical Advisory Group
SAGE	Strategic Advisory Group of Experts (on immunization)
SEARO	WHO South-East Asian Regional Office
SIVAC	Supporting Independent Immunization and Vaccine Advisory Committees Initiative
TCA	Tailored Country Assistance
USAID	the United States Agency for International Development
WPRO	WHO Western Pacific Regional Office

2. Introduction

For more than 10 years, WHO has been recommending its Member States to establish National Immunization Technical Advisory Groups (NITAG) or equivalent independent groups as a way to improve quality and ownership of national immunization programmes.

This recommendation initially endorsed by the Strategic Advisory Group of Experts (SAGE) on Immunization at the global level was then translated at regional levels though Regional Committee resolutions and Regional Technical Advisory Group recommendations. The Global Vaccine Action Plan (GVAP) objective of "all countries having a functional NITAG by 2020" was then endorsed by all Member States in 2012 at the 65th World Health Assembly. Regional committees followed by endorsing regional vaccine action plans most of which also contained specific targets for establishing NITAGs[1]. Experience during the last decade has shown that establishing and strengthening NITAGs is critical for improving leadership in making informed decisions about the introduction and financial sustainability of vaccines.

In October 2016, as part of its mid-term review of the GVAP implementation, SAGE took note of the good progress made towards the achievement of this objective as of end 2015 with steady progress in the period 2010-2015 but that the GVAP 2020 objective for NITAGs will not be achieved without additional efforts from countries and partners. The mid-term report was SAGE's first recommendation to Member States asking them to demonstrate stronger leadership and governance of national immunization systems and urging countries to establish NITAGs.

The NITAG session will update SAGE on progress achieved in the establishment and strengthening of NITAGs, the successes and challenges countries are facing, and the efforts and plans from the partners to achieve the GVAP 2020 goals. SAGE is being requested to provide guidance to countries and partners to ensure that the GVAP ambitious, yet realistic, goal of having all countries with a functional NITAG is achieved by 2020.

This document builds on partners input and attempts to provide an overview of the status of NITAG strengthening and to present challenges faced by countries and opportunities. It also presents the support provided by partners, the challenges they face and future plans and presents the way forward.

3. Background

NITAG definition

Decisions on what vaccines are included in national vaccination schedules, how to optimize the public health impact of those vaccines, and adjust existing schedules should be unbiased, comprehensive and systematic, and based on evidence-based criteria. Formally constituted national technical advisory bodies, often referred to as NITAGs, are multidisciplinary groups of national experts responsible for providing independent, evidence-informed advice to health authorities on all

[1] Regional targets are 90% of countries with a functioning NITAG by 2020 [European Region], all countries by 2017 [African Region], all countries by 2020 [Americas Region]; other regions (e.g., South-east Asia Region) which already have NITAGs in all Member States, set targets toward strengthening of existing NITAGs.

policy-related issues for all vaccines across all populations. Although each country will adjust its NITAGs roles and responsibilities based on its own needs and resources, the main 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, that take into account the local epidemiologic and social contexts. Other possible roles of NITAGs are to advise on implementation of national immunization programmes and to monitor programme impact.

Minimum criteria of functionality

As a proxy, a functional NITAG has been defined as one that meets all of the six following process indicators agreed upon in 2010 by WHO and its partners involved with the strengthening of NITAGs:

1. legislative or administrative basis for the advisory group;
2. formal written terms of reference;
3. at least five different areas of expertise represented among core members;
4. at least one meeting per year;
5. circulation of the agenda and background documents at least one week prior to meetings;
6. mandatory disclosure of any conflict of interest

These six indicators do not guarantee the functionality of the NITAG but have been agreed upon as a minimum set of indicators that will allow for monitoring of progress at the global level. As NITAGs mature at the global level, these basic process indicators will need to be adjusted over time.

Effectiveness of NITAGs

Although meeting basic criteria of functionality is necessary, NITAG performance is a combination and balance of the following elements of NITAG capacity: 1) to hold meetings regularly and issue recommendations in a timely manner; 2) to use the best available evidence and produce relevant recommendations in a given national context; and 3) to influence immunization policy decisions. For this reason, a more comprehensive set of indicators for assessing NITAG functionality, performance, outcomes and outputs was developed in 2013 by WHO, the Agence de Médicine Préventive Health Policy and Institutional Development Centre (AMP-HPID) which is a WHO Collaborating Centre, and other partners. Since this time, updated versions of this more comprehensive set of indicators (in the form of an evaluation tool) has been developed and used for country self-assessment and by partners to provide more insight into the functioning and effectiveness of NITAGs. The most recent version of the NITAG Assessment Tool is available on the NITAG Resource Center[2] (http://www.nitag-resource.org/), a global platform containing NITAG related information and supported by AMP-HPID.

At the 11–12 May 2016 international NITAG meeting, there was a strong call by countries to proceed with the establishment of a global NITAG network (GNN), which may accelerate progress on strengthening NITAGs and in evaluation of their NITAGs using the evaluation tool developed by the WHO Collaborating Centre AMP-HPID.

[2]NITAG resource center, Evaluation Tool: http://www.nitag-resource.org/media-center/document/1517-evaluation-tool-for-national-immunization-technical-advisory-groups-nitags?page=1&disease=0&document_type=0&topic=0&country=0&keyword=0&author=0&source=0&document_language=0&search=evaluation+tool

4. Update on the current situation regarding establishment of NITAGs

Data source

The process indicators outlined above, related to the establishment of NITAGs, have been included annually in the WHO-UNICEF Joint Reporting Form since 2011 (data for 2010). In this summary of information from Member States regarding the existence of a NITAG, the specific criteria are derived from the 2016 JRF with data collection for 2015 and compared with JRF data collected for previous years. For those Member States that did not submit or fully complete the JRF, information from the previous year's JRF was used. In the 2017 JRF (data for 2016), two additional questions were added to the data collection, specifically on whether the country conducted a NITAG assessment and what tool was used to conduct the assessment; these data will be available for future analyses.
The denominator used to calculate the proportion of NITAGs in existence is the number of Member States that completed the NITAG-related section of the JRF. The results are presented by WHO region, World Bank national income status categories and population size. Population figures are those from the United Nations Population Division[3].

As highlighted in the previous GVAP Secretariat Annual Report 2016 [4] these results are subject to data limitations including some lack of data completion, the absence of a systematic data validation process with national counterparts and some confusion with the country Inter-agency Coordinating Committee (ICC). This confusion was actually documented, and has diminished over time. An increasing number of countries have corrected the information provided during previous years and corrections were retrospectively applied to the reported data for the previous years concerned. In order to assess the evolution of NITAG implementation and functionality since 2010, a thorough data cleaning was conducted based on consistency of responses on the overall time trend with final approval at country level.

When Member States report the existence of a NITAG with formal terms of reference or the existence of a NITAG with a formal administrative or legislative basis, data should be less susceptible to reporting bias than the mere reporting of the existence of a NITAG, and therefore the number of such groups should be closest to the actual number with respect to the existence of a NITAG. The number of Member States reporting the existence of a NITAG which complies with all six indicators is also less susceptible to reporting bias/error.

The description of the current NITAG situation is based on the GVAP Annual Secretariat Report 2016[4] and updated from the member states reported data (through the WHO UNICEF JRF) as of 18 November 2016.

[3] World population prospects: The 2012 revision [CD-ROM]. New York: United Nations, Department of Economic and Social Affairs, Population Division; 2013.
[4] Global Vaccine Action Plan Secretariat Annual Report 2016
http://www.who.int/immunization/global_vaccine_action_plan/gvap_secretariat_report_2016.pdf?ua=1

Results

HIGHLIGHTS (as of 18 November 2016)

- A total of 79 Member States (including 50 developing countries and five low-income countries) reported access to a National Immunization Technical Advisory Group (NITAG) that met all six process indicators by end 2015, representing a 88% increase over the 42 countries reported on in 2010.
- A total of 116 (60%) Member States (accounting for 88% of the global population) reported the existence of a NITAG with an administrative or legislative basis;
- There has been minimal change in the number of countries meeting the six process indicators since 2014 (9 new countries met the six functionality criteria, while 10 countries dropped from the list – mostly due to not holding a meeting in 2015).
- Although there has been some progress in allowing small Member States to benefit from subregional or other Member States' advisory groups (e.g., subregional NITAGs are now active in small Caribbean countries), a formalized approach is still lacking.

As of 18 November 2016, 190 (98%) Member States had completed the 2016 JRF[5] reporting immunization-related data for 2015, and 187 (96%)[6] provided a response to at least one of the NITAG-related questions. Among the Member States that did not submit their JRF or their NITAG-related data for 2015, all of them had reported NITAG data in the past two years (i.e. data for 2013 and 2014). Therefore, data for 2013[7] and 2014 were included in the 2015 data set for these Member States. Monaco reported using the French NITAG and therefore data from France were included in the data set for Monaco. It is not clear from the JRF if other small states in other regions rely on a neighbouring country's NITAG like Monaco and France. As a result, data for 194 Member States were available for the analysis as presented in Figure 1 and Table 1. Table 1 also presents the 2015 NITAG-related indicators status at the global and regional levels. The comparison between 2010 and 2015 is only provided at global level as progress encountered in some regions prior to 2010 could lead to spurious interpretation of the trends when broken down by region.

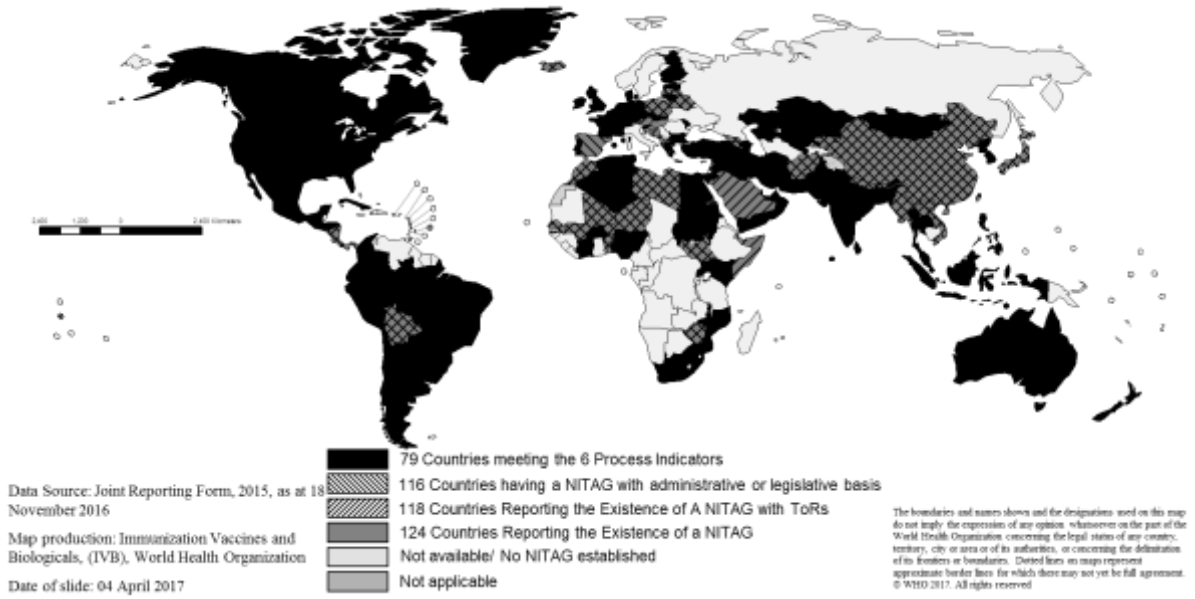
Figure 2 presents the 2010–2015 trajectory in the establishment of NITAGs. The trajectory through 2020 highlights the need for acceleration of progress to reach the GVAP NITAG target.

[5] As at 18 November 2016, Member States that have yet to submit 2016 JRF data for 2015 include Albania, Libya, Monaco, and Poland. Albania has recently submitted JRF data but too late to be included in the current analysis.

[6] Member States that have not completed the NITAG portion of JRF include Luxembourg, Sudan, and Tuvalu.

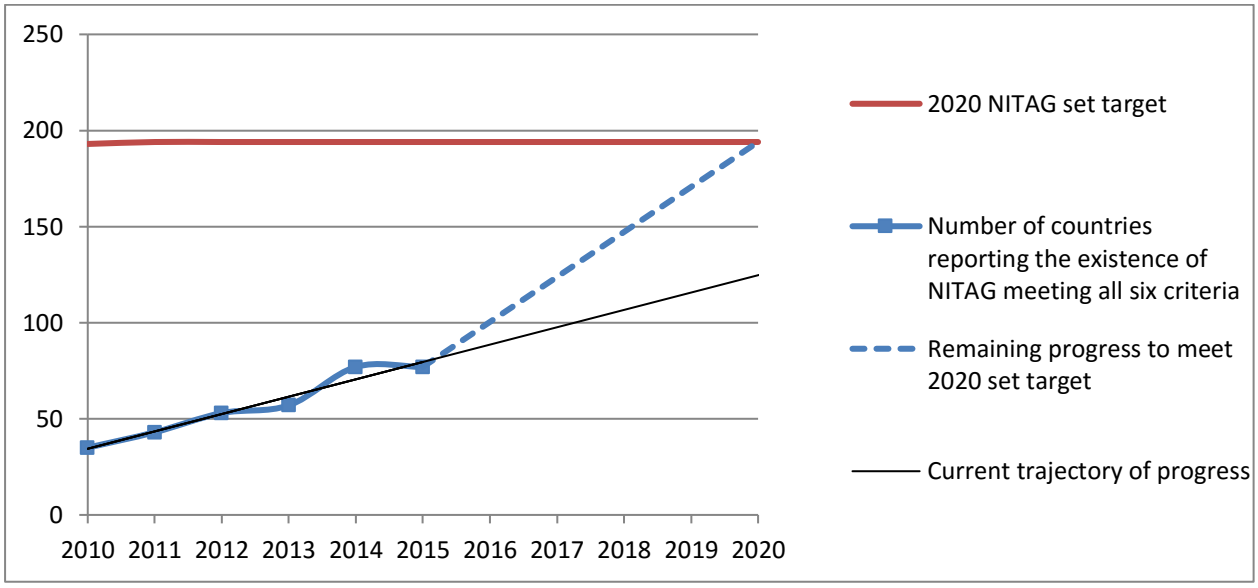
[7] Luxembourg.

Figure 1: National Immunization Technical Advisory Groups in 2015



Source: WHO-UNICEF Joint Report Form, as of 18 November 2016

Figure 2: Time trend 2010–2015 in the establishment of NITAGs meeting all six process indicators, and remaining progress needed to reach 2020 target



Source: WHO/IVB Database, as of 18 November 2016

Table 1: NITAG characteristics at global level at by WHO region, 2015

Countries reporting/ WHO Member States	Indicator	OVERALL	AFR	AMR	EMR	EUR	SEAR	WPR
Existence of a NITAG	Number of countries	124	16	21	21	42	11	13
	% of countries	64%	34%	60%	100%	79%	100%	48%
	% of the entire population covered	89%	55%	94%	100%	66%	100%	99%
Existence of a NITAG with formal terms of reference	Number of countries	118	16	20	20	39	11	12
	% of countries	61%	34%	57%	95%	74%	100%	44%
	% of the entire population covered	88%	55%	94%	99%	60%	100%	99%
Existence of a NITAG with a legislative or administrative basis	Number of countries	116	16	19	19	39	11	12
	% of countries	60%	34%	54%	90%	74%	100%	44%
	% of the entire population covered	88%	55%	94%	93%	64%	100%	99%
Existence of a NITAG with >= five areas of expertise represented	Number of countries	115	16	19	19	41	10	10
	% of countries	59%	34%	54%	90%	77%	91%	37%
	% of the entire population covered	86%	55%	94%	93%	66%	100%	91%
Existence of a NITAG which met at least once a year	Number of countries	109	9	21	18	39	9	13
	% of countries	56%	19%	60%	86%	74%	82%	48%
	% of the entire population covered	84%	45%	94%	89%	57%	97%	99%
Existence of a NITAG for which the agenda and background documents distributed >= one week prior to meetings	Number of countries	110	11	19	18	40	11	11
	% of countries	57%	23%	54%	86%	75%	100%	41%
	% of the entire population covered	85%	48%	93%	94%	65%	100%	92%
Existence of a NITAG whose members required to disclose conflict of interest	Number of countries	93	13	15	17	30	9	9
	% of countries	48%	28%	43%	81%	57%	82%	33%
	% of the entire population covered	65%	50%	91%	96%	57%	96%	19%
Existence of a NITAG meeting all six criteria above	Number of countries	79	9	15	13	27	8	7
	% of countries	41%	19%	43%	62%	51%	73%	26%
	% of the entire population covered	60%	45%	91%	80%	51%	96%	12%

Source: WHO-UNICEF Joint Report Form, as of 18 November 2016

Interpretation

Notable progress was achieved between 2010 and 2015. In 2015, 116 (60%) Member States overall reported the existence of a NITAG with a formal legislative or administrative basis. In 2015, there were 79 Member States[8] with a NITAG that met all six process indicators, including a total of 50 developing Member States. This is a 113% increase compared to 2010, when only 37 countries reported having a NITAG meeting all six process indicators. The global trend shows minimal progress, however, in the number of countries meeting the six process indicators between 2014 and 2015. In 2015, 9 new countries[9] met the six process indicators, while 10 countries dropped from the list[10]. The main cause of this drop is the fact that the NITAG did not meet in 2015 for nine of these countries.

In 2015, 16% of low-income countries, 38% of middle-income countries, and 59% of high-income countries reported having a NITAG meeting all six process indicators. Overall, 60% of the global population live in a country with a NITAG that meets all six process indicators.

Table 2: NITAG status per income-level from 2010 to 2015

Year	**2010**			**2015**			**% increase 2010-2015 all countries**
Income-level	**LIC**	**MIC**	**HIC**	**LIC**	**MIC**	**HIC**	
% of countries included in the analysis per income-level (N)	100 (30)	96 (101)	95 (53)	100 (31)	100 (105)	100 (56)	
Existence of a NITAG with a legislative or administrative basis % of countries (N)	07 (2)	41 (43)	59 (33)	45 (14)	60 (63)	70 (39)	49%
Existence of a NITAG meeting all six criteria % of countries (N)	03 (1)	19 (20)	38 (21)	16 (5)	39 (41)	59 (33)	88%

Source : WHO-UNICEF Joint Report Form, as of 18 November 2016 and World Bank Income classification as of March 2017 (classification not available for Niue and Cook Islands).

In 2010, there were 30 low income countries as South Sudan became a WHO Member State in 2011.

[8] Algeria, Andorra, Argentina, Australia, Azerbaijan, Bahrain, Bangladesh, Belgium, Brazil, Bulgaria, Burkina Faso, Canada, Chile, Colombia, Côte d'Ivoire, Cuba, Czech Republic, Democratic People's Republic of Korea, Denmark, Ecuador, Egypt, El Salvador, Estonia, Finland, France, Germany, Greece, Guatemala, Honduras, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Israel, Jordan, Kazakhstan, Kenya, Lithuania, Luxembourg, Malawi, Malaysia, Maldives, Malta, Mexico, Monaco, Mongolia, Mozambique, Netherlands, New Zealand, Nigeria, Oman, Pakistan, Paraguay, Peru, Philippines, Portugal, Qatar, Republic of Korea, Republic of Moldova, Singapore, Slovakia, Slovenia, South Africa, Sri Lanka, Sudan, Switzerland, Syrian Arab Republic, Thailand, Timor-Leste, Tunisia, Turkey, Uganda, United Arab Emirates, United Kingdom, United States of America, Uruguay, Uzbekistan, Yemen.

[9] These nine countries are Bulgaria, Burkina Faso, Egypt, Malawi, Mozambique, Nigeria, Timor-Leste, Uganda and United Arab Emirates. Data from Greece was not included in the last report but did report (late) that it met the six process indicators.

[10] The 10 countries that dropped from the list are Afghanistan, Armenia, Benin, Bhutan, Bolivia, Djibouti, Kyrgyzstan, Morocco, Nepal and Senegal.

The South-East Asia Region (where all countries have now established a NITAG) had the highest proportion of Member States reporting the existence of a NITAG that met all six process indicators (73%) and the African Region the lowest (45%). Nevertheless, remarkable progress was made in the African Region between 2014 and 2015, multiplying by more than two the total population living in a country having a NITAG meeting the six process indicators (from 20% to 45%). The South-East Asia Region also had the greatest percentage (100%) of Member States that had a NITAG based on a formal legislative decree. Percentages in the other regions were 34% (African Region), 74% (European Region), 90% (Eastern Mediterranean Region), 44% (Western Pacific Region) and 54% (Region of the Americas) – these two latter regions being affected by a substantial number of small Member States. Mandatory declaration of conflict of interest (COI) of NITAG members was the main limiting factor for Member States to meet the criteria for having a fully functional NITAG (i.e., met all six process indicators); in 2015, of the 45 countries which had a NITAG but did not meet the six indicators, 31 of these countries lacked a mandatory COI declaration. The lack of COI declaration can be a problem of both history and culture.

By end 2015, of the 70 countries globally that did not report the existence of a NITAG, 31 were located in the African Region and 23 were small countries (less than 1 million total population) located in the Western Pacific Region and the Region of the Americas. Globally, there are 40 small countries with populations of less than 1 million and 28 (70%) have no NITAG; the proportion of small countries with no NITAG varies by region: AFR (5/5, 100%), AMR (10/11, 91%), EMR (0/1, 0%), EUR (1/7, 14%), SEAR (0/2, 0%), WPR (12/14, 86%). Given limited technical capacity and resources in some of the small countries, it may not be necessary or possible to establish NITAGs in all of these countries (e.g., small island countries) and it makes more sense for countries to form and rely on subregional networks/NITAGs to fit their needs or develop relationships with a neighbouring NITAG as Monaco has done with France. Additionally, the finding that almost 40% of high-income countries do not meet criteria for having a functional NITAG does not necessarily mean that they are lacking an acceptable system for evidence-based vaccine decision making, given the country context (e.g., Norway with an advisory body embedded in their public health infrastructure). However, in these countries assessment of how well their process meets NITAG evaluation criteria has not occurred yet.

5. Issues and challenges faced by countries establishing or strengthening a NITAG

NITAGs are effective only if they are country-owned and given recognition as an expert advisory body. It is important for NITAGs to have the ability to access local resources to help prepare for sessions and reviews (e.g., access local surveillance data and outbreak investigations). However, the NITAG and work groups also need to weigh options based on resources and need, for example. Rather, existing systematic reviews or data from neighbouring countries can sometimes be used for evidence-based decision making (if possible to access that data); in addition, the global WHO contribution through the work of SAGE and other advisory groups can also be an important resource. However, there are still big gaps in vaccine preventable disease data in some regions that need to be filled to ensure local NITAGs have quality local evidence upon which to base decisions (1). There is no need for NITAGs to repeat good quality recently conducted vaccine safety and effectiveness systematic reviews.

Issues and challenges faced by countries presented in Table 3 come from regional reports and two literature searches on NITAG conducted on Pubmed and Sciencedirect databases. Twenty-one articles were considered for the purpose of this section (2-22).

Of note, most challenges faced by multiple NITAGs globally; those more specific to particular regions are cited as so.

Enabling factors and opportunities for NITAG establishment and strengthening include:

1. building on existing polio advisory committees;
2. collaborating with relevant vaccine initiatives: Rotavirus Accelerated Vaccine Introduction Network (RAVIN), Partnership for Influenza Vaccine Introduction (PIVI);
3. increasing partnerships with local and regional organizations (WAHO);
4. diversifying sources of funding for NITAG support;
5. supporting the secretariat functionality of the global and regional NITAG networks as platforms for sharing resources, best practices, experiences for providing peer-to-peer technical assistance;
6. continuing and further facilitating the sharing of expertise through the visit of members of newly established NITAG to experienced ones;
7. assessing the feasibility and functionality for small states and territories of different models such as subregional networks or partnerships with neighbouring NITAG to address the availability of expertise issue (2-4). As an example, the successful establishment of the sub-regional network of the Caribbean helped bringing a more formalized approach to reviewing and considering evidence for immunization decision-making. This built on a local history and culture of collaborative work. Monaco works with France's NITAG. One needs to ensure these models actually result in local small countries using the subregional or other country's NITAG advice.

Table 3: Challenges to NITAG establishment and functioning

Challenge	Comment
Challenge to NITAG establishment	
Lack of political commitment to establish a NITAG	Countries need to take an active role in establishing and maintaining NITAGs and to investigate innovative mechanisms to sustain funding for NITAGs.
Low awareness on NITAG role by national authorities	Confusion with other existing bodies (ICC, Expanded Programme on Immunization (EPI), Polio committees, health technology assessment (HTA) agencies), mostly in WPR and AFR, where vertical committees are numerous. Fear of delegating power to an independent group of experts which would undermine national authority, challenge prerogatives, and conflict with priorities.
Lack of financial resources	Insufficient and non-sustainable funding and resources in LMIC. In EUR, the sustainability of recently-established MIC NITAGs and of Gavi graduating countries' NITAGs is questioned due to the limited funds available for support at the regional office. In AMR, regional and income-level disparities in countries' access to donor subsidies and pooled procurement mechanisms.
Insufficient support to national authorities	Need to sustain focal points in all WHO regions. Particularly critical in regions with a high proportion of MIC considering the very limited financial support available for NITAG activities in these countries. In EMR, Regional Office supported NITAG activities and follow ups could not be carried out to the extent required, while previously EMRO was very active in this area when a WHO NITAG focal point was in place at the Regional Office. In EUR, concerns that without continuing WHO and partners' support, NITAGs established 1-3 years ago may stop functioning; recently-established NITAG have not yet acquired the visibility and credibility for sustained funding.

Lack of availability of qualified human resources	Time is the major constraint for qualified human resources to serve in the committees Scarcity of trained staff (local practitioners and researchers) to serve in the NITAG and NITAG Secretariat of small-population Island Nation-States and Territories is a challenge because immunization programs in these settings often cannot draw sufficient expertise from to build a committee. In AMR, limited technical capacity in remaining countries to generate and use evidence in future priority-setting and decision making processes. NITAGs strength resides in their multidisciplinary composition. But at the same time it is necessary that all members understand immunisation issues. Participation in vaccinology trainings remains slow
Political turmoil	Difficulty in NITAG establishment and function due to civil unrest, humanitarian crises that are not short term – guidance from WHO is coming but not yet available
Challenge to NITAG functioning	
Lack of NITAG operating procedures	Most AFR NITAGs, some WPR NITAG and some SEAR NITAG lack standards operating procedures to function. Documentation of NITAG work also limited.
Lack of the systematic declaration of conflicts of interest	Challenge in understanding the concept of conflict of interest has been reported globally. The absence of systematic declaration of interests by core members is problematic in many countries due to historical and cultural influences. The transparent process under which declarations should be revealed, the management of conflicts and the availability of related tools is detailed in a guidance document recently published by AMP.
Lack of importance given to defining annual work plans and agendas	Partners' support to countries where NITAG work plans and agendas have not been defined is all the more challenging.
Lack of health authorities' understanding of NITAG institutional independence	The philosophy of using an evidence-based process for making recommendations and of valuing the independence of national experts are foreign concepts in many cultures and can be further nourished by authorities' fear of members' lack of independence from other interest groups. National authorities have showed difficulty in understanding how compatible the concepts of NITAG independence from the government and of NITAG integration in the decision-system are.

Lack of access to necessary data	Lack of systems in place to generate country-specific data on epidemiology, disease burden, cost-effectiveness. (eg. Gap in information on pneumococcal serotype distribution in Africa). In SEAR and WPR, lack of local data is further challenged by difficulty in accessing neighbouring, regional and global data. In addition to access to data, time and resources needed for critical review of the evidence are not always available.
Language issues	Access to Russian publications either originally published in Russian or translated after initial publication in another language is rare which constitutes a major barrier to NITAG functioning in Eastern EUR countries. For example, most systematic reviews collected in the SYSVAC database (a database of systematic reviews on vaccines and immunization at http://immunisation.hpru.nihr.ac.uk/sysvac) are in English. Prioritization of publications/data to be translated need to be determined based on countries' feedbacks.
Lack of public information about NITAGs and their work processes	Lack of report of a codified and systematic process used by NITAG for collecting and evaluating data. When reported, these processes are not always as detailed, structured and transparent as for other medicines. It is difficult to find full documentation of the topics addressed by NITAGs, including the evidence used and whether (and how) it was assessed. Several NITAGs remained only focused on the introduction of new vaccines and efforts should be made to expand their scope to reviewing the use and impact and optimizing strategies for already introduced/long standing vaccines; optimizing the use of existing vaccines and strengthening national immunization programmes.
Lack of communication between NITAG members and national decision-makers	Communication channels are not clearly defined for the MoH consideration of NITAG recommendations. Countries have called for best practice guidelines on communication and NITAG integration in the national decision-making system.

Lack of ability to influence and change policy and practice	Lack of ability to influence and change policy and practice was reported as a challenge globally, particularly in LMIC (13). Linked to the country's policy environment and legislation, other influencing factors include: 1) Lack of quantity of connections between NITAG members and decision-makers, which appears to some to contradict the concept of NITAG autonomy/ independence from the government. Further advocacy is required in this regard. However, NITAG may have partners such as WHO country and regional offices, GAVI with good connections with MoH, which can facilitate the consideration of NITAG recommendations and policy change. 2) Lack of quality of connections: NITAG need to invest time and efforts in the long-run to build these connections. Staff turnover in the political arena may represent another obstacle. 3) Lack of capacity (expertise and when present, its availability) to conduct NITAG work 4) Lack of reputation which is also built in the long run. Opportunities to build on SAGE reputation have not been explored enough. The US-CDC is in the process of evaluating NITAG integration and decision-making in different WHO regions.

6. Partners roles and investments in supporting countries to establish and strengthen NITAGs

The major technical partners in NITAG strengthening are WHO and AMP-HPID which hosted the Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative. Efforts began in 2006, when SAGE recommended that WHO provide technical advice to governments on evidence-based decision-making, priority setting, and the introduction of new vaccines. WHO assumed the work of supporting countries through regional officers in each WHO region, often in conjunction with work on new and underutilized vaccine introduction, coordinated by a focal point at headquarters. In 2008, the SIVAC Initiative was launched to support the creation and strengthening of NITAGs in low and middle income countries. From 2009-2013, SIVAC was a partnership between AMP, focusing on the AFR and SEAR, and IVI on the WPR and EUR. In 2012 based on the work of SIVAC, the AMP-HPID Center[11] was designated as a WHO Collaborating Center for evidence-informed immunization policy-making with the main objectives to: 1) Contribute to WHO promotion of a systematic use of evidence-informed policy-making processes in immunization; 2) Collaborate with WHO on scaling-up initiatives to improve the use of evidence informed policy-making processes in immunization, in particular through the creation and strengthening of NITAGs; 3) Facilitate the exchange of information within the immunization community (including NITAGs) in order to foster south-south, north-south and north-north collaborations.

Partners' areas of support include: conducting high level advocacy to national authorities and funders; providing guidance in NITAG establishment processes and optimum functioning; dissemination of global and regional recommendations; facilitating NITAG capacity building (organisation of trainings, study tours, attendance to specific course i.e., vaccinology courses, literature search and appraisal; development of tools); supporting NITAGs functioning (technical assistance in development of NITAGs documents including evidence-informed recommendations); providing financial resources for NITAGs operations. Although each partner provides technical support according to its comparative advantage, it must be emphasized that assistance to NITAGs is a collaborative effort operating within the framework of the NITAG Group of Partners coordinated by WHO HQ. This group is composed of the NITAGs 'main partners, providing continuous assistance to NITAGs. AMP-HPID and WHO have led the way in developing and testing strategies and resources to help countries improve country ownership of immunization policy through the establishment and strengthening of a NITAG. Details on their contributions are given in the next section.

The main partners providing financial support are the Bill and Melinda Gates Foundation (BMGF) (through the SIVAC Initiative), GAVI, and U.S. CDC (mainly for WHO's NITAG work). In addition a few other sources of funds have been used to a limited extent to fund NITAG establishment and strengthening work such as WHO assessed contributions [core WHO funds], WAHO [for West African countries]; USAID, and some disease specific initiatives (e.g., Partnership for Influenza Vaccine Introduction (PIVI)). Overall funding has been quite limited and hard to secure.

Other partners have also contributed to the development of tools and other resources. For example, from 2009 the U.S. CDC began collaborating with WHO and SIVAC in the development and use of

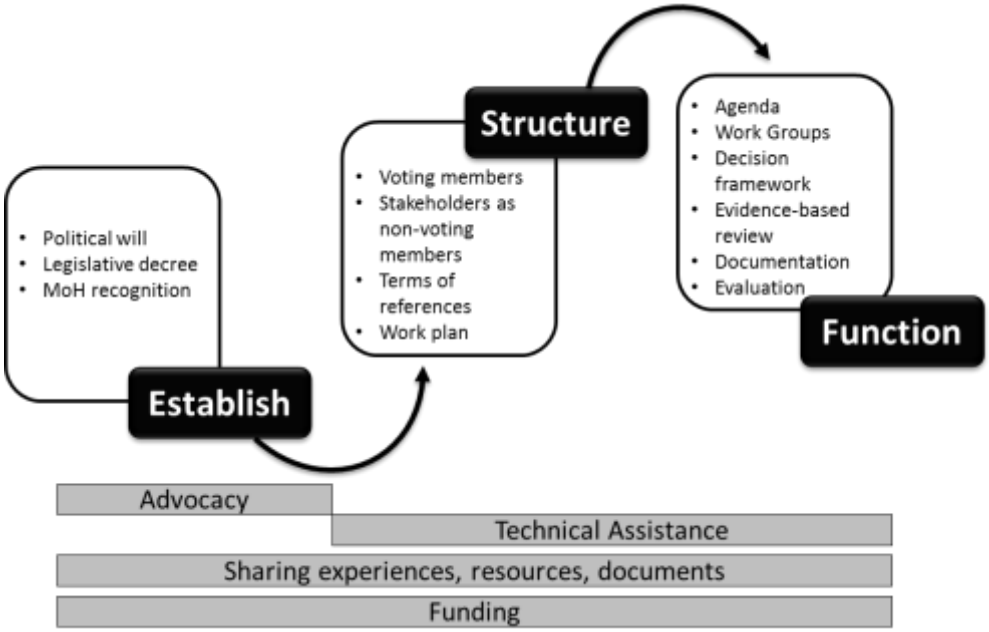
[11] AMP-HPID website is accessible at: http://amp-vaccinology.org/HPID

training materials and provision of technical assistance and resources for variety of activities. The West Africa Health Organization (WAHO) has assisted AMP-HPID with activities in West Africa. Several partners, including the European Centre for Disease Control and Prevention (ECDC), United States Agency for International Development (USAID), and National Institutes of Health (NIH)-Fogarty International Center, and the Sabin Vaccine Institute have contributed through the development of specific tools as described below. Finally, vertical disease specific initiatives such as the Rotavirus Accelerated Vaccine Introduction Network (RAVIN), and PIVI, have recently shown interest in NITAG strengthening.

Partner strategies

The process of developing a functional NITAG can be considered in terms of three stages as depicted in Figure 3. Throughout this continuum, partners have systematically and thoughtfully consulted with countries to understand the barriers and enablers for progressing through each phase. It was recognized early on that one approach does not fit all countries. A variety of strategies and resources have been developed, used in many countries, and iteratively adapted according to national and regional contexts. Access to funding to support the partner inputs is critical.

Figure 3: Three stages to outline the process of developing a functional NITAG.



Establish.

WHO and SIVAC have supported many countries interested in establishing a NITAG by advocating with the government. Such advocacy aims to raise awareness of the value of and generate political will for a NITAG, develop legislative underpinning for political sustainability, and foster recognition of the NITAG by the MoH. Because this is a country driven process, SIVAC and WHO Regional focal points have recognized the importance of 'thoughtful listening' and respectful consultation to gently guide rather than pro-actively lead. In this way, partners understand the contextual situation, political environment, and institutional stability, all of which affect the trajectory of NITAG establishment. This phase can be lengthy for several reasons. First, there are key differences

between support for NITAG creation and typical support to EPI, for example improving cold chain, access to vaccination, or disease surveillance. NITAG creation builds a new program 'from scratch', while other support usually builds on some sort of existing infrastructure. Secondly, the concept of a committee independent from the government is not familiar in many cultures. For example, some health country officials expressed that opinion that a committee not chaired by the EPI manager would not be recognized. Some have said building a NITAG is akin to putting a little bit of democracy into the policy process. As a result, helping countries by simply providing guidelines would not be adequate for NITAG establishment.

Advocacy varies by region and by country, but a common feature is that it takes time. For example, two AFR countries established their NITAGs in one year, most took 2 to 3 years and one did not establish until 8 years after the initial engagement**.** In the African region, the advocacy by AFRO and SIVAC, and of WAHO in francophone West Africa, takes the form of: 1) letters and visits to the MoH; 2) support to EPI to organize meeting of immunization stakeholders; 3) participation and presentation at EPI meetings; 4) side meetings with EPI managers and partners; and 4) invitations a NITAG orientation meeting. In EMR, early on the Regional Director sent letters to Ministers of Health emphasizing importance of establishing and strengthening NITAGs. The European region uses similar strategies, sometimes involving the Regional Director if the country has particular concerns. In addition, NITAG sessions are held during the regional meetings for Immunization Programme Managers. A key advocacy tool is the inclusion of NITAG establishment and strengthening as one of the main strategic objectives of European Vaccine Action Plan for 2015-2020, which was endorsed by all WHO EUR Member States at WHO Regional Committee Meeting in September 2014.

Globally, the most recent officially established NITAG is the NITAG in Haiti (AMR), as marked by an inauguration ceremony of the NITAG on 8 March 2017. Prominence was given to highlight the terms of reference of the NITAG, diversity of membership on the advisory group, and keen interest calling for the first meeting to be organized rapidly in order to address pressing public health vaccination-related concerns.

Structure.

Once the creation of a NITAG has legal status, it should be structured for maximum effect according to best practices described in the WHO guidelines. AMP-HPID took the lead for this phase and actively involved WHO and CDC in the development and delivery of workshops, trainings, and resources (See Table 4 and Table 5). The activities aim to convey the value of a committee independent of the EPI and composed of a broad range of expertise, to assist in the identification and involvement of immunization stakeholders, and to help countries develop written terms of reference, including conflict of interest assessment and management. AMP-HPID have developed a range of resources including simple, practical templates that committees can adapt to their context; workshop guides for facilitators and materials for participants; and guides for complex activities such as mapping immunization stakeholders and determining their role in the development of immunization policy. These materials have been used both in countries establishing new NITAGs and in those with existing committees. Many countries with existing committees decided to revise the structure after considering the WHO guidance. Examples include the Lao People 's Democratic Republic's committee that recently stated the need to replace purely administrative members with technical experts and the Afghanistan NITAG that announced plans to totally revamp their

committee. The format of the workshops includes didactic and participatory learning. In general, training materials have been developed for a particular target audience and then iteratively revised for other countries and contexts. For example, a pre-workshop needs assessment for training in one region showed particular interest in developing a charter for their NITAG. To address this, examples of charters and templates were used by participants in group work.

Functioning.

A well-functioning NITAG should be able to complete both management functions and technical activities. To enable the NITAG to function efficiently, the NITAG secretariat and members need to develop a work plan that reflects relevant immunization policy issues with input from the EPI and other immunization stakeholders, organizing and setting the agenda for each meeting, and recruiting new members as terms expire. Technical activities especially led by the NITAG chair include developing a decision framework, conducting evidence based reviews possibly through technical work groups, and making evidence based recommendations. Another important management function is documentation, for example of the decision framework and the recommendations and notes showing the evidence base. Finally, NITAGs should be able to evaluate their work and impact.

All partners have been involved in this phase and in a variety of ways. WHO, AMP-HPID and US CDC have provided technical assistance, training, and provision of resources as shown in Table 4 and Table 5. As with workshops on structure, there have multiple formats including practical case studies adapted to the target audience. Often members of well-established NITAGs have participated in trainings; there have been consistent comments about the value of such experience sharing. Partners have found other opportunities for sharing among countries through the development of web-based platforms and networks. To provide such interactions, the web-based NRC, a GNN, a SEAR NITAG network and a European Union NITAG network (VENICE) were established.

Many tools to promote evidence-based decision making on new vaccine introduction have been developed based on needs assessment. Acknowledging that one size fits all approach would not work, partners' assessments followed an iterative process and tools adapted to context. One example is ProVac which http://amp-vaccinology.org/activity/provac-iwg was developed by PAHO in response to Latin American country requests for technical support in the integration of economic decisions on new vaccine introduction. As of 2017, 15 countries in the region had completed more than 30 country-led analyses on the costs, impact and cost-effectiveness of new vaccine introduction[12]. The PROVAC International Working Group was created to extend ProVac to other WHO regions. PAHO also developed UNIVAC, a vaccine predictive impact and cost-effectiveness model that allows users to customize structure to a policy question about multiple vaccines.

Web tools are also being developed under the WHO project of optimizing NIP schedules and with the SMART Vaccines 2.0. In development by the US National Institute of Health (NIH)-Fogarty International Center, this decision-making tool will represent the dynamic, multidimensional nature of the process of decision-making. Input data goes beyond the standard data used in cost-effectiveness analyses and can capture policy, politics, and feasibility. The tool is designed to rank

[12] Andrus JK, Walker DG. Expanding the Evidence Base to Inform Vaccine Introduction: Program Costing and Cost-effectiveness Analyses. Volume 33, Supplement 1, Pages A1-A254. http://www.sciencedirect.com/science/journal/0264410X/33/supp/S1.

priorities and not answer a specific vaccine decision-making question. The adapted version SMART Vaccines 2.0 may be useful for NITAG and may be piloted in a country for this purpose.

The immunization dashboard is being used by USAID and contains a section on diagnostic indicators including GVAP indicators, stratified by the 24 USAID priority countries. A NITAG indicator may be added to show a grade for the country's NITAG based on the six indicators. The dashboard will be updated annually using information from JRF and WHO.

The European Centre for Disease Prevention and Control (ECDC; at http://ecdc.europa.eu/en/Pages/home.aspx) works in partnership with national health protection bodies across Europe and collects Europe's health knowledge to develop authoritative scientific opinions on issues related to vaccine preventable diseases. The Robert Koch Institute in Germany has convened a series of meetings to strengthen evidence-based decision-making by NITAGs and has engaged in the strengthening of NITAG processes. Other groups, such as the Johns Hopkins Bloomberg School of Public Health has been funded by Gavi for various diseases specific initiatives.

Funding.

Clearly, funding is needed throughout the entire process of NITAG development. SIVAC has been supported from 2009-2017 by the BMGF with complementary funds from Gavi in 2015-2016. CDC provides funds to WHO HQ to support NITAG members from selected countries to attend the SAGE or regional TAGs meetings and WHO country offices for NITAG strengthening activities awarded through CDC small grants program. In addition, Gavi offered countries two funding sources for NITAG support through Health System and Immunization Strengthening (HSIS) and Tailored Country Assistance (TCA) grants, but support for NITAGs has not been prioritized within these opportunities. In 2016, however, Joint Appraisals in 16 countries (13 in the AFR) eligible countries identified and prioritized NITAG support in their TCA requests.

Table 4: Activities conducted/supported by partners by three phases of NITAG development, 2009-2016 (based on information received from partners)

	2009	2010	2011	2012	2013	2014	2015	2016	2009-2016
	# of countries	# of countries	# of countries	# of countries	# of countries	# of countries	# of countries	# of countries	total # of countries
Phase I: Establish									
Advocacy meetings with national authorities or informal engagements[1]									
Phase II: Structure									
Workshop on Establishment and mode of operations of an effective NITAG[2]	1	13	4	2	3	2	6	6	37
Workshop on Analysis of immunization in the context of health systems and policy decision-making									
Phase III: Function									
Workshop on Evidence-based decision making [3]					15	11	5	7	38
Training of NITAG facilitators[4]							5	0	5
Sponsored attendance at Vaccinology course[5]			4	5			3	3	15
Sponsored attendance at SAGE[6]							16	20	36
Invitation to Regional and subregional meetings[7]									
Sponsored visit to other NITAGs[8]		3	3		1	3	6	2	18
Evaluation or needs assessment tools[9]		3				1	1	11	16

[1]Advocacy

Formal and informal activities were carried out throughout in 36 countries supported by SIVAC-AMP and -IVI, 10 counties in EUR, many countries in PAHO. The number of countries is not captured in the table.

[2]Orientation workshops

2009 National workshop in Nepal [WHO, SIVAC-IVI, CDC]

2010 Regional workshop including Belarus, Moldova, Ukraine [WHO, SIVAC-IVI, CDC]; Regional workshop including Mongolia, Vietnam, Philippines, Cambodia, Lao, Fiji, Papua New Guinea, South Korea, Hong Kong, China [WHO, SIVAC-IVI]

2011 Regional workshop including Kazakhstan, Kyrgyzstan, Uzbekistan; National workshop in Bhutan [WHO, SIVAC-IVI, CDC]

2012 National workshops in Myanmar and Mongolia [WHO, SIVAC-IVI]

2013 National workshops in Benin, Senegal, Maldives [WHO, SIVAC-AMP]

2014 National workshops in Vietnam, Kenya [WHO, SIVAC-IVI-AMP]

2015 National workshop s in Cote d'Ivoire, Uganda, Burkina Faso, Nigeria, Malawi, Timor Leste [WHO, SIVAC-AMP]

2016 National workshops in South Sudan, Kenya, Ethiopia, Zimbabwe, Tanzania, Zambia [WHO, SIVAC-AMP]

[3]Evidence-based decision-making

2013 Regional workshop including Cote d'Ivoire, Senegal, Benin [WHO, SIVAC-AMP]; Two regional workshop including Albania, Bosnia and Herzegovina, Hungary, Montenegro, Romania, Serbia, Armenia, Azerbaijan, Kazakhstan, Kyrgyzstan, Ukraine, Uzbekistan [WHO, CDC, NITAGs from Germany, Netherlands, and the United Kingdom]

2014 Regional workshop: Kenya, Uganda, South Sudan, Ethiopia, Zambia [SIVAC-AMP, WHO], Regional workshop: Bulgaria, Estonia, Hungary, Latvia, Lithuania [WHO, CDC]; Workshop with special focus on Health Economics in decision-making: Tunisia [SIVAC-AMP, WHO]

2015 National workshops in Benin, Nigeria [WHO, SIVAC-AMP]; National workshop with special focus on evidence assessment using GRADE for Kenya [SIVAC-AMP, WHO]; Regional workshop with special focus on literature search and assessment of articles including Benin, Senegal [WHO, SIVAC-AMP]

2016 National workshops in Uganda, Burkina Faso [WHO,SIVAC-AMP]; Vietnam [WHO, CDC]; Multi-country workshop with special focus on Health Economics in decision-making including Cote d'Ivoire, Burkina Faso, Senegal, Benin [WHO, SIVAC-AMP]

2004-2016 PAHO's ProVac Initiative has hosted a number of regional trainings on specific vaccines, assess local data availability and quality to address the policy question and, where relevant, understand and use modelling techniques to estimate the projected costs, health benefits and cost-effectiveness of the proposed vaccination strategy. The number of countries is not captured in the table.

[4]Training of NITAG facilitators

2015 Multi-country workshop including Mozambique, Kenya, Cote d'Ivoire, Nigeria, India [WHO, SIVAC-AMP]

[5]Vaccinology courses (Advanced Course of Vaccinology (ADVAC), Vaccines for Africa Initiative (VACFA), Charite-Berlin, WHO AFRO, or International Vaccine Institute (IVI)) (of course many more NITAG members or staff from NITAG secretariats have attended vaccinology courses and some courses such as ADVAC give some priority to the participation of such participants and offer some grants to support participation of trainees from developing countries)

2011 Indonesia, Vietnam, Nepal, Mongolia

2012 Indonesia, Kazakhstan, Kyrgyzstan, Mongolia, Vietnam

2015 Burkina Faso, Nigeria, Kenya

[6]Study visit to SAGE meeting

2015 Afghanistan, Barbados, Bulgaria, Cote d'Ivoire, Croatia, Mozambique, Oman, Philippines, Republic of Moldova, South Africa, Sri Lanka, Suriname, Thailand, Timore-Leste, Turkey, Uganda [WHO, SIVAC-AMP]

2016 Albania, Armenia, Belarus, Belgium, Bhutan, Burkina Faso, China, Georgia, Germany, Indonesia, Malawi, Maldives, Papua New Guinea, Panama, Philippines, Senegal, South Sudan, Uganda, Viet Nam, Zimbabwe, [WHO, SIVAC-AMP]

[7]Participation in regional and subregional meetings.

The number of countries is not captured in the table. Over the recent years, NITAG Chairs and secretariats have been invited to join at immunization managers meetings and at regional TAG meetings. This has also resulted in opportunities for regional NITAG meetings in the context of these other meetings. As an example between 2009-2016--NITAGs from 15 low and middle-income countries in EUR attended each ETAGE meeting and NITAGs in EUR countries were invited to attend Immunization Programme Managers Meetings and other annual regional meetings on immunization and introduction of new vaccines. NITAG chairs from AMR countries participate in the Regional TAG on VPD. NITAG chairs participate in the annual subregional meeting of

Caribbean English-Speaking immunization programs to review and consider evidence for immunization. NITAG chairs and secretariat have also been invited to join regional TAG meetings and immunization manager meetings in the other WHO regions.

[8]Study visit to other NITAGs

2010 Tunisia, Lebanon, Cote d'Ivoire [SIVAC-AMP, WHO, NITAGs of Quebec and France]

2011 Mongolia, Vietnam, Indonesia [SIVAC-IVI, WHO, NITAGs of New Zealand and Australia]

2013 Nepal [SIVAC-AMP, WHO, NITAG of Australia]

2014 Cote d'Ivoire, Senegal, Vietnam [SIVAC-AMP, WHO, NITAGs of France and South Korea]

2015 Kenya, DRC, Armenia, Moldova [SIVAC-AMP, WHO, NITAGs of South Africa, Belgium, USA, UK, France], Peru, DRC [WHO, CDC and NITAG of USA]; Belarus, Georgia [WHO, NITAG of the Netherlands]

2016 Albania [WHO, NITAG of UNK]; China [WHO, SIVAC-AMP, CDC and NITAG of USA]

Not captured in the table are regular visits to other NITAGs facilitated by PAHO

[9]Evaluations

2014 Cote d'Ivoire NITAG conducted self-evaluation using country developed tool

2014 Pilot evaluations in Mongolia and Nepal [WHO]

2015 SIVAC evaluated Armenian NITAG, using SIVAC tool [WHO/SIVAC-AMP]

2016 EURO conducted needs assessment of 10 NITAGs, using regionally developed tool; SIVAC evaluated Moldovan NITAG, using SIVAC tool [WHO/SIVAC-AMP]; SEARO conducted an assessment of all 11 countries' NITAGs to understand experiences with establishment, structure, process, function, operations, and sustainability of NITAGs in the region.

Table 5: Resources and platforms for NITAG establishment and strengthening

Although AMP-HPID (as a WHO collaborating centre) and WHO have led the way in developing and testing strategies and resources to help countries improve country ownership of immunization policy through the establishment and strengthening of a NITAG, other partners including U.S. CDC, Gavi, Sabin Foundation, RKI, ECDC, USAID, and NIH Fogarty Center have or are also contributing to development of tools and other resources. The main tools and resources for NITAG establishment and strengthening are outlined here.

Resources	Purpose	Access	Date of publication
Resources for NITAG Establishment			
Guidance Document for the development of a Concept Paper on the Establishment and Functioning of a NITAG	Builds on WHO guidance; it presents the key points to be addressed while developing a concept paper for the establishment of a NITAG.	http://www.nitag-resource.org/media-center/document/1256-guidance-document-for-the-development-of-a-concept-paper-on-the-establishment-and-functioning-of-a-national-immunization-technical-advisory-group?page=1&disease=0&document_type=55&topic=0&geographical_area=&country=0&sort=recent&keyword=0&author=0&source=0&document_language=0	2015
Guidelines for defining NITAG annual Work Plan	Make the most economical and effective use of resources, in order to ensure the development of high quality, evidence-informed recommendations	http://www.nitag-resource.org/media-center/document/698-guidelines-for-defining-nitag-annual-work-plan?page=2&disease=0&document_type=55&topic=0&geographical_area=&country=0&sort=recent&keyword=0&author=0&source=0&document_language=0	2013, revised 2015
Internal procedures manual	Provide templates to guide NITAG secretariat in setting up NITAG operating procedures	http://www.nitag-resource.org/media-center/document/844-drawing-up-the-nitag-s-internal-procedures-manual?page=1&disease=0&document_type=0&topic=0&country=0&keyword=0&author=0&source=0&document_language=0&search=Internal+procedures+manual	2014, revised 2015
Training materials--Participants' guide, facilitators' packet, including content, instructions, and slide set.		http://www.nitag-resource.org/uploads/media/default/0001/03/3475dc79774b8cf5ed712cae93048c017e6c8281.pdf	2014 piloted, 2015 finalized

EMRO Guidelines for NITAGs		http://applications.emro.who.int/dsaf/emropub_2011_1272.pdf	2011
Case studies for training materials	Guide countries on NITAG composition and operations, charter development, and technical issues.		2009, revised after every use/CDC
Guidelines for the Prevention of Conflicts of Interest in NITAGs	Introduction to principles and provide guidance to implement Conflict of Interest management policy	http://www.nitag-resource.org/uploads/media/default/0001/04/e80de42a64ee6f017cc42996b34a0cbb6e056ff0.pdf	2015
Resources for NITAG Strengthening			
Guidelines for setting up NITAG working groups; template Terms of Reference for working groups	Guide NITAG executive secretariat in considering the need for establishing a Working Group to gather and summarize data for the NITAG meetings.	http://www.nitag-resource.org/media-center/document/697-guidelines-for-setting-nitag-working-groups?page=2&disease=0&document_type=55&topic=0&geographical_area=&country=0&sort=recent&keyword=0&author=0&source=0&document_language=0	2013
Step by step guidelines to issue evidence-informed recommendations by NITAGs	Present overview of the steps involved in the process of evidence-based recommendation development	http://www.nitag-resource.org/media-center/document/692-a-step-by-step-guideline-to-issue-evidence-informed-recommendations-by-nitags?page=2&disease=0&document_type=55&topic=0&geographical_area=&country=0&sort=recent&keyword=0&author=0&source=0&document_language=0	2013
Training materials--Participants' guide, facilitators' packet, including content, instructions, and slide set.	Establishment and mode of operations of an effective NITAG available in English and French (Training 1) Analysis of immunization in the context of health systems and the policy decision-making process available in English and French (Training 2) Technical and scientific capacities of NITAGs, evidence assessment methodologies and the development of evidence-informed recommendations available in English, French and Russian (Training 3) Informing vaccine decision-making with economic evidence available in English and French (Training 4)	http://www.nitag-resource.org/uploads/media/default/0001/03/3475dc79774b8cf5ed712cae93048c017e6c8281.pdf	2014 piloted, 2015 finalized

Recommendation Frameworks (in relation to Training 3)	Samples of recommendation frameworks for 5 vaccines i.e. Hepatitis B birth dose, Meningococcal A, Rotavirus, Rubella and on Tetanus-Diphtheria. The samples of generic framework with elements and specific queries can be adapted by the NITAGs to develop their actual disease specific framework and provide specific queries for each element. Sample search process and results tables based on the above recommendation frameworks for Hepatitis B birth dose and Meningococcal A	http://www.nitag-resource.org/media-center/document/882-elements-to-consider-in-developing-a-framework-for-issuing-immunization-related-policy-recommendations?page=1&disease=0&document_type=56&topic=0&geographical_area=&country=0&sort=recent&keyword=0&author=0&source=0&document_language=0	2015
Sample of PICO formulation (in relation to Training 3)	Sample of PICO formulation, formulation of search strategies, selection of articles and results of evidence appraisal scoring done for 10 vaccines: HepB Birth dose, HPV, MR, yellow fever, Tetanus-Diphtheria, Pertussis, MenA, RotaV, Pneumococcal Vaccines, Streptococcal B		2015
Evidence to decision tools	Tools developed by the DECIDE collaboration	http://www.decide-collaboration.eu/	
SAGE guidance document	SAGE follows an evidence-based review process as outlined in the SAGE guidance document on evidence-based vaccine-related recommendations. The document was developed in cooperation with the methodology working group. The document will continue to be updated as necessary as the methodology for evidence baseddecision making evolves.	http://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf?ua=1	
Framework for Prioritization of Vaccine Introductions	Generic tool that builds on several existing tools (SMART vaccine version 1.0, WHO's Making Fair Choices on Universal Health Coverage, Guidance on Priority Setting in Health) aiming at guiding NITAGs in the	Tool not yet available. Similar tools also being developed by WHO under the optimization of schedules project.	2015

	selection of vaccines for prioritization in a systematic and transparent way		
Evaluation Tool for National Immunization Technical Advisory Groups (NITAGs)	Provides guidance and templates on NITAG self-assessment, collection of data through various sources, and analysis of information and writing of evaluation report.	http://www.nitag-resource.org/media-center/document/1517-evaluation-tool-for-national-immunization-technical-advisory-groups-nitags?page=1&disease=0&document_type=0&topic=0&country=0&keyword=0&author=0&source=0&document_language=0&search=evaluation+tool	2016
Technical briefs on Reference Management Software Tools Zotero and Mendeley (in relation to Training 3)	Provide a short training on the use of Zotero and Mendeley to help the user create a bibliography and improve reference management	http://www.nitag-resource.org/media-center/document/3463-mendeley-reference-manager?page=1&disease=0&document_type=0&topic=0&country=0&keyword=0&author=0&source=0&document_language=0&search=mendeley	2016
Guidance Document on how NITAGs can address questions raised by Vaccine Hesitancy	Presents key areas to be explored by NITAGs to better address vaccine hesitancy such as best practices to ensure independence, involvement of CSOs in the process of developing recommendations or NITAG communication strategies.	http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/publications/2016/best-practice-guidance-how-to-respond-to-vocal-vaccine-deniers-in-public-2016	2016
NITAG Financing Guidelines	Provide a list of funding options for NITAGs, based on SIVAC lessons and analysis of current global immunization financing solutions	http://www.immunizationfinancing.org/	2017
Cost effectiveness resources including PROVAC, TRIVAC, CERVIVAC (cost effectiveness models), COSTVAC (program for modeling costing), OLIVES (on-line data repository)	Strengthen national technical capacity to make evidence-based decisions on new vaccine introduction, focusing on economic evaluations.	www.provac-toolkit.com	2004
Platforms			
NITAG Resource Center	The NITAG Resource Center (NITAG-RC) (www.nitag-resource.org) in English and French, has three main components: a "NITAG observatory" a digital Library" and a Center of Expertise that includes modules for new NITAG members.	http://www.nitag-resource.org/	2010, revised 2015
NITAG Newsletter	A NITAG newsletter is published on a quarterly basis. 350 people have subscribed. It promotes the latest recommendations issued by NITAGs, useful technical and operational resources for NITAG members and informs of	http://www.nitag-resource.org/contact	2015

	upcoming events. It also enables the dissemination of documents and guidelines produced by SIVAC or other technical partners such as the training catalogue or the evaluation tool.		
Glossary (English – French)	Given the increasing number of partners working in the NITAG field, it appeared important to develop a glossary to ensure consistency in documents / guidelines / activities / workshops / concept notes, etc. and translations		2016
Global NITAG Network	Provide a global platform to facilitate and support NITAGs, to promote active exchange of information among members and other capacity building activities	http://www.nitag-resource.org/news-and-events/news/79-first-meeting-of-the-global-network-of-nitags	2016
Southeast Asia NITAG Network	Provide a regional platform to share data and technical resources, facilitate exchange of experiences, and standardize policies and procedures around NITAGs.	http://www.searo.who.int/entity/immunization/documents/the_establishment_and_operation_of_nitag_groups_in_sear.pdf	2016
PAHO National Immunization Technical Advisory Groups (NITAGs)	A resource group to focus on strengthening skills at national level to develop economic and health impact evidence to inform decision making, to improve country ownership and sustainability.		
PAHO Webinar	Leveraging an existing monthly webinar hosted by the Regional Network of Health Technology Assessments, this forum allows discussion on immunization policy topics and issues	http://www2.paho.org/hq/index.php?option=com_content&view=article&id=11581%3Apahos-role-in-health-technology-assessment-in-the-americas&catid=5870%3Aassessment&Itemid=41685&lang=en	

Challenges faced by partners

Establishment and Structure

1. Lack of awareness and support among broader global partners with respect to the value of NITAGs;
2. Lack of awareness of the difference between NITAG strengthening and other support to EPI;
3. NITAG work often involves starting from 'scratch' while other EPI support usually builds on and improves existing systems;
4. Lack of consistent messaging and support among partners. Need a global agreement for the national governance of NIP and NITAGs so that global and regional partners operate in a coordinated way.

Functioning

1. Challenges of human resources and securing technical staff focused on NITAG-related issues both within WHO and for critical partners supporting NITAG strengthening.
2. Changes in leadership at the country level often result in stalls in the process of partner support and the need to repeat training for new staff. The process is often one step forward, two steps back;
3. Unclear role of disease specific initiatives (PIVI and RAVIN) in NITAG strengthening to ensure country ownership;
4. Difficulty in monitoring the impact of partners' work. Process indicators are helpful, but do not capture functionality and integration;
5. Difficulty in NITAG function due to civil unrest, humanitarian crises that are not short term – guidance from WHO is coming but not yet available. This can affect ability of technical assistance from partners to meet with NITAGs and provide support;
6. Too small populations to be to have expertise, evidence and data for full NITAG function;
7. Inadequate access to evidence in language NITAG members can use e.g. lack materials in Russian and/or lack of quality vaccine preventable disease data relevant to country. This can affect how partners interact and share materials with NITAGs.

Funding

1. Platforms such as the NRC, GNN, and regional networks have been developed, but their sustainability can only be ensured if there is funding for core infrastructure.

Future plans

All WHO regions have committed to increase national advocacy for NITAGs and recognize the need to share technical resources through regional networks. Regions will invest in this direction and continue regional and sub-regional trainings and collaborate between members of well-functioning NITAGs with those of recently-established NITAGs; continue invitations to regional meetings; standardize policies and procedures across NITAGs; facilitate NITAGs toward written standard operating procedures and work plans, and promote the use of the NRC as the global resource center for vaccine related information. Interest in conducting NITAG evaluation is also commonly shared across regions with the aim of continuously improving NITAG functioning, quality of work processes

and integration in the decision-making system. All regions need to creatively address challenges faced by low population states – one size fits all solutions are unlikely to work.

Efforts are also going forward towards investing in NITAG integration in decision-making system and innovating in policy making processes to be more cross-cutting across the health sector and supportive of integrated policy making.

Regarding funding, regions have started to tap into different resources (e.g., Gavi, Health System Strengthening (HSS). Identifying funding and candidates for NITAG focal points in regions lacking one is particularly critical.

CDC will continue to support WHO and host country delegations to ACIP meetings. There are recently funded projects and ongoing CDC efforts to: pilot experiential learning by supporting a mentor to engage with a NITAG for 9-12 months around a specific policy question; document positive deviance on NITAG integration in the policy dialogue in Argentina, Jordan, and other countries; develop a maturity model of key milestones for sustainable NITAG development; identify contextual mechanisms developed by countries for maintaining polio assets by linkage with NITAGs; and update published systematic review of criteria for country decision-making.

WHO will further engage in the strengthening of NITAGs, e.g. by inviting selected NITAG chairs and secretariats to attend the SAGE meetings.

7. Summary and Way forward

The 2015 data shows slight progress in the establishment of new NITAGs; however, there is a relative stagnation on the strengthening of NITAGs. While the time-trend data shown in Figure 2 should not be over-interpreted, the trend is clear: the GVAP target for all countries to have a NITAG will not be met by 2020 through current activities. Although there has been overall positive progress in NITAG strengthening during the last five years, the progress has been uneven, and it is evident that there are weaknesses and threats to the current approach.

In all regions there is now clear commitment to establishing NITAGs and all Regional Immunization Technical Advisory Groups have made strong statements with regard to the need to strengthen NITAGs. In addition, NITAG chairpersons have attended regional TAG meetings with immunization managers in all but one region to date and the fostering of exchanges between NITAGs have been received very positively by all and contribute to capacity strengthening. Country and intercountry NITAG workshops and meetings continue to be very successful and will further help accelerate progress. As shown in Table 4, key areas of support to NITAG were in capacity building. There will be a need to continue supporting improvement of committees' ability to review evidence and training members including on vaccinology.

Other positive developments include attention given to strengthening NITAGs at the Ministerial Conference on Immunization in Africa held on 24–25 February 2016 in Addis Ababa. During the last several years, there have also been examples of experience-sharing between well-developed NITAGs (e.g., United States, United Kingdom, Australia, Netherlands, and Lebanon) and NITAGs more early on in their development, and anecdotally this has been a beneficial activity. Country interest in

networking is evident in the establishment of a regional NITAG network in the South-East Asia Region and interest in the establishment of the GNN expressed at the international NITAG meeting in 11–12 May 2016; however, the SEAR network is fragile and the GNN is not yet formalized. With respect to the special approaches started to allow Member States with small populations to consider options such as subregional advisory groups referred to in last year's report, definite advances have been made in the Americas (for the Caribbean islands). In part this success is due to a long regional history of these small countries working together on different issues in education and in health. Other models are needed such as partnering with a NITAG in another country. How this is best done needs work given different constraints in different small countries in the different regions. As well as the effectiveness of these models for small countries as shown by adoption of recommendations and their relevance needs to be verified.

The management board of Gavi, the Vaccine Alliance has approved a framework for its 2016–2020 strategy that includes the importance of improving country leadership, and management and coordination, which includes NITAG strengthening. As a result, Gavi organized a consultation of stakeholders and major partners in August 2015 to engage them in this process in a manner that is sustainable and builds capacity at country level. Assisting countries to access Gavi funds allocated for health system strengthening or annually requested TCA to establish or strengthen NITAGs remains necessary. There has unfortunately not been much significant progress in allocating HSIS resources for longer term support of NITAGs, however the 16 country requests for NITAG support through TCA does illustrate increased acknowledgement of the important role that Gavi resources can play to establish and strengthen NITAGs.

More recently, we have seen competing interests and unclear roles for the way forward related to NITAGs in regards to 1) overlap with disease-specific vaccine introduction initiatives (e.g. PIVI and RAVIN) and avoiding conflict of interest, and 2) the presence of HTAs in many countries and its confusion with NITAG roles. As background, in 2014, the World Health Assembly urged Member States "to consider establishing national systems of health intervention and technology assessment in the systematic evaluation of properties, effects, and/or impacts of health technology" which includes medicines, vaccines and other health technologies. Member States were also urged "to identify gaps with regard to promoting and implementing evidence-based health policy." In some countries, confusion about the relative roles of the HTA and NITAG has arisen. The issues with disease-specific initiates and HTA need to be assessed and resolved. With respect to single disease initiatives such as PIVI and RAVIN – these do not address breadth of vaccines needing NITAG assessment but may have expertise and evidence including VPD data that can feed into NITAG deliberations.

Although the Middle Income Country Strategy proposed by the MIC Task Force and endorsed by SAGE in April 2015 featured the strengthening of evidence-based decision-making as one of the four main areas of action identified as the pillars of this strategy, it was not funded and there has been only limited progress. The introduction of pneumococcal conjugate vaccine (PCV) into Malaysia, an upper-MIC, illustrates some of the issues that MICs face in using evidence-based decision making to support new vaccine introduction, especially in countries lacking strong surveillance data on burden of disease. For example, Malaysia does not have an independent NITAG but the Medical Development Division of the Ministry of Health Malaysia published an HTA Report on PCV

immunization (21); this report failed to make the case for PCV immunization because it lacked clear guidance and did not provide an evidence-based recommendation for PCV to be added to the NIP.

There is a notable lack of leadership from donors to support NITAG strengthening globally. This highlights the need for more emphasis on showing the benefit of NITAGs short and long term. The NITAG Assessment Tool (AMP-HPID, located at NRC) was developed at least partly for this purpose, specifically to better understand the factors contributing to NITAG performance, the complexities of integration versus independence of NITAGs, and how NITAG recommendations impact policy. Threats to future funding and staff turnover at AMP-HPID limited their ability to fully test the tool, and so there is currently very limited data on evaluating NITAG functionality. Despite these setbacks, there are ongoing and recently funded projects by partners to evaluate NITAGs. There is also an ongoing evaluation of SIVAC being conducted by the London School of Hygiene and Tropical Medicine (contracted by the BMGF) to better quantify the impact of the 10 year SIVAC initiative (results due in summer 2017).

The global community, while appreciating that NITAG establishment and functioning is an evolving process that needs to shape itself in the country context, still does not know the best way to improve the presence, quality and functionality of NITAGs in every country. This is especially true for outlier countries, whose infrastructure and context may not benefit from the criteria outlined in the current global NITAG guidance. These include small countries which do not have the technical resources to establish their own NITAG; for these countries, subregional NITAGs and/or partnerships with neighbouring country NITAGs may play a role. There are also high and middle income countries without functioning NITAGs, where we know there are systems in place that seem to be working but may not relate to the current model of NITAG functionality, in terms of independence or declaration of conflict of interest. We need to understand a way forward for these outliers and determine whether these countries can have assessments done that can let them meet criteria for having a functioning NITAG. For example, high income countries where NITAGs do not exist but evidence-based decision making is being done, assessments/evaluations to determine if NITAG criteria are being met and if not what changes are needed would be helpful.

Despite the model of SIVAC and its positive role in supporting countries in the initial processes of establishing NITAGs, it is evident that different approaches and types of support are needed as NITAGs mature. Taking into account the need to support NITAGs at all stages of development and the experience already available in many regions, one option would be a regional focus for future NITAG support involving: 1) designated NITAG focal persons in each WHO region and responsibility of RITAGs in advocating for NITAGs with Ministries of Health; 2) virtual subregional NITAG networks using such activities as quarterly webinars, hotline links to experts on specific technical issues, conducting NITAG assessments, and support from PIVI and RAVIN as technical resources; and 3) fora where 'leader' NITAGs share expertise and experience through mentoring developing NITAGs and work groups. To further implementation efforts and recognition of these expert groups, NITAGs need to be encouraged to expand their scope and focus also on monitoring implementation, evaluating impact, and recommending strategies to improve uptake of vaccination recommendations. Finally, to further the integration of NITAGs in the country policy process, there also needs to be networking and dialogue with policy decision-makers, sharing of policy briefs, and policy assessment. The GNN and NRC would form the bedrock of support for the regional activities

and foster collaboration and exchange of information among NITAG members globally. The subregional NITAG networks, with leadership from strong and interested NITAGs in each region, would be complementary to and support the GNN.

If a global agenda on NITAG strengthening is to move forward, the GNN and the NRC needs the support of the global community. The GNN secretariat has to have the technical capacity to do more than just organize meetings, the secretariat needs to continue developing resources, listening to countries, and providing the necessary help to countries for advocacy and other needs. Without the continued involvement of AMP-HPID as the GNN secretariat, how to support GNN and NRC going forward will need careful discussion.

Without an accelerated and joint effort, the GVAP objective of all countries having a functional NITAG by 2020 will not be achieved. Advocacy by involved stakeholders at national and global levels is necessary to ensure that sufficient time, effort and money are invested in both establishing and strengthening NITAGs. Currently, insufficient funding threatens the implementation of technical support activities by the collaborating centre (i.e., AMP-HPID), WHO and partners and limits the implementation of evaluations. Funding for the functioning of the secretariat of the global NITAG network and for maintaining the NRC is not yet secured. If a regional focus for future NITAG support is deemed essential, these activities and the regional focal points will need to be adequately funded. Countries still need to take an active role in establishing and maintaining NITAGs and to investigate innovative mechanisms to sustain funding for NITAGs.

8. Annexes: NITAG achievements: Country examples

Republic of Moldova NITAG

The Moldovian NITAG was established by ministerial decree in 2013 to provide independent advice on immunization policy and practice. The NITAG consists of 14 core members who represent wide diversity of medical disciplines. There are also 17 non-core members, including representatives of Ministry of Health, immunization programme, and medical societies. The Moldavian NITAG is generally believed to be a fully-functioning with a legal basis and terms of reference, links to the Ministry of Health, a core membership drawn from an appropriate range of disciplines and secretarial support provided through the National Centre of Public Health.

Since its establishment, Moldavian NITAG conducted four meetings and considered topics that were important for the national immunization programme and the Ministry of Health. The NITAG developed recommendations on removing BCG booster doses from national immunization schedule, introduction of one dose of IPV, switch from tOPV to bOPV, vaccination of risk groups against hepatitis A, seasonal influenza vaccination, and introduction of HPV vaccine. All NITAG recommendations were accepted and fully implemented by the Ministry of Health.

The Moldovian NITAG faces similar challenges as other NITAGs in middle-income countries, including difficulties in generating evidence-based recommendations because of limited capacity to conduct systematic literature review and lack of funding that leave the NITAG with very limited technical support from the Secretariat. In order to overcome these challenges the NITAG makes use of available information, such as WHO position papers, documents of Strategic Advisory Group of Experts together with detailed local data, to make evidence-based recommendations.
WHO and international partners support in establishment and building capacity of Moldavian NITAG was essential. It included participation of NITAG members in regional meetings and trainings, visit to well-functioning French NITAG, and a formal NITAG evaluation.

The support from the international partners should be continued to ensure recognition of the important role played by NITAG and allocation of necessary resources, by the Ministry of Health. The international partners support will also be crucial for improvement of the quality of the NITAG recommendations by conducting trainings on evidence assessment methodologies and development of evidence-based recommendations.

Timor Leste NITAG

In June 2014 WHO/SEARO proposed Timor Leste to establish NITAG. Despite initial assumption that required expertise would not be available in Timor Leste, following discussions MCH Department of the MoH, decided to pursue with available experts. Draft ToR for the NITAG-Timor Leste and expertise required was developed in consultation with Immunization and Vaccine Development SEARO. In June 2014, WR, Timor Leste wrote to the Hon. Minister of Health describing importance of establishing NITAG with draft ToR and proposed types of experts to be considered. At that time the National Certification Committees for Polio Eradication had been established in Timor Leste and

was functioning smoothly with first Timorese pediatrician (out of the two in Timor Leste and working in private sector) as the chairperson. She was proposed as first NITAG chair.

For a period of more than one year WHO constantly advocated the importance of establishing NITAG, in official and unofficial forums. Based on the anecdotal information the main concerns of the MoH were; assumption that MoH Officials will lose the decision making authority over immunization programme and by appointing another independent group outside the MoH, it may become fault finding group of the MoH. Initially, MoH was not able to well comprehend the meaning of NITAG being an "independent group of experts", how independent they are and how independently they can work. Above issues were discussed in several Council of Director's Meetings (The main Policy Making Body of the MoH chaired by Hon. Minister of Health) in late 2014 and early 2015. Meanwhile, MoH had to take some key decisions on immunization on conducting wide age range Measles/Rubella/OPV catch-up immunization campaign, introduction of five new vaccines (Hepatitis B birth dose, IPV, MR 2 dose schedule, DPT/DT booster) to immunization programme, and TOPV to BOPV switch, as part of global and regional initiatives. The Hon. Minister of Health had to take these technical decisions with support of limited number of experts. To respond some adverse events after immunization and adverse comments came up during 2015 Measles /Rubella / OPV catch-up immunization campaign and other VPD control related programmes Hon. Minister needed the views of the national experts. This situation and intense advocacy by WHO led the MoH to consider formally establishing NITAG and through Ministerial Dispatch dated 10th November 2015, NITAG Timor Leste was formally established.

In November 2015, with WHO technical support orientation workshop on roles and responsibilities of NITAG and NITAG members was conducted. With the support of SIVAC consultant, INTERNAL PROCEDURES MANUAL OF NITAG TIMOR LESTE, NITAG work plan for 2016-2018 and 2016-2018 Budget were developed. In November 2016, GAVI Immunization Transition plan, allocated substantial amount of funds to proper functioning of NITAG for 2017 and 2018. In February 2017, MoH extended the ownership by appointing medical doctor as a secretory to the NITAG and provided space in MoH to establish NITAG secretariat.

Cote D'Ivoire NITAG

COMITE NATIONAL D'EXPERTS INDEPENDANTS POUR LA VACCINATION ET LES VACCINS DE LA COTE D'IVOIRE (CNEIV-CI)

The "CNEIV-CI" was established in December 2009 with support of AMP/SIVAC. The political will contributed to the creation of this structure and materialized by a ministerial decree of creation and appointment of NITAG members. The CNEIV-CI has a Descriptive Project that defines its terms of reference and Rules of Procedure that specifies its operation. Ordinary meeting takes place quarterly and extraordinary meeting when needed.

The NITAG in Ivory Cost includes 17 expert members, 9 Ex-officio members, 3 Liaison members and a technical and scientific secretariat. There is a policy for Management of Conflict of Interest through the following documents: Charter of public declaration of interests, Privacy Policy and public interest declaration form. There are 3 ways of requesting advice from the committee:

- Request from Ministry of Health (e.g., age limit for administration of rotavirus vaccine, free management of AEFI)
- Request from the EPI programme: e.g., introduction of meningitis vaccine (MenAfrivac)
- The committee itself (introduction of the HPV vaccine)

From January 2010 to March 2016, AMP/SIVAC provided the following support to the NITAG in Cote d'Ivoire:

- Material assistance to the secretariat
- Financial assistance for meetings organization
- Capacity building of NITAG's members: Workshop on Method of developing evidence based recommendation, 27-29 January 2015;
- Workshop on The use of economic data to support decision-making related to immunization, 29-30 March 2016

Role of the CNEIV-CI: to provide scientific and technical advice and recommendations to the Ministry of Health in the definition, implementation, monitoring and evaluation of immunization policies and strategies

Successes

Since its creation in 2009, the CNEIV-CI developed the following opinions and recommendations for the attention of the Minister of health:

- Recommendation for improvement of Expanded Program on Immunization (EPI) performances (2011)
- Recommendation for immunization against Human Papillomavirus (2016)
- Recommendation on the introduction of hepatitis B birth dose in the EPI (2016)
- Notice on age restriction of rotavirus vaccine in the EPI (2016)
- Recommendation on the introduction of MenAfrivac vaccine into the EPI (under development)

Also, a number of scientific papers were published:

- Establishment of a National Immunization Technical Advisory Group in Côte d'Ivoire: Process and lessons learned. Vaccine 30 (2012) 2588–2593
- Process for developing a recommendation : case of vaccination against hepatitis B at birth by the NITAG in Ivory Coast (Submitted to La Société Française de Santé Publique in January 2017)
- Immunization outside the Expanded Program on Immunization in Abidjan city, Cote d'Ivoire (Submitted to Austin journal of vaccine and immunotherapeutics in January 2017)

In 2014, an independent evaluation was conducted with the following objectives:

- Analyze how the committee works in relation to WHO standards and recommendations.
- Appreciate the effectiveness, efficiency and performance of the committee
- Identify gaps and needs of the committee for optimal functioning

Methodology used was desk review (TOR of Committee, Meeting reports and technical notes or recommendations issued, review of activities) and interviews with stakeholders (Committee Members, EPI Directorate, EPI Technical Partners, Representatives of research institutions). The evaluation did not use the newly developed 2016 HPID/SIVAC NITAG evaluation tool which will be used for this year's evaluation. The main recommendations from this evaluation were:

To the Ministry of Health:

- Strengthen communication with the committee
- Provide grants for the committee

To the Committee

- Elaborate TOR of committee bodies
- Search resources for workgroups
- Increase transport allowances for members
- Build capacity of members

Challenges

- Limited availability of some Members to attend meetings
- Insufficient funding (for NITAG meeting organization, working groups meetings, and conducting studies to have local data)

Mozambique NITAG

COMITE DE PERITOS DE IMUNIZAÇÃO (CoPI)

CoPI Mozambique was established in 2011 with support of AMP. CoPI is independent, multidisciplinary, representing a wide range of disciplines, covering aspects of the immunization area, development and vaccines regulations and epidemiology of diseases preventable by vaccines.

CoPI is composed by 15 members with head by Prof. Helder Martins (2011-2013) and by Prof. Jahit Sacarlal (2014- to date). It has a secretariat (MoH team) and there are around 25 observers and guests (universities, UNICEF, CDC, USAID, FNUAP, LOCAL NGOs, etc). All member and secretariat must fill Conflict of interest and confidentiality agreement before start working with CoPI. All official observers must filled the Confidentiality agreement.

General objective: To give opinions and technical advice that can guide the Health Authorities at the highest level and the programme managers in order to allow them to take policy and strategy of health, based in scientific evidence that results from an accurate analysis of the available information in terms of immunization and diseases preventable by vaccines, including selection of new vaccines, technologies and other prevention tools, the need of adjustments of the new immunization programmes and of the vaccination calendar.

Mode of operation: Dates meeting are set for 3 years. There are 2 ordinary meeting per year (April & November) and also extraordinary meetings. Convocations are sent one month before meeting

and re-convocation one week before again. During meeting, there are presentation of news about vaccines (SAGE meeting, Researchers, etc) and systematic review, and also drafting of minutes.

To issue recommendation, working groups are established or invite expert to present specific systematic review and Epi data, a member of CoPI or Head of EPI programme is invited to present information regarding the issue in discussion. A draft recommendation is prepared during meeting and final draft presented all on the last day. CoPI member review it within 1 week period. President finalize Recommendation (with background, recommendation and monitoring indicators) and then submission of approved recommendation to Ministry of Health who sometimes meet with him to explain it and finally dissemination including posting on NRC.

Monitoring recommendation is done during every meeting of the CoPI: member discuss with EPI manager on any challenges for implementation. If necessary the CoPI invite members to help to EPI programme. An annual report is developed and sent to MoH and CoPI members.

Until last April 2016, CoPI produced 28 recommendations available at http://www.nitag-resource.org/
Recommendations issued included some of the following topics:

2011

- Improvement of EPI performance: (how to reach those that have not been reached)
- Calculation of the EPI target groups
- Needs and Priorities for the introduction of new and underused vaccines
- Reliability of the EPI data and Epidemiological Surveillance of the diseases preventable by vaccines
- Sustainability of EPI financing
- EPI Logistics and cold chain
- Measles elimination
- New vaccine paradigms
- Human Resources (training, new staff)

Regarding introduction of new vaccines, CoPI has recommended the adoption of a very ambitious plan of introduction of new vaccines, which would allow reaching the Goal of the Millennium 4 until 2015.

- Vaccine against pneumococcus in 2012 – delay to 2013,
- Vaccine against Rotavirus in 2013, delay to 2015
- Vaccine against Human Papilloma Virus in 2014, pilot study;

2014

- Recommendation to introduce new vaccines for 2015 and 2016 (Rotavirus, IPV and Measles 2nd dose at 18 months)
- Recommendation to implementing monitoring system at private clinics/ hospitals and consultation rooms to collect number of children vaccinated

2016

- Recommendation in delay on application in the pilot study of Mosquirix vaccine

- Recommendation to change the PCV10 vaccine to PCV13 in Epi program

Strengths

- Good quality of the members
- Extremely competent members in their specific areas
- More specialists in country in case of replacement
- Importance of CoPI for MoH
- Increase conscience of EPI program

Challenges

- Activities not included into the national budget for EPI and thus, lack of financial after year 2 of support by AMP
- Lack of dedicated EPI staff in organize CoPI meeting,- only in last meeting I received first person
- Some members not present at meetings (not often)

9. References

1. Iroh Tam PY, Thielen BK, Obaro SK, Brearley AM, Kaizer AM, Chu H, et al. Childhood pneumococcal disease in Africa - A systematic review and meta-analysis of incidence, serotype distribution, and antimicrobial susceptibility. Vaccine. 2017;35(15):1817-27.
2. Matysiak-Klose D, Ahmed F, Duclos P, Falck-Ytter Y, Forland F, Houweling H, et al. Report on the 1st international workshop on procedures for the development of evidence-based vaccination recommendations, Berlin, Germany, 22-23 November 2010. Vaccine. 2012;30(14):2399-404.
3. Perronne C, Adjagba A, Duclos P, Floret D, Houweling H, Le Goaster C, et al. Implementing efficient and sustainable collaboration between National Immunization Technical Advisory Groups: Report on the 3rd International Technical Meeting, Paris, France, 8-9 December 2014. Vaccine. 2016;34(11):1325-30.
4. Toscano CM, Jauregui B, Janusz CB, Sinha A, Clark AD, Sanderson C, et al. Establishing a regional network of academic centers to support decision making for new vaccine introduction in Latin America and the Caribbean: the ProVac experience. Vaccine. 2013;31 Suppl 3:C12-8.
5. Adjagba A, Henaff L, Duclos P. The NITAG Resource Centre (NRC): One-stop shop towards a collaborative platform. Vaccine. 2015;33(36):4365-7.
6. Adjagba A, Senouci K, Biellik R, Batmunkh N, Faye PC, Durupt A, et al. Supporting countries in establishing and strengthening NITAGs: lessons learned from 5 years of the SIVAC initiative. Vaccine. 2015;33(5):588-95.
7. Blau J, Faye PC, Senouci K, Dagnan SN, Douba A, Saracino JT, et al. Establishment of a National Immunization Technical Advisory Group in Cote d'Ivoire: process and lessons learned. Vaccine. 2012;30(15):2588-93.
8. Burns JE, Mitrovich RC, Jauregui B, Matus CR, Andrus JK. Descriptive analysis of immunization policy decision making in the Americas. Revista panamericana de salud publica = Pan American journal of public health. 2009;26(5):398-404.
9. Duclos P. National Immunization Technical Advisory Groups (NITAGs): guidance for their establishment and strengthening. Vaccine. 2010;28 Suppl 1:A18-25.
10. Duclos P, Dumolard L, Abeysinghe N, Adjagba A, Janusz CB, Mihigo R, et al. Progress in the establishment and strengthening of national immunization technical advisory groups: analysis from the 2013 WHO/UNICEF joint reporting form, data for 2012. Vaccine. 2013;31(46):5314-20.
11. Duclos P, Ortynsky S, Abeysinghe N, Cakmak N, Janusz CB, Jauregui B, et al. Monitoring of progress in the establishment and strengthening of national immunization technical advisory groups. Vaccine. 2012;30(50):7147-52.
12. Gessner BD, Duclos P, Deroeck D, Nelson EA. Informing decision makers: experience and process of 15 National Immunization Technical Advisory Groups. Vaccine. 2010;28 Suppl 1:A1-5.
13. Koon AD, Rao KD, Tran NT, Ghaffar A. Embedding health policy and systems research into decision-making processes in low- and middle-income countries. Health research policy and systems. 2013;11:30.
14. Ngcobo NJ, Cameron NA. The decision making process on new vaccines introduction in South Africa. Vaccine. 2012;30 Suppl 3:C9-13.
15. Nijsten D, Houweling H, Durupt A, Adjagba A. Overlapping topics in advisory reports issued by five well-established European National Immunization Technical Advisory Groups from 2011 to 2014. Vaccine. 2016;34(50):6200-8.
16. Ricciardi GW, Toumi M, Weil-Olivier C, Ruitenberg EJ, Danko D, Duru G, et al. Comparison of NITAG policies and working processes in selected developed countries. Vaccine. 2015;33(1):3-11.
17. Saitoh A, Okabe N. Current issues with the immunization program in Japan: can we fill the "vaccine gap"? Vaccine. 2012;30(32):4752-6.
18. Senouci K, Blau J, Nyambat B, Coumba Faye P, Gautier L, Da Silva A, et al. The Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) initiative: a country-driven, multi-partner program to support evidence-based decision making. Vaccine. 2010;28 Suppl 1:A26-30.
19. Silva ML, Paget WJ, Mosnier A, Buthion V, Cohen JM, Perrier L, et al. Development of Seasonal Influenza Vaccination Recommendations: Relevance and Influence of the Evidence on the Decision-Making Process in France and the Netherlands. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2016;19(5):670-9.
20. Stecher D, Gaiano A, Biscayart C, Gentile A, Ayala SG, Lopez E, et al. National Immunization Commission: strengthening evidence-based decision making in Argentina. Vaccine. 2014;32(16):1778-80.
21. Takla A, Wichmann O, Carrillo-Santisteve P, Cotter S, Levy-Bruhl D, Paradowska-Stankiewicz I, et al. Characteristics and practices of National Immunisation Technical Advisory Groups in Europe and potential for collaboration, April 2014. Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin. 2015;20(9).
22. Tricarico S, McNeil HC, Head MG, Cleary DW, Clarke SC. Informing pneumococcal conjugate vaccine policy in middle-income countries: The case of Malaysia. Vaccine.