

6-7th December 2018

Third Global NITAG Network meeting

Record of discussion

ABBREVIATIONS

ACIP: Advisory Committee on Immunization Practices

ADVAC: Advanced Course of Vaccinology

AFRO: Regional Office for Africa

ATAGI: Australian Technical Advisory Group on Immunisation

CAVEI: Comité Asesor en Vacunas y Estrategias de Inmunización (NITAG of Chile)

CDC: Centers for Disease Control and Prevention

CiTAG: Caribbean Immunization Technical Advisory Group

EURO: Regional Office for Europe

ICC: Inter-Agency Coordination Committee

ITAG: Immunization Technical Advisory Group (SEARO)

JCVI: Joint Committee on Vaccination and Immunisation

GNN: Global NITAG Network

GVSI: Global Vaccine Safety Initiative

NACI: National Advisory Committee on Immunization

NCC: National Certification Committee for polio eradication

NIAC: National Immunization Advisory Committee (Chinese NITAG)

NIP: National Immunization Program

NITAG: National Immunisation Technical Advisory Group

NRC: NITAG Resource Center

PAHO: Pan American Health Organization

PHAC: Public Health Agency of Canada

PHE: Public Health England

PIVI: Partnership for Influenza Vaccine Introduction

RKI: Robert Koch Institute

SEARO: South East Asia Regional Office

SIVAC: Supporting Independent Immunization and Vaccine. Advisory Committees

STIKO: Ständige Impfkommission (German NITAG)

The third Global NITAG Network (GNN) meeting was held on December 6-7th, 2018 in Ottawa and was jointly organized by the Public Health Agency of Canada (PHAC) and the World Health Organization (WHO) headquarters (HQ).

Day One

Anthony Harnden (GNN Chair) chaired the third meeting of the Global NITAG Network and welcomed the twenty six countries' representatives.

OFFICIAL OPENING TALKS

Joachim Hombach, Senior Health Adviser and Executive Secretary of SAGE at WHO HQ, Gina Charos, Director General at PHAC, and Caroline Quach, the National Advisory Committee on Immunization (NACI) chair, welcomed participants. The representatives highlighted the important role of National Immunization Technical Advisory Group (NITAG) members in leading the field of evidence-based decision-making and the tangible effect of vaccines on improving public health. Building on the GNN's objective to support NITAGs through peer-learning and information sharing, representatives acknowledged the value of collaborations between public health agencies and NITAGs.

MEETING OBJECTIVES:

Building on the first two GNN meetings and the NITAG support strategy driven by WHO HQ and Regional Offices with the support of partners such as U.S. Centers for Disease Control and Prevention (CDC), the aim of this third GNN meeting was to:

- 1) Review the Global NITAG Network activities and regional support to NITAGs.
- 2) Strengthen NITAGs in:
 - i. Dealing with conflict of interest; and
 - ii. Setting priorities.
- 3) Discuss the results of the NITAG evaluations.
- 4) Engage with NITAGs for the revision of training materials.
- 5) Identify priority activities for the GNN and its global partners.

1. Report on GNN activities

Louise Henaff presented an overview and update regarding GNN activities and the NITAG Resource Center (NRC). Work is progressing on the recommendations that came out of the 2nd GNN meeting, with seven of the eleven recommendations having been implemented. Indeed, monthly GNN updates are sent, a GNN membership list is available, more members were recruited thanks to the advocacy plan, the survey on off-label recommendations was conducted, the conflict of interest topic was addressed at the NITAG side meeting and the GNN meeting, collaboration between NITAGs was increased, and a GNN index was developed. The presenter discussed the role and responsibilities of the GNN chair and the steering committee members, ongoing recruitment efforts, and achievements that occurred within the last year.

The presentation focused on three ongoing projects:

- I. The twinning model, which is an approach to strengthen new NITAGs by having long-established NITAGs collaborate with nascent NITAGs to build their capacity.
- II. The training material/curriculum, which needs to be revised, building on the already existing material developed by the SIVAC initiative (Supporting Independent Immunization and Vaccine Advisory Committees) and taking into account new guidelines and inputs from trainers.
- III. The global registry for systematic reviews on vaccination (SYSVAC) that is currently further enhanced by STIKO (Ständige Impfkommission, German NITAG) alongside WHO HQ and the London School of Hygiene and Tropical Medicine. An e-learning tool is being developed and an international workshop will be held on the methods for identifying relevant systematic reviews. Funding for this project is being provided by the German Federal Ministry of Health.

It was suggested to list all upcoming advanced vaccinology courses on the NITAG Resource Center website in order to facilitate access to resources and advanced training. Philippe Duclos in charge of the Advanced Course of Vaccinology (ADVAC) also offered to organize an advanced vaccinology course every 3rd quarter in coordination with SAGE meetings.

Action points:

- ✚ Develop the twinning approach and pilot the model in two countries
- ✚ Make available the final version of the training on NITAG functioning and reviewing the evidence developed by CDC & WHO EURO
- ✚ Advocate for publication of peer-reviewed articles on NITAGs with a focus on evaluation
- ✚ Redesign the NITAG Resource Centre and rename it to brand it as GNN
- ✚ Add ADVAC schedule on the NRC

2. Regional Reports

SOUTH EAST ASIA REGIONAL OFFICE (SEARO)

Jayantha Liyanage (WHO Regional Office for South East Asia) provided an overview of NITAG and the regional Immunization Technical Advisory Group (ITAG) collaboration and ongoing NITAG activities in the South East Asia region (SEAR). The NITAGs in SEAR are producing an annual report on the monitoring and implementation of the National Immunization Program (NIP) that is presented to the ITAG. In turn, ITAG issues recommendations for NITAGs to strengthen their national immunization programs. A regional meeting to orient NITAG members and to discuss NITAGs' role and methods is planned for March 2019. In addition, an evaluation of all 11 NITAGs in SEAR is planned to take place from January to May 2019.

Participants requested clarifications on the mandate of NITAGs in the SEAR region. Jayantha explained that NITAGs have overall the same mandate as in the other regions (i.e. advise MoH, review new vaccines and technologies, update programs) but they are advocating for NITAGs to monitor the implementation of the NIPs. Similarities were noted between SEARO and PAHO countries. However NITAG mandates may vary by country.

PAN AMERICAN HEALTH ORGANIZATION (PAHO)

Nathalie El-Omeiri (PAHO) gave a presentation on PAHO's past approach to strengthen the use of economic evaluations in immunization decision-making in the Americas, via the ProVac initiative that started in 2014. ProVac was designed to promote and strengthen countries' capacities to make evidence-based decisions for the introduction of new vaccines. The ProVac expertise lies in economics, epidemiology, and decision support and models in low and middle-income countries. In 2010, ProVac networks of Centres for Excellence were developed. ProVac has exhausted its initial funding sources and has not secured new funding for 2019 and beyond. Hence, support is currently being provided only for very specific studies.

REGIONAL OFFICE FOR EUROPE (EURO)

Liudmila Mosina updated participants on the new NITAGs in the region such as Norway, Italy and Russia, with a total of 47 countries with a NITAG out of the 53 in the region. She presented on the new NITAG training curriculum format on recommendation development which was pilot tested in the WHO European region. Following the training in May with five NITAGs represented, the material will be further revised with inputs from U.S-CDC. Newly established NITAGs should be given the opportunity to be trained and go through the entire process of developing a recommendation at least once to enable the Secretariat to gain a deeper understanding of the process before developing the Standard Of operating Procedures (SOP). The presenter recommends conducting the orientation training before the NITAG develops its SOPs.

REGIONAL OFFICE FOR AFRICA (AFRO)

Louise Henaff, on behalf of Blanche Anya gave a presentation on supporting NITAG establishment and capacity strengthening in the AFRO region. There are still challenges and issues related to the sustainability of the funding, the lack of clarity of the roles of Inter-Agency Coordination Committee (ICC) and NITAGs, the lack of training and the misuse of existing guidelines available for NITAG support. AFRO took some key steps in reinforcing the support to NITAG. First, a training of trainers was organized in February 2018 to set up a pool of experts able to train NITAGs on short notice. Second, a NITAG side meeting was organized at the Regional Immunization Technical Advisory Group (RITAG) meeting and a NITAG session is being planned for the January RITAG meeting in 2019. Finally, a dedicated staff member is being hired to support NITAG strengthening activities.

Representatives from Zimbabwe and Mozambique shared their experience in training other NITAGs in the region. The importance of assigning an active role for trainers shortly after the training of trainers was underlined.

The lack of clarity of the roles of ICC and NITAGs is concerning, as many efforts have been done to get this clarified. The same confusion was voiced in the SEARO region. A survey could be done to understand how the long-established NITAGs addressed this challenge.

Action points:

- ✚ Plan a session on the role of NITAGs in relation to other existing committees in their respective countries for next year's GNN meeting.
- ✚ Conduct a survey of GNN members to better understand how NITAGs function alongside other committees and how they clarify the importance of the NITAG.

3. 2018 at a glance

SUCCESS STORIES OF THE YEAR

Caribbean: Tracy Evans-Gilbert (CiTAG-Caribbean) presented on the establishment of the Caribbean Immunization Technical Advisory Group (CiTAG), priorities, and next steps. CiTAG's success in establishing a common framework for policy and evidence-based decision making for immunization relies on their ability to build on the existing collaborations in the CARICOM. The written process for the establishment of the CiTAG will be shared for other countries to use.

China: Ma Chao (Acting Secretary of National Immunization Advisory Committee (NIAC) and the Technical Working Groups-China) gave a presentation on the re-establishment of China's NITAG (NIAC) and its working groups. The kick-off training workshop was held in China in December 2017 with the help of GNN members and was attended by all NIAC members and the working group members. During the training workshop, several In-depth case studies were presented in parallel sessions, including Tdap in pregnancy in the U.S., HPV vaccination of males in Sweden, introduction of Meningococcal B vaccine in the UK and developing and refining PCV recommendations in the U.S. The next NIAC meeting is scheduled in April 2019 and is closed to the public. The theme of opened vs closed meetings has been proposed to be a topic to address during a next GNN meeting.

Norway: In the EURO region, 37 of 47 countries have now established a NITAG. The Norwegian NITAG is one of the most recent ones. Ingeborg Aaberge (NITAG Secretariat-Norway) presented on the establishment of the Scientific Reference Group for National Immunisation Programs (Norway's NITAG), building on the experience of the Swedish NITAG and the expertise of the Norwegian Childhood Immunisation Programme. The strength of the Norwegian NITAG is that it is fully incorporated within the national health technology assessment infrastructure. This should be documented as it is a rare example of how a NITAG can interact with HTA to consider vaccine specificity.

Action points:

- ✚ Topic for discussion at the next GNN meeting: benefits and challenges of open or closed NITAG meetings

RESULTS OF SURVEYS

Karina Top presented the results from the *environmental scan of public health recommendations for off-label use of vaccines* among GNN members. Off-label vaccine recommendations are made in a range of settings and circumstances, yet few countries have SOPs in place to guide off-label vaccine recommendations. As many low-income countries use the experience of high-income countries to guide development of their SOPs, the absence of country-specific procedures for making off-label recommendations presents a challenge. The presenter concluded that best practice guidelines for developing and implementing recommendations for off-label vaccine use that recognize country contexts are needed globally. The scan will be further developed with interviews of key informants to collect more data on development and implementation of off-label recommendations.

Shawn Harmon shared the preliminary results of the scan on *legal basis for implementation of NITAG decisions*. Further investigation is needed on the topic as the scope of this pilot was relatively narrow.

Matthew Tunis reported on the quick survey conducted by NACI on *Post regulatory guidance on therapeutic vaccines*. The presentation highlighted the complex relationship between Health Technology Assessment (HTA) and NITAGs.

4. Building NITAG Structure

EXECUTIVE SECRETARIES: STRUCTURE AND FUNCTIONS

Representatives from the NITAG secretariat of UK, Chile, China and Germany gave an overview of the structure and functions of their respective secretariats.

China: The Secretariat is responsible for developing recommendations and reporting to the MoH, which makes the final decision regarding the introduction of new vaccine programs. The 37 NIAC members are currently not fully involved in the technical working groups. Technical Work Groups are led by China CDC experts from various hospitals and universities. There are currently three long-term and 13 temporary Work Groups. The Work Groups provide technical support to the NITAG and compile background evidence and relevant material for recommendations. NIAC meetings are held once per year and are arranged by the MoH. Materials and reports are shared with members one month prior to the NIAC meeting. NIAC meetings have a rule of minimum 80% attendance for recommendation approval.

UK: The Joint Committee on Vaccination and Immunisation (JCVI) is a statutory advisory committee which provides the Secretary of State with information about vaccines for the prevention of illness, including advice on considerations such as the burden of disease, safety, and efficacy of vaccines. It originated as an advisory board on polio. The JCVI meets three times per year and the Secretariat is supported by consultants and epidemiologist from Public Health England (PHE). The JCVI follows a strong process to develop the recommendation:

- ✦ Understand the issue.
- ✦ Review evidence pertaining to disease epidemiology, vaccine safety, and cost-effectiveness is gathered, as well as new intelligence about the vaccine pipeline and possible shortages.
- ✦ A systematic review may be performed in conjunction with modelling work. Both published and unpublished literature is explored. Any data gaps identified are resolved by requesting additional information from industry and other sources.
- ✦ Once modelling is completed it is sent out for peer review and sent to the subcommittee for additional review and approval.
- ✦ There is limited stakeholder consultation with academia and other organizations in the formulation of advice.
- ✦ Consensus (vote of simple majority) is required for the approval of recommendations.

The secretariat publishes the minutes within six months. Additional information can be requested by the public, however commercial or academic confidentiality restrictions may apply.

Germany: Within the Ministry of Health, the STIKO Secretariat has the following responsibilities:

- ✦ Arranging regulatory and stakeholder meetings

- + Performing systemic reviews and meta-analysis
- + Drafting recommendations
- + Collaborating with the 12-18 unpaid STIKO members

Declarations of conflict of interest are collected from speakers and Advisory Board members. Members with a conflict of interest are excluded from voting on the conflicting agenda point. STIKO meetings are not open to the public and permanent guests are non-voting. Recommendations are evidence based and developed according to standard operating procedures. There are 10 major steps for developing recommendations, beginning with prioritization of relevant topics and ending with published recommendations. The STIKO Secretariat initially formulates a public health objective which includes prevention of infection and/or sequelae. Key items that must be investigated during the process of making recommendations include vaccine effectiveness, efficacy, safety, data collected from systematic reviews, health economics analysis comparing different vaccination strategies, consideration of whether vaccination is of particular public interest. STIKO is independent from the federal government. However, a non-voting representative from federal Ministry of Health is present at every meeting. Background evidence and recommendations are published in German and English in the fall. The STIKO secretariat developed an android and IOS app in German to promote its recommendations.

Chile: Comité Asesor en Vacunas y Estrategias de Inmunización (CAVEI) was officially established in 2010, however, advisory group on vaccines' activity dates from the 1990s. The NITAG is comprised of members with expertise in a wide range of areas, including immunization, law, and public health nursing. Currently, representatives specializing in education and economics are being recruited. Meetings are held monthly; weekly supplementary meetings are scheduled as needed to continue work. Monthly meetings with the Chief of the Immunization Department ensure that interests align and foster enhanced collaboration to identify and address gaps. Up until October 2018 NITAG met with industry only if an audience had been requested; from November 2018 on, it only accepts scientific evidence submitted for review. NITAG members decline to participate in industry gatherings or conferences. The process for crafting CAVEI recommendations begins with an investigation into the context in order to gain a better understanding of factors such as epidemiology and population immunization coverage. CAVEI utilizes current global and regional available recommendations as guidance and as a proxy for main discussion topics. CAVEI uses many different sources of evidence beyond randomized control trials and this underscores the importance of having different experts as NITAG members. GRADE methodology is not used. CAVEI's Executive Secretariat works with all the key stakeholders and partners. Recommendations are submitted to Ministry of Health of Chile (MINSAL). The NITAG is associated with the state through MINSAL but not related to government changes. The Immunization Department makes decisions based on the information and recommendations submitted by CAVEI, along with other information such as vaccine product changes and required legislative changes. The secretariat is in charge of publishing CAVEI's work on its website, which promotes passive visibility.

The discussion that followed touched upon the funding sources to sustain the NITAG secretariat. In China, the funding is provided by MoH to subsidize members' travel. Currently there are no salaries provided for NIAC members, however, there are plans to discuss compensation. In the UK, there is no budget to compensate JCVI members; only accommodation and travel expenses are covered with limited funding available. There are 3.5 salaries for Secretariat staff supporting JCVI and funded by Public Health England. Public Health England (PHE) consultants are not paid; it is not in JCVI's interest to support specialists from PHE. The situation in Germany is very similar. There are only four persons in the STIKO Secretariat who work on compiling background evidence and developing recommendations and are funded by the Robert

Koch Institute. They are supported by scientists from the Immunization Unit who are allotted time to work specifically on recommendations. In Chile, MoH provides funding for NITAG meetings' associated costs (location, food and travel) and one salary for the executive secretary position.

The discussion also focused on the turnover of NITAG members and the available expertise in countries. In the UK, members serve in their post for a three year term with the possibility of renewal for two additional terms. Members may leave early and appointments are staggered to ensure staff stability. Staffing Secretariat positions with the right people is difficult; one needs to have sufficient scientific understanding of a particular area but not be a specialist in order to shift between concepts easily. Secretariat staff needs to have good writing skills to summarize information, interpret evidence correctly, and know when to be vague vs. specific to ensure the right level of detail. There are difficulties in finding appropriate persons to work on the Secretariat, especially epidemiologists. Furthermore, it is difficult to find persons for the secretariat with the skills necessary for NITAGs who are willing to work at government wages. JCVI has one international member from Switzerland. In Chile, members of CAVEI serve for a three year term with the possibility of a renewal for one additional term. After the sixth year, there is the option of membership renewal after a three-year break. In Germany, members are appointed for a three-year term and the renewal is not restricted. There is not much turnover within the German NITAG. The Secretariat does not have a fixed position for health economist in China and it was reported that NIAC members serve for a three year term. It is possible to serve on NIAC for two continuous terms. Currently, there are no international NIAC members but the committee collaborates with US CDC and other international experts.

The last point raised was NITAG collaboration with academia. JCVI works with academia but there is currently no framework for this relationship. Modelling is an important aspect of the process for the development of vaccine recommendations. There is a small group of modellers from the London School of Hygiene & Tropical Medicine and University of Cambridge in UK that work with JCVI and PHE. However, academics must be flexible enough to work with JCVI members who have very specific parameters. Working with JCVI can provide significant benefits for academics' careers because they can get publications in high impact journals and increased publicity.

CONFLICT OF INTEREST GUIDELINES

Philippe Duclos presented the guidelines on managing conflict of interests available at: <http://www.nitag-resource.org/media-center/document/3465-prevention-of-conflicts-of-interest-in-nitags>

The presentation was followed by a discussion on the language used (conflict of interest vs declaration of interest). Another question alluded to non-financial conflicts of interest such as devotion of a career to an academic idea. There can indeed be a vested interest involved in the development of a vaccine and sometimes a loss of critical judgement. Sometimes people can have a monolithic vision and while they should not be fully excluded the information needs to be balanced. It was also reminded that interest is not limited to industry. Conflicts of interest may also come from relationships with other types of organizations such as donors and funding agencies. Need to keep adjusting the standards.

CONFLICT OF INTEREST: EXPERIENCES AND LESSONS LEARNED

SAGE: Joachim Hombach described SAGE experience in managing conflict of interest: the declarations of interest are governed by organisational processes and organized through the Secretariat. The relevant forms and guidelines can be found on the SAGE website. These processes have been put into place not only to

ensure public confidence and trust in the WHO's work but also to protect the experts. This is important for upholding the WHO's reputation and ensuring ethics. All experts and SAGE members are required to submit a declaration of interest form, confidentiality undertaking and CV when they first join and prior to each meeting. This is especially important when an item related to a potential conflict of interest will be discussed. All declared interests are disclosed and information that goes back 4 years is published on the website. Screening is also conducted for members of the Secretariat. Potential conflicts of interest for experts and their immediate family members (spouse and children) should be disclosed. Conflicts of interest can be related to intellectual property, unfair commercial/competitive advantage (including close partners), and intellectual bias when experts have made public statements that bind them to a particular position. What actually constitutes a conflict of interest, including what is perceived as conflict of interest, is not always absolute. Conflicts of interest may be personal or non-personal (ex. income for an institution). Whether an interest is significant (ex. beyond \$5,000 in business or more than \$1,000 for stock) and the magnitude of interest will be highly dependent on circumstances and context. Managing conflicts of interest is often a balancing act. Alternative experts may be difficult to find and thus full exclusion or partial exclusion from the deliberation and the evidence review process may be needed for particular items. Although it is important to have people with interest at the table, careful management is needed. Ensuring that you have the highest level of expertise on the committee may require that you have experts with some connection with private industry. Therefore, meeting agendas must be carefully considered to identify areas where issues relating to conflict of interest may arise.

Australia: Hope Peisley described the Australian Technical Advisory Group on Immunisation's (ATAGI) experience managing conflict of interest: ATAGI meets 3 times per year and members are asked to declare conflict of interest before each meeting. This conflict of interest declaration policy extends to Working Groups. ATAGI's conflict of interest policy outlines the rationale and the process for how this issue will be managed. An algorithm categorizes conflict of interest into scenarios:

- + No participation in discussions
- + Participation in discussions but no involvement in decisions

To promote transparency, the conflict of interest declarations are shared with members and published online. There have been recent discussions about the conflict of interest policy. Members reported some issues with knowing what activities and affiliations should be part of the declaration. A form has been instituted for reporting the type of activity, who is managing or organizing it, and where the funding is coming from (to an organization the individual is affiliated with or directly to the individual). Members are required to explain why they were selected. For example, in Australia a number of members have been on advisory committees for safety and declared conflict of interest for transparency. However, it became apparent that the lead investigator working with the company sponsoring a product wanted to work with ATAGI. If this lead investigator came to present to ATAGI there may be conflict of interest if there are other vaccines available that may be competitive. Therefore, it became apparent that declarations of interest may need to be updated, especially if a specific product was being discussed.

Zimbabwe: Nhamo Gonah described the Zimbabwe NITAG's experience in managing conflict of interest: Zimbabwe's NITAG has 18 members with typical expertise. There are three ex-officio members. The presenter related a situation when the liaison members representing an NGO seemed to have an undue influence on the NITAG decision-making process.

France: Laura Zanetti described the Technical Vaccination Committee's (CTV) experience in managing conflict of interest in France. The French NITAG has existed since 1995. It is composed 26 members with expertise from a range of relevant disciplines. Since 2017, the new commission for immunization is hosted by the French National Agency for health 'Haute Autorité de Santé' (HAS), an independent public body, which also hosts a number of other commissions including those examining reimbursement of drugs and medical devices.

Declaration of conflict of interest is mandatory for all NITAG experts and is established by the the law. Experts working for the HAS as all as others Agencies (the French National Public Health Agency , Ministry of Health, etc.) are all required to fill in an online standardized public declaration of interests form, reporting the last five years. The forms are posted on a unique ministry website to ensure transparency. All remuneration, benefit received as well as research involvement and personal connection are documented. A declaration of interests Validation Committee chaired by a deontologist is charged with analysing declarations and evaluating all new expert candidates for conflicts of interest that may impact decision-making. The Committee also provides recommendation on how to deal with a conflict of interest situation. Because of this heavy process, when the new commission for immunization was renewed at the HAS, some long-standing experts from the previous committee were confronted with conflict of interest and could not be re-nominated.

The guide describing the different type of conflict of interests and how to respond to them is available online: https://www.has-sante.fr/portail/upload/docs/application/pdf/guide_dpi.pdf

In France, there is an exclusive conception of conflict of interests. If a conflict of interest is detected, the expert cannot take part in the working group. Furthermore, Committee experts with conflicts of interest may not be allowed to participate in debates related to the area where they have the conflict of interest and they are not allowed to vote.

DAY TWO

Christoph Steffen summarized the first day of the meeting, highlighting the active and engaged community of NITAGs that is quickly expanding through the GNN, and the increasing number of success stories as new NITAGs are being established. He also welcomed the training opportunities and collaborations with mature NITAGs that are strengthening the capacity of newly formed NITAGs. He underscored the major concepts outlined in regional updates, including the involvement of other NITAGs in evaluation process, the accountability between RITAGs and NITAGs and the effective collaboration in smaller regions. Opportunities to apply and adapt resources and approaches developed by different NITAGs are being identified and this needs to continue outside the GNN meeting.

5. NITAG evaluation

EXTERNAL EVALUATION

U.S.-CDC: Erin Kennedy reported on the two NITAG evaluation projects conducted by CDC, exploring the linkages between the national certification committees for eradication of polio (NCC) and the NITAGs as well as the NITAG integration into the policy process of vaccine introduction from initiation through implementation. The first project was a study conducted in countries in the AFRO and EMRO regions with the objective to document the collaboration between NCCs and NITAGs. The second was an assessment of NITAGs in South Africa, Argentina and Jordan. The objectives of this study were to describe the country-specific context and policy dialogue; identify relevant partners and stakeholders; and describe the integration of the NITAG into the policy process. The results of these evaluations will be shared in a comprehensive report in 2019.

Euro: John Spika presented a report on the evaluations conducted in Kyrgyzstan and Kazakhstan, using the SIVAC tool. The main recommendations following the evaluation included rethinking of the legislation supporting the NITAG, drafting of SOPs, use of working groups to prepare the statements for discussion, and training of NITAG members.

ACIP: Jessica MacNeil gave a presentation on the evaluation of the U.S. Advisory Committee on Immunization Practices (ACIP) that was required by legislative mandate. The evaluation encompassed the criteria used to evaluate new and existing vaccines, the use of GRADE and the consistency of work group processes. The secretariat helped prepare the evaluation by filling in the SIVAC tool and including links to ACIP documents (most of them can be found on the website). The evaluation was conducted by an external consultant selected through CDC process, with no experience on NITAGs. An external consultant experienced in NITAG evaluations may have been able to tailor and target questions better to get more useful feedback. Overall, interviewees felt comfortable sharing their opinions and gave positive feedback on this exercise. It was noted that the SIVAC tool did not offer the possibility to assess working groups and had to be adapted.

NITAG SELF-ASSESSMENT TOOL

Abigail Shefer gave a presentation on the simplified evaluation tool developed by U.S.-CDC, WHO and partners with inputs from NITAGs attending SAGE meeting in April 2018. This tool was a request from recently established NITAGs who wanted to improve their processes without going through a lengthy external evaluation. The tool also attempts to clearly outline the extent to which the NITAG has fulfilled the criterion for each element. The tool was pilot tested in Chile and CDC and partners are expecting other NITAGs to use it to collect additional feedback. Versions in French, Spanish and Russian will be made available.

SELF-ASSESSMENT EXPERIENCES

Chile: Magdalena Bastias Garcia (Executive Secretary of the Chilean NITAG) gave a presentation on the pilot of the simplified evaluation tool for NITAG assessment in Chile. The results from the assessment led to recommendations that CAVEI updates the terms of reference, improves the recommendation process by using GRADE, and requests systematic feedback on MoH consideration of recommendations. The results of the evaluation will be published to enable other countries to learn from the experience. Regarding the tool itself, it was suggested to add new indicators or clarify others and accompany the results with a NITAG maturity level/stage of development.

Mozambique: Jahit Sacarlal (Chair of CoPi, Mozambique NITAG) gave a presentation on his experience conducting a self-assessment using the SIVAC tool. Overall, the evaluation process lasted 3 months and was conducted by the Chair and one member of the secretariat. The chair explained that the NITAG receives funding from GAVI and the MoH does not allocate any money to the NITAG from the national budget. The main recommendations made as an outcome of the evaluation include sustaining the funding sources for the secretariat, obtaining participation from experts outside Maputo, strengthening the technical capacities of CoPi members, and revising the way meetings are planned.

A live poll was conducted through the app to identify whether GNN members were supportive of the idea of having stages of development to rank their NITAGs. 77% voted yes.

Action points:

- ✚ Develop a stages of development framework, which would enable NITAGs and partners to formally categorize the stages of NITAG growth.

6. Setting priorities

Representatives from the NITAG of Senegal, Germany, Brazil and Malawi were invited to describe their current priorities and how they set priorities. However, the discussion was broader than setting priorities.

Senegal: Anta Tal Dia (Chair of the NITAG) shared that the committee was established in 2013 and makes recommendations when requested by the MoH. The committee conducted a self-assessment in 2017, followed by an external evaluation conducted by the West African Health Organization (WAHO) in 2018. These evaluations revealed the need to foster collaboration with other professional organizations and other NITAGs.

Germany: Eva Hummers shared that the STIKO agenda is formally set by the secretariat and STIKO chair and agenda items are prioritized based on suggestions from NITAG members. According to the standard operating procedures, there must be epidemiological evidence to evaluate impact of interventions as well as evidence from peer-reviewed literature to evaluate efficacy, effectiveness, immunogenicity and safety. The public's view of the public health problem, feasibility of implementation into the existing immunization schedule, and expected future information are also considered. ETAGE does not influence the STIKO agenda. The secretariat scans scientific literature and media for emerging immunization issues.

Brazil: Isabella Ballalai shared the experience of the Brazilian NITAG, which was created in 1991. The country is divided into 27 states and all of them also have a NITAG. The federal level defines the recommendations and pay for vaccinations. States may include vaccine not provided by the federal level, but in such cases, they must pay for vaccination. The national immunization program is protected by law and public vaccination is guaranteed. Future priorities include: strengthening vaccination coverage among children, improving communication around vaccines to address and overcome vaccine hesitancy, improving vaccination uptake among adolescents and adults, including those with chronic illnesses and introducing new vaccines for adults, including those of 60 years of age and older. In case of vaccination for adolescents, priorities are shared by ministry of health and ministry of education.

Malawi: Mac Mallewa shared the experience of the Malawi's NITAG, which was incepted three years ago. The agenda is set by the Secretariat with input from stakeholders: EPI, health organizations, and the NITAG chair. As the NITAG is new, members and the Secretariat need to be trained and this is the priority; another priority is having a robust secretariat. There are competing EPI priorities. Major research institutions such as Johns Hopkins may play a role in setting agenda items; however there can be a conflict of interest when a research institution wants to fund meetings to discuss their research focus. The committee works closely with the Ministry of Health as their research agenda aligns closely with NITAG's mandate.

Action points:

- ✚ Topic for discussion at the next GNN meeting: how to increase NITAG's recognition by MoH and partners?

TOTAL SYSTEM EFFECTIVENESS:

This project originated from the need to understand the products and product characteristics by low and middle income countries, the barriers to uptake and the desire to build a more robust link between country preferences and product development. The Total System Effectiveness (TSE) objective is to create a link between country decision-making and Research & Development prioritisation. The project was pilot tested through workshops in three countries (Indonesia, Thailand and Mali) with the objective to understand how these countries were selecting products. In Mali where the NITAG had been recently established, the TSE workshop was aligned with NITAG training.

Participants were not clear whether the TSE framework would help support their NITAG. Further workshops are being planned in 2019 in French and English speaking countries in the AFRO region. The feedback will help improve the TSE project and products.

7. Breakout sessions

REVIEWING TRAINING MATERIALS

An overview was provided of the current status of NITAG training materials. Members discussed training needs, best practices, and future directions.

Revision of the SIVAC training

The SIVAC training was revised by CDC and WHO EURO and piloted in Copenhagen with representatives from five NITAGs. The four day training was conducted by three facilitators. It covered the role and composition of NITAGs, the process to review the evidence (without emphasizing on GRADE), the use of evidence for making recommendations, including information from the grey literature and other sources. It alternated between generic presentations and group exercises, using mock scenarios to contextualize NITAG work. The European training used HPV vaccine introduction as an example. The training will need to be tailored depending if the audience is a newly established NITAG or a NITAG with previous experience in issuing recommendations. Further revisions to the training materials are ongoing and the final material should be available in February.

Participants commented on the need to repackage the material and format it with a GNN template and logo to avoid circulation of different versions of the training material. It was suggested to set up a GNN working group to oversee the training material development and ensure the trainings fit NITAGs' needs. It was also noted that NITAG mandates are not limited to vaccine introduction, but also revision of existing programmes and introduction of new strategies. It was suggested that the training exercises should reflect these mandates. In the EMRO region, RITAG meetings are attached to the EPI meeting and it may be useful to link training programs with these meetings.

Task Force for Global Health

The Task Force for Global Health in conjunction with CDC conducted trainings focusing on influenza. The trainings were based on SIVAC existing material and were facilitated by ex-SIVAC staff. Workshops alone were not sufficient to allow NITAGs to issue an evidence-based recommendation on influenza vaccination. Therefore further support was provided to countries in developing a technical dossier for assessing evidence and developing recommendations. An influenza resource package was developed, which includes six modules encompassing the global perspective, disease-specific information, economics, health policy, and vaccine safety. Once the GNN Working Group on NITAG training is established, it would be helpful if the group can provide more input and comments about the helpfulness of the resource package, especially as a similar package is being planned for HPV.

Participants asked how the countries were identified for training. The PIVI representative explained that requests came from the WHO regional offices. It was also noted that disease specific training may not be the most ideal approach. However, trainings still need to be customized as much as possible because this is a more efficient and beneficial approach for countries than just providing general training.

General comments

The training package under development could include shorter refresher trainings to quickly train newly appointed members. In this regard, ACIP conducts an annual half-day training in which methods are reviewed and updated before the fall meeting. It is also important to promote country ownership over trainings of their NITAG members.

Applying the skills learned shortly after being trained as a NITAG member is very important so that recent trainees can practice the skills learned and be more likely to remember these skills in the future. Thus, practical and interactive training sessions are essential and continuous training is needed for people to consolidate and apply new skills. It would be valuable to set up a consistent mechanism to provide trainings and opportunities to apply skills learned on an on-going basis.

Some barriers were mentioned including:

- ✦ Conducting a sufficient number of NITAG training is difficult given the high turnover and rotation in roles among NITAG members. One solution for this may be to develop a brief refresher training module that takes fewer resources to implement.
- ✦ Obtaining political commitment and sufficient funding to send members for trainings.
- ✦ NITAG work is unpaid; outside training may be a motivator to recruit experts to NITAGs.
- ✦ Language can be a problem when training material and support documents are only available in English.

Action points:

- ✦ Establish GNN training Work Group that is representative of the GNN membership. This work group would support WHO in the finalisation of standard NITAG training material documents and also assist in identifying additional training gaps and solutions
- ✦ Draft the terms of reference for the Work Group
- ✦ Ensure GNN Steering Committee has representation on the training work group
- ✦ Identify the type and scope of training that is required by NITAG members

LEARNING FROM COMMON CHALLENGES

This session was an open discussion chaired by Noni MacDonald.

Funding for NITAGs remains an issue in a number of countries. More needs to be done to support NITAGs. Pressure and encouragement could be provided by GAVI and WHO (for both GAVI and non-GAVI eligible countries).

Building credibility as a NITAG comes up frequently in the discussion and the representatives' suggestions included: strengthening relationships with MOH and professional bodies, making sure there was no connection with the industry, publishing background papers and research material, being present at professional meetings and introducing to the community the critical thinking behind the decision making.

The *process to communicate and disseminate NITAG recommendations* to both MoH and the public varies. Participants suggested to develop a template for communication and/or to identify best practice examples. This can increase credibility and visibility. WHO EURO's template for crisis communications was mentioned as an example.

While countries are partnered with GAVI, GAVI does the *economic analysis for vaccine introduction*. Opportunities to learn how to do an economic analysis could be provided while the NITAG is partnered with GAVI. This could help to strengthen these skills before the GAVI partnership ends.

Participants felt it was worthwhile to attend *GNN meetings*. Countries were looking for strategies and support regarding how to create support and approvals from their governments to allow NITAG members to attend. The GNN is seen as a credible source for technical assistance. The opportunity to share successes and challenges is appreciated, especially with countries at similar or more advanced stages of NITAG development.

Action points:

- ✦ Topic for discussion: how can we improve vaccine preventable disease data quality and accessibility?
- ✦ Advocacy for GNN attendance by NITAG members to governments
- ✦ Advocacy for NITAG funding
- ✦ Develop a template for communication of NITAG recommendations

8. Future plans

The plan is to organise the next GNN meeting back to back to the ACIP meeting, allowing participants to attend both meetings. The planned date is February 2020. In the current funding situation, WHO HQ will be able to support two countries per WHO region, selected by the NITAG focal points within the regions. NITAGs are encouraged to seek support/plan for their attendance in their annual budget.

GNN is considering adding additional breakout sessions during the next meeting to facilitate discussions between NITAGs. The speed dating format may facilitate the discussion around various topics and provide networking opportunities.

The Global Vaccine Safety Initiative will be presented at the next GNN meeting, as it is important for NITAGS to have an understanding of their mandate. The discussion on NITAG barriers during the breakout session could be deepened and could be split into different breakout sessions at the next meeting.

The GNN needs to scale up and set up a work plan that includes active working groups. The GNN chair and secretariat will draft the terms of reference for the working groups and the SOPs for the GNN.

Action points:

- ✦ Set final meeting dates for the next GNN meeting
- ✦ Further discussion of the various NITAG barriers should be added to the next meeting agenda
- ✦ Include small groups discussions and breakout sessions in the agenda for the next GNN meeting
- ✦ Begin discussions regarding the location of the 5th GNN meeting; a LMIC country will be prioritized