



**Gnn**  
GLOBAL - NITAG - NETWORK

# **FOURTH GLOBAL NITAG NETWORK MEETING**

**Record of discussion**

This version was finalized in April 2020

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## Abbreviations

AEFI	Adverse events following immunization
AFR	African Regional Office
AMRO	American Regional Office
AMR	Antimicrobial resistance
ATAGI	Australian Technical Advisory Group on Immunization
EBDM	Evidence-based decision-making
EEA	European Economic Area
EMRO	Eastern Mediterranean Region
EU	European Union
EURO	European Regional Office
GNN	Global NITAG Network
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GVAP	Global Vaccine Action Plan
IA2030	Immunization Agenda 2030
ICC	Interagency Coordination Committee
IPD	Invasive pneumococcal disease
LMIC	Low-and middle-income countries
NCIRS	National Centre for Immunisation Research and Surveillance
NRC	NITAG Resource Center
PCV	Pneumococcal conjugate vaccine
RO	Regional officer
SEARO	South East Asia Regional Office
SP	<i>Streptococcus pneumoniae</i>
SR	Systematic review
SYSVAC	Systematic reviews on vaccination
WG	Working group
WPRO	Western Pacific Region
VPD	Vaccine preventable disease

### NITAGs of GNN participants

Acronym	NITAG	Country
ATAGI	Australian Technical Advisory Group on Immunisation	Australia
NACI	National Advisory Committee on Immunization	Canada
NIAC	National Immunization Advisory Committee	China
HAS	Haute Autorité de la Santé	France
STIKO	Standing Committee on Vaccination	Germany
CONAPI	Consejo Nacional de Prácticas de Inmunizaciones (National Council on Immunization Practices)	Guatemala
NITAG	National Immunization Technical Advisory Group	Jordan

NCIP	National Committee on Immunization Practices	Malaysia
CNTSCV	Comité National Technique et Scientifique Consultatif de Vaccination	Morocco
NGI-TAG	Nigerian Immunisation Technical Advisory Group	Nigeria
NITAG	National Immunization Technical Advisory Group	Norway
CCVS	Comité Consultatif pour la Vaccination au Sénégal (Advisory Committee for Vaccination in Senegal)	Senegal
TL-NITAG	Timor-Leste National Immunization Advisory Group	Timor-Leste
UNITAG	Uganda National Immunization Advisory Group	Uganda
JCVI	Joint Committee on Vaccination and Immunisation	United Kingdom
ACIP	Advisory Committee on Immunization Practices	United States

## Executive Summary

On February 24-25, 2020, the Fourth meeting of the Global NITAG Network (GNN) was convened in Atlanta, Georgia, USA. The 104 participants represented 38 WHO member states. Plenary sessions included presentations on priorities and achievements of WHO regional offices and SAGE, new approaches to systematic reviews, maturity model, decision-making support tools, ACIP meeting, GNN workplan, activities, and next steps. Break-out sessions took place on a number of topics described below.

Topic	Action points for GNN
Monitoring NITAG performance	<ul style="list-style-type: none"> <li>✓ Survey GNN on suggested revisions to the six criteria<sup>1</sup> collected annually in the WHO/UNICEF Joint Reporting Form (JRF) and recommended by WHO for functional NITAGs</li> <li>✓ Develop guidance on advocating to MoH for sustainable financing</li> </ul>
Vaccine hesitancy and creating demand for vaccination	<ul style="list-style-type: none"> <li>✓ Develop guidelines on how NITAGs address vaccine hesitancy and respond to demand for vaccination</li> </ul>
Data for action – VPD surveillance: Where to start?	<ul style="list-style-type: none"> <li>✓ Implement strategies to build capacity in data collection and analysis</li> </ul>
Managing with little resources	<ul style="list-style-type: none"> <li>✓ Provide guidance on advocating to MoH for sustainable finances and resources</li> <li>✓ Build capacity to analyze and interpret health economics data</li> <li>✓ Raise awareness among members of existing programs that provide access to high impact journals for reference (e.g., Hinari)</li> </ul>
NITAG evaluations	<ul style="list-style-type: none"> <li>✓ Translate existing tools into more languages, e.g., Portuguese, Russian.</li> <li>✓ Find opportunities to follow up on evaluation results (e.g., via twinning relationships)</li> <li>✓ Develop an evaluator guide</li> </ul>
Off-label recommendations	<ul style="list-style-type: none"> <li>✓ Explore strategies to foster dialogue among regulatory agencies, programs, manufacturers, and NITAGs</li> <li>✓ Develop guidance on how lawsuits are addressed</li> </ul>
Maturity model	<ul style="list-style-type: none"> <li>✓ Seek input from regional offices, NITAGs, and partners on maturity assessment</li> <li>✓ Include adaptations for small countries</li> <li>✓ Ensure maturity model is adaptable depending on NITAGs' mandates</li> <li>✓ Complete and pilot maturity assessment tool</li> </ul>

<sup>1</sup> WHO/UNICEF JRF criteria: (1) the provision of a legislative basis for the NITAG, (2) the availability of written terms of reference, (3) representation of at least five disciplines within NITAG, (4) conducting annual NITAG meetings, (5) advance sharing of the meeting agenda and documents, and (6) declarations of interest by NITAG members.

Other sessions addressed new methods and collaborations on systematic reviews and novel decision-making tools, but no action points emerged. In discussion of the capacity building section of the 2020 GNN work plan, participants' input prioritized evaluation, networking, and training. When asked to specify training topics, participants suggested systematic reviews, collaboration, using existing analyses, twinning, and economic evaluation.

After the meeting, 56 and 33 participants remained to attend the meeting of the United States' NITAG, the Advisory Committee on Immunization Practices (ACIP) on February 26 and 27, respectively.

ACIP session	Scope of participation
Ebola vaccine	100% attendance in person or by video in overflow room
2019 Novel Coronavirus information	
Influenza vaccine	Participants chose to either attend in person or participate in one of four facilitated discussions described below.
Rabies vaccine	
Dengue vaccine	
Polio Information	
Hepatitis B Vaccine update	
General Best Practices Update	

ACIP Workgroup leads and members made presentations and facilitated discussion on 1) Use of safety data for NITAG deliberations, 2) Role of ACIP workgroups, 3) Use of ACIP's evidence to recommendation framework, and 4) Attendee observations on ACIP structure, role of stakeholders, voting, and public comment.

## Day 1: Record of discussion during GNN meeting

The Fourth Global NITAG Network (GNN) meeting was convened on February 24-25, 2020 in Atlanta, Georgia, USA. It was organized by the GNN Steering Committee, the U.S. Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO) in coordination with the Task Force for Global Health, Decatur Georgia. The timing was chosen to allow participants to attend the meeting of the Advisory Committee on Immunization Practices (ACIP), the U.S. NITAG, on February 26-27. The details below attempt to summarize what was said by the presenters and participants. Some sessions elicited more discussion than others.

Althea House (GNN Chair) chaired the fourth meeting of the Global NITAG Network and welcomed the 57 NITAG representatives of 38 countries.

### Official Opening Talks

Joachim Hombach (WHO HQ) welcomed Althea House as new Chair of the GNN and thanked the GNN steering committee and the U.S. Centers for Disease Control and Prevention (CDC) for organizing the meeting. He stated that WHO values the role of GNN to collect and understand NITAG needs, provide access to relevant publications and tools, foster exchange and interaction between NITAGs and explore innovative solutions to NITAG barriers.

Will Schluter (CDC, Global Immunization Division) thanked the GNN steering committee, WHO regional representatives, and CDC staff. He emphasized that NITAGs add credibility to the policy process in the context of an ever-changing vaccine landscape with new products and producers, administration technologies, supply constraints, and shortages.

Nancy Messonier (CDC, National Center for Immunization and Respiratory Diseases) focused on the historical value of lifesaving vaccines, the recent emergence of novel viruses and the resurgence of preventable disease due to vaccine hesitance and highlighted the need for transparency and objectiveness in decision-making. She also discussed ACIP's use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach and an evidence to recommendation framework, with meetings open to the public, and publication of recommendations.

### Report on GNN Activities and NRC

Althea House presented key GNN milestones which include her appointment as the new chair, a new steering committee, development of terms of reference, a resourced secretariat, development of surveys to collect evidence on NITAGs, and revamped website for the NITAG Resource Center (NRC). Louise Henaff demonstrated the revamped NITAG Resource Center (NRC) website with a new search function, a dedicated training tab and request for training option, and private access allowing a forum for discussion.

Link to presentation:

## Reports from WHO Regional Officers (RO) for NITAG strengthening

### South East Asia Regional Office (SEARO)

Sunil Bahl presented that all 11 member states have NITAGs that meet the six criteria<sup>2</sup> collected annually in the WHO/UNICEF Joint Reporting Form (JRF) and recommended by WHO for functional NITAGs. He highlighted successes including enhancement of the NITAGs role in monitoring the national immunization goals and the development of a pool of facilitators. All NITAGs report annually on immunization goals to the regional TAG using a structured format. Next steps include follow up on external evaluations.

Link to presentation:

### American Regional Office (AMR)

Nathalie El-Omeiri presented that the region has 21 NITAGs of which one is a regional body for 22 Caribbean countries. She indicated that 86% met all six WHO/UNICEF JRF criteria. Successes include the involvement of 11 NITAG delegates in a WHO Regional consultation on Immunization Agenda 2030 held in conjunction with the Regional Immunization Technical Advisory Group (RITAG). Key achievements are in-depth evaluations in three countries and a training in Haiti. Next steps include a regional NITAG meeting in 2020 in Argentina.

Link to presentation:

### European Regional Office (EURO)

Liudmila Mosina reported that 50 of 53 member states have NITAGs; 70% meet all six WHO/UNICEF JRF criteria. She reported key achievements including the training of eight countries using new materials with practical hands-on exercises. Successes include support to Kyrgyzstan and Tajikistan leading to progress on a systematic evidence-based approach in developing recommendations on PCV and HPV vaccines. Next steps include evaluations of NITAGs in middle income countries (MICs).

Link to presentation:

### African Regional Office (AFRO)

Sidy Ndiaye reported that the African Region (AFR) has 30 NITAGs in the 52 member states; 60% meet the six WHO/UNICEF JRF criteria. He noted successes including support from Zimbabwe NITAG to four other countries in the subregion to build capacity and Senegal NITAG's role in countering misinformation about the HPV vaccine. Next steps include setting up a Regional Scoping Hub with the University of Cape Town to support countries in AFR.

Link to presentation:

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<sup>2</sup> WHO/UNICEF JRF criteria: (1) the provision of a legislative basis for the NITAG, (2) the availability of written terms of reference, (3) representation of at least five disciplines within NITAG, (4) conducting annual NITAG meetings, (5) advance sharing of the meeting agenda and documents, and (6) declarations of interest by NITAG members.



## Western Pacific Regional Office (WPRO)

Nyambat Batmunkh reported the presence of 12 NITAGs in 16 member states of which nine meet all six WHO/UNICEF JRF criteria. He noted the on-going development of a regional NITAG network for member states in the Association of Southeast Asian Nations as a success story. A key achievement is the re-activation of the Brunei NITAG consistent with WHO/UNICEF JRF criteria. Next steps include a visit of the PNG NITAG to the AUS NITAG.

Link to presentation:

## Eastern Mediterranean Regional Office (EMRO)

Quamrul Hasan shared information on the 21 NITAGs among 22 members states, of which 15 meet all six WHO/UNICEF JRF criteria. Key achievements include adoption and revision of national immunization policy in member states; however, decision-making processes are not consistent. Next steps include an open internet platform with access for NITAGs for collaboration.

Link to presentation:

## Break-out sessions 1

### Monitoring NITAG performance

Althea House (Manager, NITAG, Canada) presented an overview and evolution since the establishment of the Canadian NITAG in 1964. She reported that as an external advisory body, the NITAG is routinely monitored and every five years is evaluated with standard government tools. The Secretariat also evaluates technical elements. Challenges include difficulty recruiting experts in a relatively small country by population, Secretariat resources sometimes not sufficient to meet demand given ever increasing vaccine landscape, and timely web-publishing of NITAG recommendations.

Link to presentation:

Christoph Steffen (WHO/HQ) presented on the measurement of NITAG performance by several methods. He noted that since 2010, six criteria for NITAGs have been collected in the WHO/UNICEF JRF and reported as one of the Global Vaccine Action Plan indicators. As these are revised every other year (next May 2020) and the Immunization Agenda 2030 (IA2030) is currently being developed, now is a good time to consider whether to discontinue, continue, or enrich these indicators.

Perspectives and input from NITAGs in the GNN are critical.

Link to presentation:

Liudmila Mosina (EURO Regional Officer) presented on tools used to measure NITAG performance. She reported on a questionnaire administered in 2016 to NITAGs in low-and middle-income countries (LMIC) followed by a regional meeting resulted in best practices and understanding of weaknesses. The approach required minimal resources. In addition, the visit of a well-established NITAG to a LMIC NITAG

resulted in advice in clarifying NITAG and ICC roles in decision making and on interactions with the MoH.

Link to presentation:

Amina Abdul-One Muhammed (NITAG, Nigeria) presented on the Nigerian NITAG established in 2015. She reported on monitoring through the WHO/UNICEF JRF and a self-assessment conducted in 2018 that revealed strengths in independence, productivity, quality of processes and outputs, and integration into the decision-making process. A budget line for meeting costs has been approved and expertise on statistics and health economics added. Key focus areas are demand generation and financing.

Link to presentation:

Highlights of participant discussion:

- ✓ Suggested changes/additions to six WHO/UNICEF JRF criteria:
  - Change number of annual meetings from 1 to 2-4.
  - Add written records of NITAG meetings.
  - Add core competencies in Evidence-based Decision Making (EBDM) of members and Secretariat.
  - Add existence of annual workplan and goals.
  - Add % of Gross Domestic Product (GDP) provided to NITAG (measures country ownership).
- ✓ Suggested indicators or approaches to evaluate NITAG recommendations:
  - Indicate the origin of a particular policy question (NITAG or MoH)
  - Develop a method to evaluate the EBDM process used for a recommendation on a scale from 0-5.
  - Indicate the type feedback from MoH after recommendation is submitted (written, approval, rejection, request for more information, etc.)
  - To evaluate output, indicate the quantity, quality, and revisions of previous recommendations.
  - Note whether recommendations are implemented completely or partially
  - To evaluate outcome, report on vaccination coverage of recommended vaccines.
  - Indicate the role of NITAG in follow-up on the implementation of a recommendation.
- ✓ Suggest that conflict of interest guidance be broadened to political issues since it currently overemphasizes financial conflicts.
- ✓ Measure collaborations with specialists to generate necessary evidence.
- ✓ Measure ability to leverage regional support structures (RO, RITAG, NITAG network).
- ✓ Suggest each NITAG issue annual report with achievements, challenges, plans and share with neighboring countries to enable coordination.

Proposed action points:

- ✓ Develop guidance on advocating with MoH for sustainable financing and resources.
- ✓ Survey GNN members on how to revise the 6 criteria.

## Vaccine hesitancy & creating demand for vaccination

Noni MacDonald oriented participants to terminology proposed in 2014 by the WHO SAGE working group on vaccine hesitancy. She described a continuum from 'acceptance' of vaccine, to non-acceptance, to delayed acceptance. In case of stock out, the problem is supply, not hesitancy. Hesitancy is context-, time-, place-, and vaccine-specific, influenced by complacency, confidence, trust and convenience. 'Demand' is the action of individuals and the community to support vaccine and immunization programs. NITAGs should adjust recommendations to country context.

Laura Zanetti (NITAG, France) reported that France is among the top 10 countries with the lowest confidence in vaccines, with 40% of physicians and nurses hesitant. She suggested possible links to several events. In 1988, the association of Hepatitis B (Hep B) vaccine with multiple sclerosis led to temporary suspension of Hep B vaccination. In 2000, aluminium-containing vaccines were linked to macrophagic myofasciitis. A 2009 influenza vaccine campaign was impacted by worries of a conspiracy between pharmaceutical companies and government.

Cecelia Gonzales Caro (NITAG, Chile) explained that all vaccines in Chile are state funded and free to recipients. She reported coverage for infant vaccination (96-98%), and for influenza vaccination (88%) demonstrates high acceptance. It is key to eliminate problems as soon as possible to maintain trust. Reactogenicity with pentavalent vaccine was addressed by a prompt change to hexavalent. Of 16 instances of adverse events following vaccination (AEFI) involving HPV vaccination that went to court, all ended in decisions in favour of vaccination.

Sarah Mbaeyi (NITAG, U.S.) reported that in the U.S., 99% of children receive some vaccine by two years of age, and 90% receive at least one dose of MMR. She noted sub-national coverage varies (20 states with coverage <90%) which may reflect hesitance or lack of access from poverty or insurance coverage issues. Vaccination is not free but may be covered by insurance. Laws require vaccination of children entering school, but some states offer exemptions. Measle outbreaks are occurring in some pockets. A problem is the spread of misinformation regarding safety and autism.

Highlights of participant discussion:

- ✓ Mandatory vaccination for children entering schools and health care providers can backfire. Positive reinforcement and proactive information dissemination may be more helpful than vaccination mandates.

- ✓ Develop and implement strategies in LICs to talk with mothers at birth about the benefits of vaccination.
- ✓ Influence providers through medical education, incentives, and penalties to train and encourage them to promote vaccination.
- ✓ Educate children about the benefits of vaccination as a way to influence parents.
- ✓ Give positive reinforcement for people who get vaccinations.

#### Data on vaccine hesitancy

- ✓ Need data on community concerns about vaccine safety to guide development of ways to address them.
- ✓ Need record of parents' reasons for not vaccinating their children.
- ✓ In Pakistan, 20% of non-acceptance is due to pain.
- ✓ In UK, annual surveys show many do not believe in social media but trust the National Health Service.

#### Policy

- ✓ NITAGs should consider number of injection sites per immunization visit and try to minimize them.
- ✓ Emphasize to MoH the negative impact of stock-out on confidence in vaccination program.

#### Proposed action points:

- ✓ Consider GNN/NITAG role in:
  - Development of recommendations to mitigate pain during vaccination to increase acceptance.
  - Advocating for better tracking and management of vaccine stocks.
  - Tailoring messages about vaccination to specific populations.
- ✓ Develop guidelines on the role of NITAGs in addressing vaccine hesitancy and creating demand for vaccination

## Break-out session 2

### Data for action – VPD surveillance: where to start?

Imane Jroundi (University Mohamed V, Jordan) presented efforts to identify all available sources of *Streptococcus pneumoniae* (SP) surveillance data in Morocco to evaluate the outcome of the introduction of pneumococcal conjugate vaccine (PCV). She noted data gaps in measuring incidence of invasive pneumococcal disease (IPD) and antimicrobial resistance in children < five years of age due to different approaches and data description in the various surveillance systems. This experience exemplifies NITAG challenges in evaluating outcomes of recommendation due to disparate data sources.

Link to presentation:

Anta Tal-Dia (Chair of NITAG, Senegal) reported on IPD surveillance data seven years after PCV13 introduction. She said PCV13-1 and -2 coverage in 2016 was 97% and 93%, respectively; IPD surveillance demonstrated reduction in all serotypes. Challenges include implementation of molecular characterization of SP nationally, harmonization of surveillance data, and training of surveillance stakeholders.

Link to presentation:

Matthew Ferrari (Pennsylvania State University) reported on two methods of using surveillance data to parameterize mathematical models. He explained the catalytic method made inferences from age-specific serology using Demographic Health Survey data in the Democratic Republic of Congo to estimate age-specific per capita rate at which susceptible individuals contract infection and vaccine effectiveness. The triangulation method can provide relative indicators even if surveillance data are too biased to estimate absolute values.

Highlights of participant discussion:

- ✓ Models can use remote sensing to measure population distribution.
- ✓ With unreliable data sources, modelers use an ensemble approach to aggregate estimates from multiple models.
- ✓ Barriers to accessing and using data
  - Lack of local data and lack of knowledge of how to use existing data.
  - Difficulty in getting government funding for vaccine preventable disease surveillance.
  - Finding and understanding health economics data.

Proposed action points:

- ✓ Consider twinning to help build capacity in data collection and analysis.

## Case studies of latest recommendations

Thomas Harder (NITAG secretariat, Germany) reported on recommendations for Tdap vaccination during pregnancy. He outlined the decision-making process of defining priorities and public health problem; developing a question to specify patient, intervention, comparator, and outcome (PICO); defining other elements to consider for recommendations (infectious agent, disease, vaccines, implementation strategy, and risk-benefit analysis); conducting systematic review; assessing quality of evidence (GRADE); making a decision; and finalizing the recommendation. Based on 14 safety and eight effectiveness studies and survey data on acceptance, Tdap was recommended at start of the third trimester in each pregnancy.

Link to presentation:

Kristine Macartney (Director, National Centre for Immunisation Research and Surveillance (NCIRS), Australia) reported on twinning of NCIRS and the Timor-Leste (TL) NITAG. She described a five-year project involving 2-3 annual visits to TL, remote technical support, and capacity building for PCV, HPV, and AEFI causality work groups. Successes include attendance by TL NITAG chair to a vaccinology course and a tailored one-one training in secretariat functions. Challenges include language diversity and unstable internet connection.

Link to presentation:

Highlights of participant discussion:

- ✓ Using GRADE allows transparency and reveals that recommendations are sometimes made on low quality data.
- ✓ Twinning must account for time needed for well-developed NITAG to understand the level and needs of the supported country.

Proposed action points:

- ✓ Provide guidance on starting a twinning relationship, including who initiates, scope, etc.

## **Systematic Reviews: New Approaches**

Kari Johansen (European Centre for Disease Prevention and Control (ECDC)) reported on collaborative systematic reviews (SR) among NITAGs in EU/EEA Member States since 2018. She noted the voluntary collaboration supports the advisory role of NITAGs, without interfering in country decision-making and vaccine recommendations. Two models for a working group conducting SR (in-house or outsourced) are being tested to document pros and cons. A closed Extranet forum allows discussion and evidence sharing. The network fosters technical collaboration and will reduce duplication.

Link to presentation:

Matthew Tunis (Secretariat of NITAG, Canada) presented on artificial intelligence (AI) innovation projects to support the NITAG. He proposed that emerging technologies may alleviate strained NITAG workflow and improve timeliness and capacity in environment scanning, evidence collection, and knowledge dissemination. A local AI company built an automated system for SR, with an average 88% accuracy in data extraction across all PICO elements. Challenges include open access or pay-for-use medical literature.

Link to presentation:

Thomas Harder and Catherine Jo (NITAG secretariat, Germany) reported on SYSVAC, a global registry for systematic reviews on vaccination. He explained that it builds on a previous version to provide a user-friendly registry of SR on vaccination and help NITAG secretariats use them. In 2020 SYSVAC-2 will seek input from NITAG secretariats on current processes of gathering and synthesizing evidence and factors that enhance their use of databases. This will be followed by an e-learning course on how to use systematic reviews and the launch of the registry.

Link to presentation:

## Day 2: Record of discussion during GNN meeting

### SAGE report and Maturity Model

#### Report from SAGE

Alejandro Cravioto (Chair, SAGE) reported on the October 2019 SAGE meeting. He shared that given the end of the Global Vaccine Action Plan (GVAP), a new Immunization Agenda 2030 (IA2030) was endorsed to set a compelling, country-centric vision to engage immunization stakeholders. Updates were given on the use of vaccines against measles and rubella, human papillomavirus, and Ebola, as well as on polio eradication status.

Link to presentation:

- ✓ Highlights of participant discussion:
- ✓ SAGE recommendation on HPV takes into consideration the current shortage and prioritizes countries with highest burden. Specifically, if there is no issue with quantity of vaccine in country, countries can go ahead and implement a gender-neutral program. The aim is not to stop a program that is already vaccinating boys, but to delay implementation of a vaccine program for boys if it has not been put in place.
- ✓ SAGE recommendation on HPV takes into consideration current shortage and prioritizes countries with highest burden.

#### Maturity Model

Erin Kennedy (CDC, GID) presented on progress in development of a maturity model for NITAGs. She outlined the methodology that included a literature review, definition of NITAG domains, and criteria of advancing maturity within each domain. The next steps are to finalize the draft, circulate the tool among stakeholders for feedback, revision of the tool based on feedback received, integration into existing tools, pilot testing, and finalization of the tool.

Link to presentation:

Highlights of participant discussion:

- ✓ Maturity model
  - Mandates of NITAGs may differ and should be considered.
  - Model should be applicable also to very small countries.
  - Not every country needs to reach the highest maturity level.
  - Publicizing maturity of a NITAG has implications for its credibility.
  - Could be used prior to a training to ensure approach is appropriate.

Proposed action points:

- ✓ Survey all regions for feedback on maturity model.

### Break-out session 3

#### Off-label recommendations

Noni MacDonald (Dalhousie University) presented a study of recommendations for off-label vaccine use in GNN countries. She clarified that an off-label recommendation does not recommend off-license use but recommends use of licensed vaccines in a way that is not directed on the label. The aim of the study was to determine the rationale, policies, and procedures of such recommendations. The absence of country-specific procedures highlighted the need for best practice guidelines.

Link to presentation:

Ma Chao (NITAG, China) presented on off-label vaccine recommendations in China. He shared that the NIAC is currently developing guidelines for off-label recommendations because it needs to make recommendations on rabies and DTaP vaccines that are not covered in the product information.

Link to presentation:

Hope Peisley (Secretariat of NITAG, Australia) discussed off-label recommendations in the Australian experience. She noted that variations from product information are allowed and communicated through digital manual on vaccination recommendations to providers, but the individual recipient of an off-label vaccination accepts liability, for example, influenza for pregnant women.

Link to presentation:

Sarah Mbaeyi (Secretariat of NITAG, U.S.) discussed the U.S. perspective. She explained that if ACIP recommends off-label use, insurance covers the costs (influenza vaccine for pregnant women, booster doses of meningitis vaccine, and exceeding age limits in at-risk populations). ACIP recommends Td boosters every 10 years, but some providers substitute Tdap which ACIP later approved. Off-label use is communicated in the immunization schedule.

Highlights of participant discussion:

- ✓ Decisions on off-label use depends on many different factors, including safety.
- ✓ MIC MoH worry about lawsuits after off-label use.
- ✓ Need for dialogue with regulatory agency to minimize need for off-label use. Regulatory agencies can ask for a blanket statement from manufacturer, e.g., vaccine should be given in accordance with official MoH recommendations.
- ✓ Can or should the WHO develop good regulatory practices for off-label vaccine recommendations?



Proposed action points:

- ✓ Identify solutions to bring together regulatory agencies, programs, manufacturers, and NITAGs.
- ✓ Look at WHO prequalification process as way to address off-label recommendations.
- ✓ Provide information to GNN members on how lawsuits are addressed
- ✓ Include a session on off-label recommendations as a standing item of GNN meetings.

## Latest NITAG recommendations

Laura Zanetti (NITAG, France) discussed the 2019 recommendation on HPV for boys, following the 2007 implementation of HPV for girls. She noted that the French NITAG considers analysis of reports of a pharmacologic center that collects reports of adverse events. There is good acceptability for gender-neutral vaccination. Manufacturers are involved in the consultation phase of decision-making by providing written feedback.

Link to presentation:

Jamiatul Aida Md. Sani (NITAG, Malaysia) reported experiences of a committee of which 95% of members belong to the MoH and the only stakeholder is the pediatric association. They do not practice EBDM, but make decisions on pressure from the government. A maturity model may help convince the government to revise the composition (more independence) and mandate (advisory).

Link to presentation:

Celia Nalwadda (Secretariat of NITAG, Uganda) reported on the prioritization of five new vaccines requested by the MoH. She described challenges in funding, human resources, data access, access to and ability to use prioritization tools. The top 2 recommendations were partially implemented with a plan to complete implementation over the next three years. Drivers for adoption were a clear, transparent independent process, foundation of NITAG establishment, dedicated membership, and opportunities for networking with other NITAGs.

Link to presentation:

## Decision-making support tools

Kelly Moore (CAPACITI steering committee) presented on CAPACITI (Country-led Assessment for Prioritisation on Immunisation) that provides a process to structure and document EBDM using 3 frameworks: EPI programme review, decision-support, and innovation. She explained that CAPACITI can be used to prioritize or select vaccine products or strategies. After pilots in Mali, Indonesia, and Zambia, it may be integrated into NITAG training materials.

Link to presentation:

Stacey Knobler (Sabin Vaccine Institute) presented on Priority Vax, a web-based platform to support evidence-informed priority setting and decisions, originally called Smart Vaccines 2.0. She described the multi-criteria decision analysis framework that Priority Vax uses as it lends itself to the complexity of vaccine decisions. Priority Vax enables sensitivity analysis and recording the data used in the process for transparency.

[Link to presentation:](#)

## **Break-out session 4**

### **Managing with little resources**

Ingeborg S. Aaberge (NITAG, Norway) discussed the strong collaboration among Nordic countries. She said these countries coordinate on vaccine policy which includes meeting every other year, maintaining close contact on vaccine supply, and plans to work together on health economics evaluations. Challenges include funding, legal framework, different settings by country, and part-time employees.

[Link to presentation:](#)

Kristine Macartney (Secretariat, NITAG, Australia) spoke on behalf of the NITAG of Timor-Leste which receives support from Gavi, WHO, and twinning with AUS. She noted that the young NITAG is challenged by implementation issues, lack of knowledge, limited data, and funding insecurity.

[Link to presentation:](#)

Mario Melgar (Chair, NITAG, Guatemala) reported on the composition of the Guatemala NITAG. He explained that the challenge of a weak Secretariat is overcome by members doing technical work for the NITAG that would ordinarily be done by a Secretariat. Meeting venue is provided by partners and evidence for discussion provided by universities and members. Plan includes the establishment of vaccination laws and regulation and learning best practices at the Second Central American NITAG meeting in November 2020.

[Link to presentation:](#)

Nhamo Gonah, (NITAG Chair, Zimbabwe), reported on challenges with implementation of recommendations due to lack of funding. He noted that in 2020, only about 25% of the funds requested by EPI have been allocated. Major barriers exist with human resources for providing immunizations. Nevertheless, the NITAG, revitalized in 2017, has made eight recommendations.

[Link to presentation:](#)

Highlights of participant discussion:

- ✓ The greatest difficulty in resource-poor areas is the ability to have a scientific secretariat that can generate evidence-based recommendations.
- ✓ Funding from MoH after donor funding has ended requires NITAG advocacy.
- ✓ NITAGs need more access to health economics expertise.

- ✓ Funding shortfalls don't always compromise ability for NITAGs to meet, rather the impact of limited funding is felt elsewhere.
- ✓ Fruitful Scandinavian collaboration provides a promising model for resource-limited settings, e.g. many countries in Africa.

Proposed action points:

- ✓ Raise awareness and promote use of existing programs that provide access to high impact journals for reference (e.g., Hinari)
- ✓ Provide guidance on health economic analysis and interpretation.
- ✓ Provide guidance on advocating to MoH for sustainable NITAG support.

## NITAG evaluations

Nathalie El Omeiri (WHO, AMR) presented on lessons learned from NITAG assessments in Chile, Costa Rica, and Guatemala to assess functionality, quality of NITAG work processes and outputs, and integration of NITAG into the policy process. The process included a desk review, in-depth individual interviews with NITAG members and stakeholders, and group discussions. Lessons learned included understanding the assessment is not an 'audit', it is important to identify a key informant to prepare for the mission, conduct interviews prior to application of the tool, allow members to collectively complete the tool and agree on the score of each item, and record members' suggestions for improvement.

Link to tool:

Link to ppt:

Imane Jroundi (University Mohammed V, Morocco) presented on an evaluation of the NITAG of Morocco. The process included desk review and in-depth interviews. The evaluation resulted in recommendations to advocate for NITAG operating budget, seek a twinning partner, strengthen the Secretariat's skills in evaluating scientific literature, develop standard operating procedures, add research and ethics expertise to the NITAG, and build multidisciplinary teams by topic and disease. Next steps include attending trainings on epidemiology and GRADE and twin with a Francophone NITAG.

Link to presentation:

Magdalena Bastias (NITAG, Chile) facilitated real-time feedback from participants using web-based application throughout the session. Results:

Question	Most frequent response
Have you heard of NITAG evaluation?	Yes
What are major concepts in evaluation?	quality, maturity, outcome, independence, function, performance

How could an evaluation contribute to your NITAG's performance?	improvement, transparency
Would you consider discussing evaluation with your NITAG?	Yes
What concept most closely represents your understanding of the role of NITAG evaluation on NITAG performance?	strengthening, projection, planification, judging, not useful.

#### Highlights of participant discussion:

- ✓ Evaluations are best conducted in the local language. The comprehensive evaluation tool and the simplified one are currently only available in English, French, and Spanish.
- ✓ Length of evaluation varies based on quantity of documents needed to review; 3-7 days.
- ✓ Evaluations are useful for learning strengths and envisioning what steps are needed for NITAG improvement.
- ✓ Evaluation sometimes show that a NITAG is not independent or systematic; or that it functions like an Interagency Coordination Committee (ICC).

#### Lessons learned:

- ✓ Country must have interest in evaluation and self-reflection.
- ✓ Evaluations can be conducted as self-evaluation, peer to peer, or facilitated by WHO RO.
- ✓ The evaluation process includes desk review, interviews, group discussions, and then advocacy with the MoH regarding recommendations made for NITAG strengthening.
- ✓ Process when conducting external evaluations should including sharing primary observations after evaluation is completed and before leaving, followed by development of a final report with feasible and achievable recommendations.

#### Proposed action points:

- ✓ Translate existing tools into more languages, e.g., Portuguese, Russian.
- ✓ Find opportunities to follow up on evaluation results (e.g., via twinning relationships)
- ✓ Develop an evaluator guide

### **Orientation to the ACIP**

Jose Romero (Chair, NITAG, U.S.) oriented participants on the structure and function of the ACIP to prepare them for their observation of the sessions. He presented on its origins and history, role, charter language, structure of 15 voting and eight ex-

Officio members, and 31 liaison organizations. Most of the work is done by nine Work Groups responsible for data collection and analysis, presentations, and participation in discussions of the ACIP.

Link to presentation:

Highlights of participant discussion:

- ✓ One member represents consumers to ensure consumer interests.
- ✓ ACIP reviews previous recommendations in light of newer evidence.

## Summary and next steps

### Setting up 5th GNN meeting, work plans, and priority activities for the network

Louise Henaff (WHO,HQ) focused on the three pillars of capacity building in the GNN work plan: facilitating learning experiences, supporting development of tools, and twinning approach. She noted that all training materials are reviewed by the GNN and then made available on the NRC. To guide GNN work plan development, Louise elicited real time feedback on the following questions using a web-based application:

Questions	Most frequent responses
What are your priorities for the 2020 GNN work plan?	Evaluation, Networking, Training
For training, what are the priority topics that should be considered?	Systematic reviews, Collaboration, Using existing analyses, Twinning, Economic evaluation
In how many surveys are you willing to participate each year?	two

### Closing

Althea House thanked the members for their travel and participation and partners for having supported and organized the meeting. She received comments from many participants who highlighted the value of the GNN, and in particular this meeting, to further the development of their country's NITAG.

## Days 3&4: Record of discussion during ACIP meeting

The GNN meeting was planned to take place immediately before the February 2020 meeting of the ACIP; 56 and 33 participants remained to attend the meeting on February 26 and 27, respectively. Before the meeting, an orientation to the ACIP was given by the ACIP Chair. The agenda and level of participation among those having attended the GNN meeting is shown in the table below. Facilitated discussions were held to focus on some aspects of ACIP's structure and function. Workgroup leads and members presented and facilitated discussion on 1) Use of safety data for NITAG deliberations, 2) Role of ACIP work groups, 3) Use of ACIP's evidence to recommendation framework, and 4) Attendee observations on ACIP structure, role of stakeholders, voting, and public comment.

ACIP Agenda and Level of Participation	
ACIP session	Scope of participation
Ebola vaccine	100% attendance in person or by video in overflow room
2019 Novel Coronavirus information	
Influenza vaccine	Participants were assigned to either attend in person or participate in one of four facilitated discussions described below. Assignments were made based on answers to a survey on participant interests.
Rabies vaccine	
Dengue vaccine	
Polio Information	
Hepatitis B Vaccine update	
General Best Practices Update	

## Record of discussion of facilitated discussions at ACIP

### Use of safety data for NITAG deliberations

Tom Shimabukuro (CDC, Immunization Safety Office), discussed how the Immunization Safety Office is separate from the National Immunization Program to prevent conflict of interest. He spoke on post-licensure vaccine safety surveillance and research and its role in the policy decision-making process. CDC monitors vaccine safety through the passive Vaccine Adverse Event Reporting System (VAERS), the active Vaccine Safety Datalink (VSD), and the Clinical Immunization Safety Assessment (CISA).

Link to presentation:

Jane Gidudu (CDC, Global Immunization Division) presented on addressing safety of immunizations globally. Each country should have passive AEFI surveillance and can use the AEFI Global Vaccine Action Plan indicator. Resources and tools on vaccine safety were presented and the role of NITAGs in communication points of AEFI surveillance was raised.

Link to presentation:

Highlights of participant discussion:

- ✓ One participant suggested that the head of AEFI surveillance and causality assessment committee should report to NITAGs.
- ✓ Passive AEFI surveillance data can help in decision-making, but investigation of the cause of the adverse event is needed

### Role of ACIP work groups

Kathleen Dooling (Lead Herpes Zoster ACIP Work Group), gave an overview of Work Groups. Topics included the purpose and composition of Work Groups; the rules of engagement including managing conflicts of interest, confidentiality, and working with the pharmaceutical industry; and the roles and responsibilities of WG members.

Link to presentation:

Highlights of participant discussion:

- ✓ Work Group members declare potential conflicts of interest (COI), but the Secretariat makes determination on what is determined to be a conflict.
- ✓ Implementation of conflicts of interest policies is challenging for all countries; realistic examples of how countries determine conflict would be useful.
- ✓ Formal, uninterrupted presentation of work groups adds efficiency to NITAG discussions.

Proposed action points

- ✓ Compile realistic examples of COI for members of NITAG, Secretariat, and WG.

### Use of evidence to recommendation framework

Angela Guo (CDC, Division of Viral Diseases) discussed use of the Evidence to Recommendation (E2R) Framework used by ACIP during considerations for the recombinant Zoster Vaccine (Shingrix). Framework components include Statement of problem, Benefits and harms, Values and preferences of target population, Acceptability to stakeholders, Resource use, and Feasibility. Participants selected a policy question, completed an abbreviated framework, and considered the types of information needed for each component.

Link to presentation:

Highlights of participant discussion:

- ✓ Stakeholders from local areas can add to discussions on feasibility of recommendations in the E2R process.
- ✓ A limited number of national experts can be overcome by regional networks.

Proposed action points

- ✓ Leverage regional networks to provide experts from neighboring countries.

### ACIP operations

Erin Kennedy (CDC, Global Immunization Division) used an ACIP observation guide used by participants to discuss observations on the structure of the ACIP, role of stakeholders and how they are engaged, voting by core members, and public comment at ACIP. Because ACIP is governed under the Federal Advisory Act, meetings must be open to the public and the public must be able to comment.

Link to presentation:

Highlights of participant discussion:

- ✓ Public comment is disjointed from the ACIP agenda; commenters need 1-1 dialogue with ACIP members rather than the current format where the public is able to speak but there is no response from ACIP.

### Closing

Louise Henaff used the final session to thank participants for their attentive participation and to check back on their expectations. Participants unanimously expressed gratitude for the valuable opportunity to spend extended time with other NITAG members and to attend the ACIP.

Highlights of participant discussion:

- ✓ Networking with other NITAGs has been extremely useful and will help us improve.
- ✓ The opportunity to visit the ACIP was a dream come true.



On behalf of all of CDC, Erin Kennedy thanked participants for their participation and attendance. She expressed the sincere hope that countries would take their observations and lessons learned back home, and that these would be useful to improve NITAGs where appropriate.

Louise thanked participants for their input on the GNN work plan which will be finalized accordingly. She reminded participants that they received a data drive with all the presentations.