FIFTH GLOBAL NITAG NETWORK MEETING

Record of discussion

14-16 June 2023, Amman, Jordan

Contents

Abbreviations

ACIP Advisory Committee on Immunization Practices United States of America
AEFI Adverse events following immunization
AFRO Regional Office for Africa
AMRO Regional Office for the Americas
AMR Antimicrobial resistance
AMSTAR A Measurement Tool to Assess Systematic Reviews
ATAGI Australian Technical Advisory Group on Immunization
DOI Declaration of interest
EMRO Regional Office for the Eastern Mediterranean
EMPHNET Eastern Mediterranean Public Health Network
EPI Expanded Programme on Immunization
EtR Evidence to recommendation
EU European Union
EURO Regional Office for Europe
GNN Global NITAG Network
GRADE Grading of Recommendations Assessment, Development and Evaluation
HAV Hepatitis A virus
HIC High-income countries
HPV Human papillomavirus
HQ Headquarters
JCVI Joint Committee on Vaccination and Immunisation United Kingdom
JRF Joint Reporting Form on Immunization
LMIC Low- and middle-income countries
MCDA Multi-criteria decision analysis
MoH Ministry of Health
NACI National Advisory Committee on Immunization (Canada)
NCIRS National Centre for Immunisation Research and Surveillance (Australia)
NISH NITAGs Support Hub
NMAT NITAG Maturity Assessment Tool
NRC NITAG Resource Center
PCV Pneumococcal conjugate vaccine
RKI Robert Koch Institute (Germany)
RSV Respiratory syncytial virus
RTV Rotavirus
SAGE Strategic Advisory Group of Experts on Immunization
SEARO Regional Office for South-East Asia
SOP Standard Operating Procedures

SR Systematic review

SYSVAC Systematic reviews on vaccination

STIKO Ständige Impfkommission (Standing Committee on Vaccination, Germany)

TFGH Task Force for Global Health

UAE United Arab Emirates

US-CDC Centers of Disease Control and Prevention of the United States

WAHO West African Health Organization

WG Working group

WPRO Regional Office for the Western Pacific

VPD Vaccine-preventable disease

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Coordinator and facilitator

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Executive summary

The fifth Global NITAG Network (GNN) meeting was convened from 14-16 June 2023 in Amman, Jordan. It was organized by the GNN Steering Committee and the World Health Organization (WHO) with input from NITAG partners. The meeting was chaired by Dace Zavadska, GNN Chair, who opened and warmly welcomed in-person NITAG members of 39 countries and the CITAG that represents 22 countries and territories of the Caribbean and the remote audience from 67 participants from 54 countries.

The objectives of the meeting were:

1. to review the GNN activities and regional support to NITAGs;
2. to document the functioning of NITAGs after working in a pandemic;
3. to share country experience on COVID-19 vaccines and health workers vaccination;
4. to facilitate exchange on the role of NITAGs in making off-label recommendations and catch-up vaccination policies; and
5. to identify priority activities for the GNN and its global partners.

The agenda of the meeting was developed by the GNN Steering Committee and included topics identified during the NITAG partners' retreat 2022.

Plenary sessions included presentations on GNN activities, new tools for NITAG strengthening, report from and feedback to SAGE, learnings from the COVID-19 pandemic, off-label use of vaccines, catch-up vaccination, prioritization and National Immunization Programme optimization, and NITAG working groups experience on developing recommendations for RSV vaccination. Break-out sessions covered discussions on need for and timing of future COVID-19 vaccination programmes, health workers vaccination recommendations, product switch complexity in the context of vaccine portfolio optimization (GAVI). In groups, participants brainstormed on actions to tackle performance challenges, NITAG-SAGE relationship strengthening, regional networking, and actions for NITAG preparedness in the context of a health emergencies.

This 3-day meeting resulted in clearer understanding of the NITAG-SAGE communication and engagement, improved guidance on NITAGs' role in health emergencies and responding to programme recovery and catch-up, and a call for actions to address NITAG

performance challenges, and to better document the underlying drivers for the non-adoption of NITAG recommendations by the Ministry of Health (MoH).

DAY 1 Record of discussion

Official opening talks

Dace Zavadska, GNN Chair, welcomed the on-site and remote audience to the fifth GNN meeting. She summarized GNN achievements and developments since the last GNN meeting in 2020, including GNN response to NITAGs needs during the COVID-19 pandemic, e.g., through an increased frequency of GNN webinars. Dace encouraged the audience to collaborate, interact, and openly speak about their experiences, achievements, and needs.

Jamela Al-Raiby, WHO Jordan, welcomed NITAGs, country authorities, partners, and WHO HQ, regional and country offices. She described the purpose and role of NITAGs, including their support to the core principles of the Immunization Agenda 2030, catch-up vaccination, and to ensure everyone, everywhere at every age fully benefits from vaccines for good health and wellbeing. She emphasized that all NITAGs, regardless of their stages of development, share the same goal, which is to support evidence-based decision-making on immunization.

Joachim Hombach, SAGE Executive Secretary, WHO HQ, thanked the GNN Steering Committee and WHO regional and country offices for making the fifth GNN meeting possible. He recalled the last GNN meeting in February 2020 in Atlanta, the COVID-19 pandemic that unfolded rapidly afterwards and the strain imposed by it on NITAGs during the past years. Joachim reviewed the meeting agenda and provided context for each topic.

GNN report

With the mission of enhancing the ability of NITAGs to efficiently make evidence-informed recommendations on immunization through global collaboration and cooperation with input from regional networks, the GNN reported the following:

- As of June 2023, the GNN has 83 NITAG members including CITAG (serving 22 Caribbean countries and territories), a 57% increase since 2020.

- The NITAG Resource Center website was revamped based on users' feedback in 2022. New training modules have been made available.
- The GNN monthly update is received by 700 subscribers, including NITAG members, partners and interested parties.
- NITAG tools were revised with the support of the GNN.
- Increased number of GNN Steering Committee meetings and webinars during COVID-19 pandemic.
- GNN 2023 workplan includes:
  - Documenting NITAG work: NITAG roles on pandemic preparedness, results of NITAG evaluation using NMAT[1], and off-label recommendations.
  - Participate in the development of AFRO and PAHO regional NITAG networks.
  - Capacity building: revision of SYSVAC[2], training modules piloting and feedback.
  - Fostering information exchange: webinars, increased touchpoint with SAGE, and the GNN monthly updates.
  - Of note: GNN membership is entirely free and simply requires an official email from NITAG secretariat to GNN secretariat to request membership.

Discussion highlights

- Benefits GNN membership include sharing of experiences and promotion of NITAG production, closer collaboration, support from peers and partners, up-to-date information on global and regional policies and tools, exposure to SAGE recommendations and deliberations.
- Interest of countries in gaining insight into what neighboring countries within the same WHO region are doing, through regional or subregional networks.

Global indicators and trends for NITAGs

The six NITAG functionality indicators remain the official measures. Currently, 81% of the global population is covered by a functional NITAG.

Two new indicators were added in 2021, i.e., "at least one recommendation issued by NITAG" and "at least one recommendation adopted by the MoH". Of existing NITAGs, 75% issued at least one recommendation in 2021, 87% of functional NITAGs, and 38% of non-

[1] https://www.nitag-resource.org/resources/complete-guide-using-nmat
[2] https://www.nitag-resource.org/sysvac-systematic-reviews/about

functional NITAGs. A majority of countries with NITAGs in all regions saw their MoH adopt at least one recommendation (ranging from 63% of countries in AMR, to 82% in SEAR)

Discussion highlights

- Need for better understanding the process of NITAG recommendation adoption by MoH. **Action point:** Conduct a study on the process of NITAG recommendation adoption by MoH, in different countries/settings.
- Lack of data about the existence of recommendations not adopted by MoH.
  Action point: Document NITAG recommendations not adopted by MoH to understand the underlying drivers explaining non-adoption.
- The NITAG data collected through JRF is not completed by NITAG representatives, which explains some inaccuracies. The Information is checked and reviewed by WHO focal points yet final revisions and endorsement lie with country focal points.
- JRF will be revised to have one single question for core membership expertise, advising new areas of expertise to reflect the life-course approach.
- The NITAG functionality remains monitored by the 6 core process indicators. The supplemental output indicators will provide additional information and trends.

Available tools for NITAG strengthening

The NITAG Support Hub (NISH) for Africa.

NISH[3] has signed a memorandum of understanding with AFRO and EMRO, partnership with WHO to propose vaccinology training in the African continent. This one-week course offers training customized for NITAGs in areas that include health systems, evidence-informed decision-making, health economics, mathematical modelling, epidemiology, immunology, immunization priorities, and design thinking. Additionally, NISH organizes webinars and research stays, and develops library guides and evidence guide maps.

To date, 32 countries have benefited from those vaccinology trainings, either as part of a face-to-face training on the evidence-to-recommendation process or during the annual July dedicated course.

Tools for NITAGs developed by RKI in partnership with EURO WHO

[3] http://www.vacfa.uct.ac.za/vacfa_nish

The **NITAG Evaluation Tool**[4] is an extensive questionnaire compiled from existing evaluation tools. The aim is that NITAGs identify strengths and areas for improvement, looking at their functionality, quality of work and outputs. The tool includes an improvement plan to document the process of addressing identified challenges. The tool has been used by Belarus, Uzbekistan, Albania, Armenia, Bosnia, Kazakhstan, Moldova, Serbia, and Turkmenistan, while many other countries are planning to participate in the evaluation. Both external and self-evaluation versions of the tool are available for implementation.

The RKI-WHO EURO **EtR**[5] training, based on existing WHO EURO training material and standard operating procedures from long-functioning NITAGs is an adapted tool for use among NITAGs with limited resources. In a four-step process while includes 1) policy question, 2) elements to consider, 3) evidence, and 4) recommendation– the training provides support in the development of the policy question, systematic collection of the evidence using generic criteria tables, and systematic and transparent synthesis of the evidence using EtR framework.

The **template for NITAG terms of reference**[6] (ToR) is a form compiled from existing NITAGs' ToRs and WHO guidance for establishment and strengthening of NITAGs. It facilitates the development and revision of NITAG ToRs. The template is generic and should be adapted to each country context.

SYSVAC by RKI in partnership with WHO

The SYSVAC[7] project is both a global registry of systematic reviews on vaccination and an online course. Both the registry and online courses are integrated into the NITAG Resource Center website and thus freely available.

The registry allows NITAGs to identify relevant systematic reviews that have been screened using MEDLINE/PubMed, Embase, The Cochrane Database of Systematic Reviews, and iL·OVE Database[8] by Epistemonikos. As of May 2023, 2 009 systematic reviews have been included in the registry, which is updated monthly. Information on accessibility, link to full text, quality rating using the AMSTAR2 quality appraisal tool, date of last literature search,

[4] In publishing process
[5] https://www.who.int/europe/publications/i/item/WHO-EURO-2022-5497-45262-64756

[6] https://www.who.int/europe/publications/m/item/template--terms-of-reference-of-the-national-immunization-technical-advisory-group

[7] https://www.nitag-resource.org/sysvac-systematic-reviews/about
[8] https://iloveevidence.com/

number of included studies in the review, and tags for topic, population, disease, and region/country are displayed for each systematic review.

The e-learning courses on the use of existing systematic reviews, with a version both for beginners and advanced users, offer interactive learning, handouts to download, a test of knowledge and a certificate upon completion of the course.

NITAG Maturity Assessment Tool (NMAT) by US-CDC in partnership with GNN, WHO HQ and regional offices and TFGH

Based on the Capability Maturity Model methodology, the NMAT working group defined maturity levels and identified core NITAG capacities and functions which became the tool's indicators and sub-indicators. The NMAT[9] aims at identifying the NITAG maturity level and building up an improvement plan to meet recommended capacities, structures, and functions.

The evaluation can be done as self- or external assessment. It consists of determining a maturity level for each indicator. This provides a baseline measure of function that can be used for repeat assessments. The tool can be used to assist in NITAGs strengthening activities over time and to communicate NITAG needs to MoH.

Discussion highlights

- Although essential for NITAG work and public health purposes in general, at a local level there is a gap in epidemiological and surveillance data generation and quality.
- The use of a tool like EtR strengthens the NITAG recommendation process and decision-making transparency.
- RKI-WHO EURO EtR training concept is similar to TFGH's.
- NMAT and RKI-WHO EURO evaluation tools are complementary.
- External assessments take more time but give more insight and a more balanced view of NITAG functionality and areas for improvement. Many NITAGs start with a self-assessment, which is less resource intensive.

[9] https://www.nitag-resource.org/resources/complete-guide-using-nmat

Learnings from COVID-19: Impact on NITAG performance. How to be prepared for future similar scenarios?

NITAG survey on COVID-19 policy development process

The survey was requested by the GNN steering committee in September 2021 and echoed the needs of SAGE. The response rate was 45%. Results indicate that for 63% of the countries, the NITAGs were the main advisory body. In 57% of countries there were additional COVID-19 vaccination committees where, in 72% of them, NITAGs had also representatives. In 38% of countries with dual committees, no formal interaction mechanism existed between the NITAG and the COVID-19 committee.

Only a small percentage of NITAGs noted an increase in staffing capacity to accommodate the extra policy workload (18%), while multiple guidance statements on COVID-19 vaccination were issued (82% of responding NITAGs).

Over half (58%) of NITAG recommendations were adopted by MoH and the main reasons for not adopting recommendations were political choices (product choice, social measures, equity choice), differences/inconsistencies with other committees' recommendations (age cutoff, list of comorbidities) and logistical issues.

WHO SAGE interim recommendations were the most accepted and reliable source of information among NITAGs to inform policy development.

The most frequent challenges when producing COVID-19 vaccination recommendations were the prioritization of population groups and safety concerns. Most significant policy enablers were the interaction with other NITAGs and improved access to WHO global level recommendations and emerging evidence.

Review of Recommendations on NACI Pandemic Functions

The National Advisory Committee on Immunization (NACI) in Canada conducted a review in October 2021 in response to concerns about the unmanageable workload on this committee during the pandemic. The review intends to identify the key stressors for NACI in order to improve the committee's way of working during a pandemic.

Phase 1 of the review included key informant interviews with select NACI Executive, past and current and unstructured interviews focusing on what was working well, what the challenges were, and opportunities for improvement. Phase 2 of the review used an online survey open to voting members, liaisons, ex-officio representatives, and NACI secretariat staff and key informant interviews with NACI members, liaisons, and other NITAGs

comparable to NACI. Data collection was centered around processes, secretariat-provided support, communication, and wellness.

The recommendations include ensuring meetings are efficient and well managed, e.g., by activating the COVID-19 working group and by planning ahead to ensure members know what work is coming to them, ensuring key information is presented at each meeting; provide acknowledgement and appreciation, e.g. by scheduling in regular breaks for the members, considering rotating “vacations” for members, explore ways to make voting members and liaisons feel engaged, valued and energized; facilitate communication, e.g. developing a communication strategy including identifying and supporting persons who engage with media on NACI’s behalf, by providing media training and other supports for key spokespersons for NACI, adding a communication specialist to the NACI secretariat; and continue to facilitate NACI’s work through strategic planning and partnerships.

Panel discussion highlights

- The extension of NITAG members mandate to guarantee continuation of WG and avoid rotation of members during emergency scenarios.
- Participation of NITAG members in additional COVID-19 vaccination committees improves communication between groups.
- Increased number of meetings to respond to the emergency.
- Interim recommendations produced by COVID-19 working group can inform MoH directly without being endorsed by the NITAG itself.
- Access to local data is challenging in some settings where registration is on paper and then digitalized.
- Lack of adult vaccination platforms caused challenges for COVID-19 vaccination roll-out.
- Regarding COVID-19 vaccination in children, the audience discussed the occurrence of political pressure experienced in the decision-making process and the challenges faced in access to vaccines.
- Communication specialists are needed to provide guidance during health crisis to improve and enhance the public trust in vaccines.

Group work highlights

In groups, participants were asked to come up with the first steps a NITAG should carry out in the event of a new pandemic:

- It is critical that NITAGs are seen as competent bodies to advise the MoH during emergency scenarios. This mandate should be reasserted.
- Communication with MoH should be more frequent, e.g. via weekly meetings. This should be reflected in the SOP, which should include a pandemic action plan that defines how the NITAG should operate during an emergency scenario.
- Increase human resources and avoid rotation of members during an emergency scenario.
- Establishing working groups with relevant expertise is helpful not only to address the different aspects of the emergency but also to allow NITAG members to take time off in turn and accommodate the heavy workload.
- NITAGs should be more proactive to communicate with the media and scientific community. Media training should be offered in advance and a spokesperson should be identified.
- Networking with other NITAGs is seen as a great enabler to get early access to information and recommendations and pool resources. GNN and regional networks are seen as one way to convene and share information in a timely manner.

Breakout sessions

GAVI Vaccine Investment Strategy and vaccine portfolio optimization

GAVI **Vaccine Investment Strategy**[10] (VIS) is the prioritization process for inclusion of new and underused vaccines that will be made available to countries through GAVI vaccine support programmes.

Under an evidence-based approach to identify immunization investments for future strategic cycle(s), while sending valuable advance signals to vaccine developers and suppliers, VIS reassesses investment strategies every five years and reviews vaccine for endemic and epidemic diseases. However, diseases with epidemic / pandemic potential can be evaluated in real time, outside five-year cycle in response to a public health threat or an R&D milestone for a priority pathogen. The VIS 2024 longlist (based on a landscape analysis carried out by WHO) includes licensed and/or pipeline vaccines against eight pathogens: Mpox and COVID-19; dengue; chikungunya, hepatitis E, group B streptococcus, tuberculosis, and

[10] https://www.gavi.org/our-alliance/strategy/vaccine-investment-strategy-2024

shigella. In June 2024, the GAVI Board will take a final decision on vaccines to be added to the Gavi portfolio between 2026 – 2030.

Vaccine Portfolio Optimization refers to the opportunity or requirement for a Gavi country to switch from the current vaccine product, schedule or use to more opportune one(s) containing the same antigen. Potential benefits and impacts could include reduced programmatic complexity, reduced cold chain space, improved efficacy, effectiveness or safety, increased coverage, reduced costs, and securing vaccine availability.

Gavi supports countries with vaccine optimization and switches by enabling awareness of available options on the Gavi menu, facilitating an evidence-based impact assessment of the vaccine switch based on six criteria (efficacy and effectiveness or safety; ease of use; coverage; cold chain, transport and storage; financial sustainability; and supply availability and security), and offering switch grants to cover some of the implementation cost.

There are several optimal times to consider vaccine optimization and switches: changes from manufacturers, such as changes in product supply availability, pricing, or new presentation; new evidence and recommendation (new SAGE recommendations or WHO position papers); or critical timepoints in countries' context (Gavi's Full Portfolio Planning, updating their NIS, or transitioning out of Gavi support).

Countries switching vaccine preferences can impact the market and affect vaccine choices available to other countries. Therefore, Gavi works closely with UNICEF and WHO to ensure switches have a net positive impact on a specific country while not negatively impacting the market. As more options become available on the Gavi menu, vaccine portfolio optimization will become increasingly relevant for countries' vaccination programmes moving forward[11].

Discussion highlights

- Country eligibility for GAVI was explained. The Gross National Income per capita cutoff is decided by the World Bank. Countries below the cutoff threshold are eligible.
- A comparative advantage of GAVI is its market shaping role because it procures vaccines in large quantities. By investing in vaccines, GAVI provides a signal to manufactures.
- GAVI has a diagnostic team to help NITAGs tailor vaccine choices based on specific country context.
- GAVI Health Systems Strengthening can be used for NITAG activities.

[11] https://www.gavi.org/our-support/guidelines

- To understand the full value of vaccines - vaccine costs, implementation and operational costs must be considered, along with other criteria that are key to ranking vaccine value. These may include health impact, value for money, equity, GAVI's comparative advantage, economic impact, and other modulating criteria (e.g., the broader benefit to the health system, alternative interventions, and the feasibility of implementation). GAVI is interested in feedback from NITAGs on key ranking criteria.
- In an investment case, where arguments are made to invest in a vaccination strategy, regional vaccine manufacturing could be considered. However, the same will not apply to the key ranking criteria because the regional vaccine manufacturing processes are new and their development and level of maturity to be reached remains to be seen.

Evidence used to recommend health workers vaccination

With focus on sharing NITAG experience on health workers vaccination, the introduction to the session was given by WHO, followed by two country examples: France and Brazil.

WHO defines health workers as “all people engaged in work actions whose primary intent is to improve health”, and the benefits of their vaccination as their protection against occupational exposure to VPDs, patient safety, health system strengthening by protecting workforce, and positive health behavior modelling. WHO published recommendations outlining the importance of vaccinating health workers against a number of antigens including measles, hepatitis B, influenza, and meningitis. WHO’s Implementation Guide for Vaccination of health workers outlines how a policy and framework for health worker vaccination can be developed and integrated into existing national occupational health and safety policies and programmes, as well as how health worker vaccination strategies and practices can be implemented, communicated, delivered, and monitored.

Vaccination is also a key intervention for all occupational health and safety programmes, and is included as a right to safety in the workplace, under the WHO health worker safety charter.

In **France**, the health worker vaccination framework was revised in 2022. It was requested to include acceptability, and to consider societal and ethical aspects of mandatory vaccination. The French National Health Authority (HAS) followed the assessment criteria defined by the Haut Conseil de la Santé Publique that includes the risk of exposure for caretakers (patient to caretakers' transmission), risk of transmission to patients or persons

under their care, severity of the disease, effectiveness of the vaccination, and the potential adverse effects of vaccination (frequency and severity). A preliminary recommendation was drafted followed by a public consultation to collect stakeholders' viewpoints. The amended recommendation state that vaccination against diphtheria, tetanus, and poliomyelitis is strongly recommended for students and professionals; COVID-19 vaccination is strongly recommended; and vaccination against hepatitis B for students and professionals working in institutions and exposed to the risk of contamination should remain mandatory while for self-employed professionals exposed to a risk of infection it should be made mandatory.
Currently, vaccination recommendations on pertussis, influenza, hepatitis A, measles, mumps, rubella, and chickenpox are being revised. Public consultation will take place in June and July 2023 and final recommendations will be available in late August[12].

In **Brazil**, health workers vaccination includes DTP/dT (3 doses) and Tdap booster (every 10 years), Hepatitis B (3 doses post-vaccination serology (anti-HBs)), measles, mumps, and rubella 2 doses, chickenpox (2 doses), if susceptible, yellow fever, influenza (annual dose), and COVID-19 (primary and booster doses). Special situations in which vaccine could be offered include vaccination against meningococcal disease group C vaccine – subject to epidemiological situation – and Mpox vaccine for laboratory professionals directly exposed to virus. Senior health workers that fall into the older adult vaccination recommendations may access pneumococcal, herpes zoster, and high-dose influenza vaccines via the supplemental healthcare system in Brazil.
Applied to the case of influenza vaccination for health workers, part of the evidence reviewed for decision-making in Brazil included risk of infection, which is increased for health workers compared to the general population (demonstrated during the 2009 influenza pandemic but less clear for seasonal influenza); infection transmission to patients, most often affecting older patients; and health workers vaccination benefit to patients since increased immunization coverage of healthcare professionals was associated with decreased morbidity from influenza and/or pneumonia in adult hospitalized patients, but not in the pediatric wards.

Need and timing for future COVID-19 vaccination programmes

[12] https://www.has-sante.fr/jcms/p_3456351/fr/actualisation-des-recommandations-et-obligations-vaccinales-des-professionnels

Representatives of SAGE, JCVI and NACI presented the state of the art in their current respective COVID-19 vaccination work.

SAGE presented the **revised WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines** that reflects the evolving situation of COVID-19: Abundance of vaccine while programmatic constraints persist; high population-level immunity >90% in all countries; Omicron causes overall less severe disease and less post COVID-19 conditions compared to pre-Omicron variants; the pandemic has peaked and transitioned globally into an endemic situation; significant fatigue in countries; cost-effectiveness/opportunity cost considerations become increasingly important.

In response to five policy questions – 1) What is the optimal timing for additional booster doses in older persons? ; 2) Do healthy younger adults (aged 18-59 or 18- 49) need additional boosters? ; 3) Do healthy children and adolescents (aged 6 months to 17 years) still need primary series in the context of Omicron and high population immunity? 4) Do health workers need additional booster doses? ; and 5) Do pregnant persons need additional booster doses? – the revised roadmap provides updates for COVID-19 vaccination in relation to new priority-use groups, specific recommendations for primary series and boosters according to priority-use groups, need and frequency for boosters beyond the first booster dose, variant-containing vaccines, vaccination during pregnancy, and post-COVID-19 conditions.

The roadmap will be further adapted should new variants of concern emerge that do not have characteristics of Omicron, in the event of significant changes in COVID-19 disease epidemiology, or changes in vaccine attributes that are relevant to the roadmap.

JCVI is reflecting on the question of **how to adapt the Covid-19 vaccination programme to the UK high population immunity context**.

The primary aim remains the prevention of severe disease, hospitalization, and death. In the absence of cost-effectiveness data, the number needed to vaccinate (NNV) to prevent one event (hospitalization, ICU admission, death) is a tool the JCVI is using in decision-making. NNV decreases with risk and age, a drop observed around age 70.

The complex and fast changing health impacts, e.g., asymptomatic COVID-19, symptomatic non-hospitalized COVID-19, and post-COVID syndrome for non-hospitalized, are challenges to cost-effectiveness estimation.

Considerations for a future COVID-19 vaccination programme include age (strongest driver) and whether primary series with booster dose(s) offer should align; re-evaluation of clinical

risk groups; programmatic and operational delivery considerations; and equity considerations.

To determine whether to continue with bi-annual vaccination which targets those most at risk or to move to a seasonal programme, better data on the durability of protection and special consideration for some cohorts, such as the immunocompromised is required.

In **Canada**, **NACI** is currently working on the policy question of who should be offered a fall booster around the following themes: universal versus targeted age / risk-based population, potential for alignment with influenza recommendations, benefit of boosters to individuals under 18 years of age, potential off-label booster for children under 5 years of age, if / how past history of infection should be considered, and should the duration of the fall booster programme be limited.

There is no rationale for a new fall programme, but a combination of factors may point towards an additional COVID-19 vaccine dose for some. COVID-19 hospitalizations and death remain, relatively to the other risk groups, highest in older adults and unvaccinated individuals.

By March 2023, seroprevalence due to infection data in Canada shows highest levels of seropositivity in children and young adults at 80.9%. Seropositivity due to infection decreases with increasing age: 75% in middle-aged adults (40–59 years) and 65% in older adults (60+ years). The data for children is limited. Seroprevalence may give an indication of groups to target in future vaccination campaigns.

Off-label use of vaccines

Aiming at sharing NITAG experience with off-label use of vaccines and their relationship with regulatory agencies, the session was opened by **WHO** with an **introductory presentation** on technical aspects of off-label use of vaccines that was followed by a **panel discussion**.

Off-label use of vaccines is understood as the use of a product for an unapproved indication or for use not described in the approved labelling. Off-label recommendations tend to be directed at groups usually left out of clinical studies such as pregnant persons, people with comorbidities, and immunosuppressed individuals. Phase IV post-marketing studies are required by regulatory authorities for continued safety and effectiveness monitoring of a vaccine and to support an extension of the label to different population groups, different

schedules use, number of doses or route of administration. However, the kind of design of studies that usually support “off-label” use of vaccines (cohort and surveillance) differ from those required for market authorization and may not be sufficient for label change. Of note, product labels are owned by the manufacturer. SAGE may issue off-label recommendations if there is a clear benefit for specific population groups, in case of vaccine shortages, or to improve programmatic ease and cost savings and respond to a disease outbreak.

Potential limitations to off-label use of vaccines are liability concerns (adverse reactions, breakthrough infections) and decreased confidence in the vaccine or in the market authorization process, which may lead to reduced vaccine uptake or a lack of confidence in immunization programmes.

The results of a 2020 NITAG survey on off-label recommendations (68% response rate) show that 54% responding countries made off-label vaccine use recommendations and 43% had policies for implementing off-label recommendations. Barriers to off-label recommendations included liability concerns, lack of off-label definition, and reluctance of manufacturers to update product information. Facilitators, on the other hand, include confidence in the decision-making process, transparency, and open communication with stakeholders.

Panel discussion highlights

- NITAG engagement with regulators and manufacturers regarding data to inform decisions is needed. This dialogue could identify important public health use cases, and if not covered by the clinical trials programme and the intended label, the regulator could ask for such evidence to be produced.
- Communication of the rationale of the decision for off-label use could help transparency and liability.
- Regulators can request dedicated post-authorization data that could facilitate future label extensions.
- Liability claims should be protected by no-fault compensation programme as long as supported by federal or state recommendation.
- Regulators and NITAGs could consider strengthening their relationship. Chile is an example of close collaboration where a NITAG member sits in the regulator’s medicinal products for human use assessment committee. Also, Chile NITAG recommendations have served as input for the process of harmonization of vaccine-related documentation between the MoH and the regulatory agency.

- AEFI compensation programmes and increased post marketing surveillance could strengthen off-label recommendations.

DAY 2 Record of discussion

Report from SAGE

SAGE is the principal advisory group to the Director-General of WHO for vaccines and immunization across the life-course and the main advisory board on vaccine policy and technical guidance for GAVI, the Vaccine Alliance, and the Global Policy Eradication Initiative. SAGE advises national immunization programmes (NIPs), NITAGs and RITAGs through its position papers, meeting reports, interim guidance, and statements.

SAGE interaction with NITAGs occurs in many ways: GNN chair attends the SAGE meetings, all NITAG members may attend SAGE meetings virtually, RITAGs chairs may underscore NITAG needs during SAGE meetings, SAGE digest webinars after each SAGE meeting, GNN webinars that host SAGE members, and GNN monthly updates that disseminate SAGE's work. The SAGE agenda-setting process incorporates country needs via RITAGs.

Discussion highlights

- NITAG-RITAG-SAGE dialogue could be intensified.
- SAGE provides global guidance and specific implementation guidance is provided by RITAGs to address regional and national differences.
- Local epidemiological and surveillance data helps the customization of SAGE recommendations which in turn allow better interpretation of vaccine utility. SAGE supports local data production indirectly by indicating gaps of evidence needed to be filled locally.
- Timeliness of SAGE recommendations have been flagged as an issue, especially during COVID-19. Yet, timeliness is impacted by different factors, including staffing resources and the time to gather necessary data for strong recommendations. SAGE recommendations need to be of relevance at global level and cannot always address very country specific and time limited concerns.

- SAGE works primarily with published and peer-reviewed information on authorized products available in the public domain.
- SAGE WG are established around the time when a licensed product becomes available. For novel indications and complex products, work starts ahead. In the case of tuberculosis, there is preparatory work currently.

Feedback to SAGE

Aiming at strengthening the relationship between NITAGs and SAGE, breakout groups were asked to discuss how has SAGE contributed to NITAG's work and how SAGE can continue to evolve to meet NITAGs' needs.

Discussion highlights

- SAGE is the main advisory body whose work informs and supports NITAGs. However, NITAGs are not necessarily aware of SAGE processes and workplan. Therefore, ongoing outreach to NITAGs must continue to ensure awareness of SAGE's role and work.
- All NITAG members should receive an invitation to participate online in the SAGE meetings.
- NITAGs welcome the SAGE digest webinars as a direct communication channel with SAGE. However, they flagged that a clearer communication flow with RITAGs would also be needed, especially if RITAGs embody the NITAGs' voices in the SAGE meetings.
- There are different immunization-related needs between LMIC and HIC, and within WHO regions that should be highlighted and addressed.
- SAGE should avoid ambiguity in its recommendations and include definition of key concepts in the reports. The conditionality of recommendations stems sometimes from insufficient data, which then prevents SAGE to provide strong recommendations. Thus, interim statements can serve as provisional guidance until new or more evidence becomes available.
- NITAGs can participate in defining priorities for SAGE particularly through RITAGs, i.e., providing suggestions of topics where global policy is needed.
- NITAGs could consider giving SAGE feedback on policy implementation issues.

Catch-up vaccination policies and schedules: What is the role of NITAGs?

The session was opened by WHO with an introductory presentation followed by NITAG examples of their role on catch-up vaccination: ATAGI, Timor-Leste NITAG, and CITAG.

Catch-up vaccination refers to vaccinating an individual who is missing doses for which they are eligible per the national immunization schedule. Providing catch up vaccination via routine service delivery should be an essential and ongoing part of all immunization programmes. This way, catch-up can reduce dropouts, increase overall population immunity, integrate mobile populations into national immunization programmes, improve immunization system resilience, and reduce need for and frequency of catch-up campaigns. WHO guide "Leave no one behind" outlines the key policy and programmatic considerations for implementing catch-up vaccination across all aspects of the immunization programme. WHO also offers recommendations for interrupted or delayed immunization. Based on their NIP schedules, all countries should have a catch-up schedule that includes age cohorts for whom the catch-up schedule applies; minimum age and maximum/upper age limits; and minimum intervals permissible between doses for each antigen. Across the life course, multiple catch-up schedules for different groups will be needed because vaccine presentations, number of doses required, and minimum intervals differ by age.
Challenges to catch-up vaccination include lack of health worker understanding around delayed vaccination schedules, concerns about multiple injections, insufficiently designed data collection tools, concerns about wastage and/or vaccine supply management, low home-based record retention, and financial sustainability. A whole system life course approach is required for catch-up vaccination and some strategies include training of health workers on checking vaccination status at every contact and on catch-up eligibility, routine catch-up, and NITAG engagement in the revision of current policies.

ATAGI presented the **Australian National Immunization Catch-up Calculator**[13], NICC, an automated tool to determine a catch-up schedule. The tool is able to provide a clear and timely catch-up schedule for an individual patient. The tool is more efficient than manually determining a catch-up schedule. ATAGI was involved in the development of this user-friendly tool that significantly saves time and reduces errors. Available online and compatible

[13] https://immunisationhandbook.health.gov.au/catch-up-calculator/calculator , accessed 12 September 2023.

with mobile devices, the calculator considers the recommended schedule, additional rules for specific populations, minimum age for each dose, minimum intervals between each dose, formulations / brands available for each age group, contraindications, and nationally funded vaccines. Currently available for children under 10 years of age, NICC is expanding to include people up to 20 years.

The **NITAG** of **Timor-Leste** presented its work on PCV introduction for infants. Within this work, the NITAG recommended catch-up vaccination in children 1 to 4 years of age with one dose of PCV vaccine to accelerate the impact of PCV introduction on pneumococcal disease. The recommendations followed an evidence-based approach that included data generated locally by the pneumococcal carriage study composed of the hospital carriage study completed in 2021, the community carriage study ongoing during 2023, and the PCV serosurveillance study in planning phase. NCIRS supported the drafting of the recommendation.

To improve vaccination coverage and improve vaccine confidence in the PAHO region, the **CITAG** proposed a legislative framework for the Caribbean based on locally generated data. They conducted qualitative research on regulations and legislations concerning childhood vaccination in the Caribbean subregion, completed a comparative analysis of the legislative frameworks, and analyzed trends in vaccination. CITAG found that most countries have a legislative framework for school entry, with variability in the framework, sanctions and exemptions, and limited dedicated budget to complement the vaccination programme. Themes around which the immunization legislation will be modelled include vaccination as public good, duty of every parent to have their child immunized, anyone who impedes a child from being vaccinated is liable, children must be adequately vaccinated according to age at entry into school/ nursery, exemption from vaccination should be limited to medical reasons only, and provisions for sanctions are necessary to increase compliance with the law.

Discussion highlights

- Support is now available from GAVI for additional vaccine quantities needed for countries to provide catch-up with certain antigens up to five years of age and contribute to build a system for catch-up vaccination that is in place as part of the immunization programme.

- Legislation and delivery services are to be taken into account when developing a catch-up schedule and tools (such as a catch-up calculator) in a country.
- Out of 40 NITAG responders to the menti survey on site, 23 indicated that catch-up vaccination has been recommended and 10 that catch-up vaccination is included in their NITAG workplan. The schedule of catch-up vaccination was the element considered most frequently by NITAGs in their in past catch-up recommendations.

NITAG performance challenges

WHO AFRO and EMRO presented jointly on NITAG performance challenges identified during recent NITAG evaluations. The presentation was followed by a breakout activity where groups were asked to identify actions and best practices to overcome the identified challenges.

NITAG performance challenges identified by AFRO, EMRO, and actions and best practices to tackle the previous are described below:

NITAG establishment and composition	
Challenges	**Actions and best practices**
• ToR once developed not regularly updated • No official competition for core members selection	• New members should be oriented when joining • Ensure there is a scientific secretariat • Extend membership outside health agency • Terminate the membership of members if they do not follow the requirements
NITAG independence and non-bias	
Challenges	**Actions and best practices**
• Declaration of interest (DoI) limited to core members • Limited sharing of documentation publicly	• DOI policy should be extended to NITAG secretariat and experts sitting in WG • Prepare documentation for internal use and for external use. Publish only external documentation to keep sensitive information confidential • MoH to take action to publish the approved recommendations
Resources and secretariat support	
Challenges	**Actions and best practices**
• Lack robust and sustainable funding • Gaps in documentation and limited access to reliable local data • Insufficient human capacity for secretariat	• Dedicated full-time NITAG secretariat rather than EPI manager covering that function • Identify and involve international NITAG experts when there are limited skilled professionals for a specific topic area • Raise the NITAG visibility to get more funding during scientific days of medical association for example

	• Request to have a dedicated budget to MoH but can also investigate with NGOs and medical association
Operations	
Challenges	**Actions and best practices**
• Lack SOP or update of SOP (e.g., during pandemic) • Irregular meetings • Lack of systematic evaluations of the NITAG	• Include a chapter on operations during pandemic in the SOP • Flexibility of mode of meetings (online, in-person, hybrid) • Regular self-assessment (not necessarily with NMAT could be other tools)
Making recommendations	
Challenges	**Actions and best practices**
• Lack of rigorous and standard process	• Use a framework • Build up a workplan • Organize regular horizon scanning to anticipate upcoming topics
Integration into policy making process	
Challenges	**Actions and best practices**
• Monitoring of recommendations not formalized	• Ask formal feedback from MoH on each recommendation • If there is no answer, programme a reminder • MoH could appoint NITAG members into ministry technical working groups
Stakeholder recognition	
Challenges	**Actions and best practices**
• Majority of NITAGs not open to inputs from the public • Limited dissemination of recommendations	• Agree with MoH on what the public can and should know • Develop and design a webpage dedicated to the NITAG • Commit to publish scientific position paper every year • Developed policy briefs drafted in lay terms • Create a feedback mechanism open to public experts • Involve stakeholders at the start of the process • Publish the NIP and a brief history of the different recommendations produced by the NITAG over the years

Discussion highlights

- The NMAT was new to many in the audience. The wording of the tool's indicators proved difficult in some cases. **Action point**: Several NITAG members and RITAG chairs called for a revision of the NMAT indicators.

Respiratory syncytial virus

The purpose of the session was to facilitate NITAGs discussion on latest scientific evidence around current RSV vaccination policy development. The session was opened by WHO with an introductory presentation followed by NITAG experiences on RSV working groups.

WHO presented RSV disease burden in children under 5 years of age in whom RSV is a leading cause of severe respiratory infection, pediatric hospitalization, and pediatric mortality. Controlling RSV is critical in the larger pneumonia fight because it is the most common cause of infant pneumonia and bronchiolitis and a leading cause of pneumonia deaths in the first 6 months of life. It causes up to 40% of severe pneumonia cases before 1 year of age and increases vulnerability to pneumonia caused by other viruses and bacteria. Most RSV data are from high-income areas. More RSV testing and surveillance is needed, particularly in low- and middle-income areas.

Currently, no RSV vaccine is licensed to prevent infection in early life. Short-lasting monoclonal antibody that can prevent severe RSV in high-risk infants is available, although expensive and impractical for LMIC. There are two new products likely to be available soon for RSV prevention in early life: a long-acting monoclonal antibody (L-mAb) and a maternal vaccine. For both, the earliest possible SAGE review would be in 2024. RSV product costs are still unclear; however, the leading products are not anticipated to be affordable for LMICs without subsidies. GAVI approved RSV prevention in infants as part of VIS for 2021-2025.

ACIP started consideration of products for prevention of RSV disease in infants 12-18 months before potential licensure. ACIP shared its considerations of the candidate RSV immunization products, L-mAb and maternal vaccine, in terms of their characteristics, proposed indication, efficacy against outcomes of interest and timing for dosing. Issues related to immunization product safety and efficacy, as well as shifting epidemiology, implementation, and health economics are complex and inter-related.

FDA decisions regarding licensure of the RSV immunization products are expected in the third quarter 2023. If licensed, ACIP votes regarding public health recommendations will follow shortly thereafter[14].

In **Finland**, the **RSV NITAG WG** is being established while the discussion on RSV prevention is growing in the public domain. Medical societies have already posed key cost-

[14] https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/rsv.html.

effectiveness, operational and programmatic questions around the RSV candidate products, including target groups, time of administration, and if the products should be introduced in the NIP.
As for previous vaccination introduction processes, the Finnish NITAG work on RSV prevention product introduction will follow a four-step approach: sufficient public health disease burden, vaccine safe to the individual (benefit / risk), vaccine safe on population level, and intervention reasonably cost-effective.

In **South Africa**, **NAGI**'s preparation for RSV prevention introduction includes working around the following questions: clarity on the burden of RSV disease, understanding of the meaningful efficacy or effectiveness threshold, safety of the vaccine in target population, investment capacity for cost-effectiveness / impact on burden, competing immunisation priorities, ability to get meaningful vaccine coverage of target group, impact of introducing a dose on the whole schedule, logistical considerations, registration status, and what WHO/SAGE vaccine specific guidelines will be.

DAY 3 Record of discussion

Regional sessions for networking

To promote regional networking and experience sharing, NITAGs gathered by WHO region to discuss success stories and improvement plans.
WHO regional offices focal points opened their respective sessions with a presentation of the NITAG status in the region. These included progress of NITAGs functionality, support available to NITAGs, existing or developing regional networks (PAHO and AFRO), evaluations conducted.

Selection of NITAGs' stories of success

Country	Area of success/ improvement	Brief description
Belgium	Interests' management	• Systematically, an ethics committee is checking potential conflicts of interests for all members and experts involved in the recommendation making process. Minor conflicts of interests are written in the recommendation for full transparency.
Serbia	Improve the evidence to recommendation process	• The NITAG attended EtR workshop organized by EURO and established the first working group to revise HPV schedule
Libya	Establishment and functioning	• Newly notified NITAG (Nov 2022) – self-assessment of the NITAG that led to the updated ToR and SOP • First time to have NITAG members to sign declaration of interests • Intend to use the EtR format for new vaccine introduction
Kuwait	Vaccine introduction Programme implementation	• Gender neutral HPV vaccination, for 9 to 45 year old. Recommended in May 2022 despite low incidence of cervical cancer. • Vaccination schedule optimization – multiple injections reduction while maintaining the robustness of the vaccination schedule • Identification of missing vaccinations using electronic vaccination registry
PAHO	Network	• Creation of the regional NITAG network • Increased publication of recommendations (Paraguay, CITAG, Argentina)
Madagascar	Establishment and functioning	• Formally established in October 2022, members have been identified from the national academia. All NITAG members have been trained both on their role and responsibilities and the EtR process. • Six on-site meetings since its inception. Invitation is sent two weeks prior to the meeting and use of online technology. • One consultant contracted out to support the secretariat.
Lao People's Democratic Republic (PDR)	Recommendation	• NITAG was involved in the COVID-19 pandemic and helped prioritize population for vaccine access. • NITAG issued a specific recommendation for returning migrants into Lao PDR
China	Prioritization	• Introduction of new vaccine – large pipeline so needed a scientific mechanism to decide which one to prioritize. They used a MCDA tool to select prioritized vaccines (varicella, HPV, HAV, influenza)
SEARO	Evaluation	• External evaluation of the 11 NITAGs. All countries have a NITAG and the regional office wanted to assess their impact in countries. Although there are variations in the functionality level, they all contributed to the new vaccine introduction and monitoring of the national indicators in countries.

Prioritization and National Immunization Programme optimization

With the purpose of gaining insight into the NITAG vaccine prioritization process, the session was opened by WHO with an introductory presentation and live survey followed by a discussion in plenary.

Immunization-related decision-making takes place in different complex scenarios that include country interest in introducing a new product, coverage increase to improve efficiency, and research and development investments for disease prevention for which there currently is no vaccine. Vaccine introduction and NIP optimization respond to local drivers/epidemiology, health security, socio-economic impact, political considerations- and to external factors- global recommendations, health emergencies / pandemic and outbreaks, donor or manufacturers driven priorities.

Prioritization and optimization through strategic trade-off decisions include the assessment of feasibility (supply availability, political will), sustainability (financial implications), and impact (health impact, equity, programmatic improvements) in an evolving context where long term objectives can be disrupted by immediate needs. Agility is required to reshuffle priorities. The session aimed at triggering discussion on the role of NITAG to support these prioritization efforts.

Discussion highlights

- The notion of prioritization can be interpreted differently and clarifications on the definition would be helpful to refine the scope of NITAG engagement in the process.
- NITAGs felt they should play a role in the prioritization process, to support the country government in the best investment when there are limited resources for immunization. Both in vaccine introduction and immunization programme planning.
- Elements that NITAGs consider critical for prioritization recommendations are disease burden and cost-effectiveness as well as feasibility.
- Some NITAGs have already been requested to support their MoH on vaccine prioritization.

- There are tools to help with prioritization decision-making. EtR can help the prioritization process as well as multi-criteria decision analysis (MCDA) tools. The Country-led Assessment for Prioritization in Immunization (CAPACITI) is an MCDA tool designed for questions that require comparison of two or more options.
- Economic analysis versus cost-effectiveness threshold: JCVI conducts cost-effectiveness studies that allow them to establish what cost per vaccine would be cost-effective for vaccine introduction.

Closing remarks

The meeting closed after reviewing the key messages and the highlights of the discussions. The benefits of being part of GNN were emphasized, including that it is free, that the network provide a wealth of information and exposure to the work and activities of other NITAGs, a platform where NITAGs can find support, flag their needs and identify opportunities for collaboration, leading to the development of appropriate tools and constructive discussion with relevant stakeholders.

A survey was conducted to evaluate the fifth GNN meeting and to collect information for future activities.