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Working Group

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Acronyms

AMP-HPID	Agence de Médecine Préventive-Health Policy and Institutional Development Unit,
	WHO collaborating center for evidence informed immunization policy-making
COVID-19	COronaVIrus Disease-2019
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Agreement
EMA	European Medicines Agency
EU	European Union
EU-JAV	European Union - Joint Action on Vaccination
GAVI	Global Alliance for Vaccines and Immunization
GDPR	General Data Protection Regulation
GNN	Global NITAG Network
GVAP	Global Vaccine Action Plan
Hib	Haemophilus Influenzae type b vaccine
HPV	Human Papilloma Virus vaccine
IPV	Inactivated Polio vaccine
MoH	Ministry of Health
MS	Member State
NFP	National Focal Points
NIP	National immunisation Programmes
NIAC	National Immunisation Advisory Committee
NITAG	National Immunisation Technical Advisory Group
NRA	National Regulatory Authorities
PAHO	Pan-American Health Organization
PCV	Pneumococcal conjugate vaccine
PICO	Patient/ Problem, Intervention, Comparison and Outcome
SARS-CoV-2	Severe Acute Respiratory Syndrome CoronaVirus 2
SAGE	Strategic Advisory Group on Immunizations
Tdap	Tetanus, diphtheria, acellular pertussis vaccine
ToR	Terms of Reference
UNICEF	United Nations Children's Fund
VPD	Vaccine-Preventable Diseases
WHO	World Health Organization
WP	Work Package





Executive summary

National Immunization Technical Advisory Groups (NITAGs) are independent, multidisciplinary groups of national experts, tasked with providing scientific evaluations and recommendations to their respective ministries of health and other stakeholders, to enable them to make evidencebased immunization-related policy and programme decisions, including recommendations on vaccine introduction and immunization schedules. It is generally agreed among experts in this field that increased collaboration is desirable, not only between individual NITAGs, but also between NITAGs and other EU/EEA competent authorities and their networks (e.g., ECDC, EMA). This could reduce the duplication of efforts that frequently occurs between different NITAGs and different organizations, in the assessment of the evidence for making vaccination-related policy decisions. It would also make possible a more efficient process for making evidence-based decisions, through the sharing of literature reviews and other data, and improve dialogue between EU experts involved in preparing the evidence in the different organizations, and in generating new evidence.

In the context of the European Joint Action on Vaccinations (EU-JAV), Task 4.3.2 of Work Package 4 aimed to "*Explore the possibility to establish an appropriate cooperation structure between EU/EEA NITAGS*". The methodology used for this deliverable is as follows: i) review of existing documents on establishing cooperation structures between NITAGs and competent authorities, and identification of existing EU/EEA NITAGs; ii) collaboration with European Centre for Disease Prevention and Control (ECDC) and the newly established system for EU/EEA NITAG (or equivalent expert Committee) collaboration for the sharing and generation of scientific evidence on EU authorised vaccines and their use in immunisation practices, and iii) perform a survey on NITAG costs and tools. The survey also aimed to better understand the legal framework of NITAGs, their functioning, how topics and research questions for evaluation are defined, whether the NITAGs have budgets, terms of reference, and whether the latter make any reference to possible collaborations with other NITAGs.

Regarding the review of existing documents on establishing cooperation structures between NITAGs, at the EU/EEA level, discussions around the issue of strengthening collaboration between





NITAGs have been ongoing since 2010. A 2017 report carried out in the framework of the Vaccine European New Integrated Collaboration Effort known as the VENICE project (supported by ECDC through a grant until May 2018), found a considerable duplication of work carried out by NITAGs and a need for improved collaboration e.g. by jointly assessing the scientific evidence related to a specific vaccine which contributes to a considerable extent to the decision-making by each NITAG. Another VENICE report entitled "*Roadmap for improving collaboration on data, methodology and resource sharing to support NITAGs in the EU/EEA*" included a proposal for a network and a hypothetical scenario for collaboration.

Effective and synergistic collaboration occurred between the ECDC and EU-JAV projects, with a continuous bidirectional exchange of information. During the project, collaboration occurred in survey development, attendance at respective meetings and comments on respective reports.

The EU-JAV survey on NITAG costs and tool used was launched in January 2020. Sixteen of 29 invited NITAGs completed the EU-JAV survey by 15 September 2021. The institution/person responsible for appointing the NITAG members is usually, with few exceptions, either the Ministry of Health or the national public health institute. Different institutions are involved in deciding the research questions/work plan. Many NITAGs do not have a budget, and when a budget is available, it is limited and mainly covers expenses related to travel or subsistence or NITAG functioning, but not expenses for generation of evidence. This is often performed by staff at public health institutes, during their working hours. Half of responding NITAGs produced at least five outputs each in the five years preceding the survey, using a range of tools, including estimation of disease burden, systematic and non-systematic reviews, meta-analyses, expert opinion, modelling, and health economic assessments. However, most were not able to quantify the costs for producing the outputs, most likely because of the reasons stated above (work performed by PHI staff during normal working hours). In some cases, cost information was reported to be confidential. However, lack of resources was frequently reported by NITAGs

There were very few examples of previous collaborations, with only few NITAGs reporting to have previously collaborated with other NITAGs. All the reported collaborations occurred in an informal manner; no formal agreements were established between NITAGs. Finally, although most NITAGs





had ToRs, most did not include a reference to collaboration with other NITAGs. Ideally collaboration between NITAGs should occur within the context of a formalized network, and the pilot ECDC collaboration initiated in 2018 is an example of such a network. Implementing collaboration requires that NITAGs be committed to sharing information and documents, that the terms of reference of the collaboration be defined and endorsed by all members. The collaboration may consist in sharing already completed documents and joint work to develop common documents.

It is known that NITAG sustainability and functioning requires secured adequate funding that ensures the availability of at least one full-time secretariat post and the possibility of providing independent, evidence-informed advice to policymakers. The problem of funding is relevant also to collaborations between NITAGs, during which it is necessary to make clear the funding source of any joint work.

Besides lack of resources, other obstacles in collaborating with other NITAGs commonly reported in our survey, were lack of time, heterogeneity in policy, legal and health system settings, lack of agreement on methods, different priorities, the high number of NITAGs in Europe and differences in their national roles.

During the COVID-19 pandemic, NITAGs faced many challenges in developing vaccine recommendations. Although the ECDC expert network was created mainly to jointly develop and share scientific products and outputs, such as systematic reviews, new ways of collaboration were implemented during the pandemic, by using regular and timely webinars to facilitate dissemination and exchange of information on COVID-19 vaccines. Likewise, the WHO Regional Office for Europe, with the support of the Robert Koch Institute, organized a series of webinars, provided materials and remote technical assistance to address the challenges faced by NITAGs.

This innovative approach provides new opportunities for more frequent sharing of information and experience, communication, and easier participation of international experts, and should be further built upon. As highlighted by WHO-Europe, this format can be regularly used in the future also for online trainings which can include all members of NITAGs and their secretariats as well as varied interested colleagues from MoH, public health institutes and others. It may also facilitate participation of NITAG members in other country's NITAG meetings as observers (i.e., peer-topeer learning).





Based on the information collected, we propose the following recommendations to strengthen collaboration between EU NITAGs.

- Further develop the online webinar format to allow countries to have opportunities to more frequently and directly share experiences, data and technical resources. Besides communication the format can also be used for training.

- Establish an online platform to allow members of the collaboration to interact and share documents and materials. A web platform has been developed by the ECDC in the context of the EU/EEA NITAGs collaboration but has not been fully completed; more work is needed to increase uptake and usage by the members. Of note, the WHO Regional Office for Europe is planning to establish a EURO regional online platform for NITAGs in the entire Region.

- To avoid duplication of resources, when deciding the NITAG workplan, choosing or initiating work on a specific research question, NITAGs can, through the online platform, verify what relevant evidence has already been produced by other NITAGs. Consideration may also be given to exploring the possibility of jointly examining the evidence with other NITAGs. Based on our survey results regarding the institutions/persons involved in deciding the NITAG research questions/workplans, consideration can be given to evaluating the possibility of further expanding the existing EU/EEA collaboration network to formally include not only National Focal Points (NFP) for vaccine-preventable diseases (which only in some cases are also NITAG Chairs or members of NITAG secretariat), but also inviting other relevant experts and representatives of Ministry of Health and public health institutes to participate. In some cases, the latter may already be represented in the collaboration for their role as NFP. Participation should be voluntary and should not hamper NITAG work and independence.

- The cooperation structure should have specific ToRs that describe the framework and terms of the collaboration. This strategic document can be shared and approved by all NITAGs wishing to participate in the network.

- Each NITAG should also include in their own ToRs a reference to possible collaboration with other NITAGs, and the terms of collaboration and sharing with other NITAGs.

- Attempts should be made, in individual countries, to quantify the costs incurred for NITAG evaluations. Funding is important to facilitate the work of NITAGs and, as highlighted by





our survey results, several countries reported this as an issue at the national level for collaborations between NITAGs, with most work within the individual NITAGs being performed free of charge. Besides national funding, EU funds could also be tapped on for collaborative across-country projects.

- Individual NITAGs and the existing ECDC NITAG collaboration group are encouraged to interact with other NITAG networks (e.g., GNN), as relevant.

The implementation of such recommendations could also be taken into account by the ECDC in its efforts to strengthen collaboration across EU/EEA NITAGs in the interest of maximizing the use of platforms, tools and collaborative efforts already in place.





Background and objectives of the deliverable.

National Immunization Technical Advisory Groups (NITAGs) are independent, multidisciplinary groups of national experts, tasked with providing scientific evaluations and recommendations to their respective ministries of health and other stakeholders, to enable them to make evidence-based immunization-related policy and programme decisions, including recommendations on vaccine introduction and immunization schedules. In 2011, the World Health Organization (WHO) recommended that NITAGS or other equivalent expert committees be established in each member country. At the World Health Assembly in 2012, countries endorsed the Global Vaccine Action Plan (GVAP) 2011-2020, agreeing to establish NITAGs by 2020 that conform to the international standards defined by WHO. (1, 2)

Although NITAGs are organized differently in each country, there has long been a recognized need for increased collaboration and/or sharing of resources between individual NITAGs in different countries and at regional and global level, to help minimise the duplication of work that occurs across countries and facilitate greater evidence-based decision making (3). This was also highlighted by the Strategic Advisory Group of Experts (SAGE) on immunization; in their April 2017 meeting, members stressed the importance of NITAGs as a core institution of well-functioning immunization programmes, urged that countries, WHO, partners and the donor community continue to provide support and facilitate the work of NITAGs and their secretariats in order to meet the GVAP 2020 goal, and noted that fostering collaborations between countries and at regional and global level was essential for success (4,5). However, NITAGs worldwide are facing numerous challenges in fulfilling their roles, as highlighted in a 2017 literature review performed by the SIVAC Initiative at the French Agence de Médecine Préventive (AMP) and Health Policy and Institutional Development (HPID) Center (2). These include funding challenges, lack of work plans and agendas, lack of human resources, insufficient training on evidence-based review processes, language, and limited access to critical literature and publications.

In the context of the European Joint Action on Vaccinations (EU-JAV), Task 4.3.2. "*Explore the possibility to establish an appropriate cooperation structure between EU/EEA NITAGs*" aims to map the legal frameworks and operational platforms needed for establishing an appropriate cooperation structure between EU/EEA NITAGs and other EU/EEA competent authorities and their networks (e.g. ECDC, EMA). Specifically, the described aims of Task 4.3.2 were to:





1) put forward EU-level and national legal, technical frameworks and operational criteria for decision-making on vaccination policies and available platforms relevant for an EU/EEA cooperation with the support of ECDC, and

2) perform a survey on the range of attributable costs and tools used for the most recent MS-NITAG evaluations available. The collected information and tools can serve as the basis for a pilot of a technical collaboration, in view of establishing an active cooperation structure across NITAGs that can be sustainable at EU level with support from the ECDC.

Methodology used to produce this deliverable

The methodology used for this deliverable is as follows:

- Review of existing documents on establishing cooperation structures between NITAGs and competent authorities, and identification of existing EU/EEA NITAGs.

Some work has already been done, at the regional and global levels and at the EU/EEA level, to increase collaboration and/or sharing of resources between individual NITAGs in different countries, help minimise the duplication of work that occurs across countries, and facilitate greater evidence-based decision making. Therefore, the first step in this deliverable was to identify existing EU/EEA NITAGs and other stakeholders and review the existing documentation on strengthening NITAG collaboration (e.g., VENICE, Global NITAG Network & NITAG Resource Center).

- Collaboration with ECDC.

A few months after the launch of the EU-JAV project, in October 2018, the European Centre for Disease Prevention and Control (ECDC) established a system for EU/EEA NITAG (or equivalent expert Committee) collaboration for the sharing and generation of scientific evidence on EU authorised vaccines and their use in immunisation practices (6). This is a network of experts in the field of public health and immunisation from across the EU/EEA who are working within or supporting national NITAG. The decision regarding the launching of this network had been held





at the 53rd meeting of the ECDC Advisory Forum in May 2018 (7). The aim of the network was to develop an EU/EEA-wide system for the exchange of existing and new scientific evidence and the joint generation of up-to-date scientific evidence on vaccines and immunisation practices between EU/EEA NITAGs (or equivalent expert committees), their secretariats, ECDC, and key partner organisation

In establishing the network, EU/EEA Countries were each asked to nominate two national experts well informed on key priorities for the national immunisation programme, the needs around the scientific evidence to support immunisation-related decisions, and areas where EU-wide collaboration to share and/or generate scientific evidence would bring value, to contribute to the project. The two experts should ideally be members of, or working closely with, the country's NITAG or similar body e.g., National Focal Points (NFP) for vaccine-preventable diseases, NITAG Chair or NITAG secretariat depending on national structures). One of the nominated experts would serve as a core member of the group while the other would be an alternate member.

The ECDC initiative in fact anticipated the EU-JAV objective of examining the feasibility of implementing a collaboration between NITAGs and putting forward legal, technical frameworks and operational criteria for the collaboration. The EU-JAV was identified as a key stakeholder of the ECDC project. To avoid any duplication of efforts between the ECDC-supported collaboration and the EU-JAV, EU-JAV and ECDC worked closely to create synergies in the two projects.

- Survey on NITAG costs and tools.

We developed and online survey and shared it with ECDC. The questionnaire was then piloted for comprehensibility and answerability by three reviewers from three different EU/EEA countries (Germany, France, and Finland), all of whom were familiar with NITAGs.

To identify the persons to whom the questionnaire should be sent to, EU-JAV Member State Committee Members were asked to send contact details of NITAG chairperson of their country. In January 2020, 29 NITAG chairs of consortium Member States and other EU/EEA countries were invited to participate in the survey, through the Survey Monkey tool. A personal link was provided





for accessing the questionnaire which could be completed at different times, since information entered each time was automatically saved.

The survey was initially open from January 2020 to September 2020. Participation was impacted by the ongoing pandemic and as of 25 September 2020, only 10 of 29 invited countries had responded: Belgium, Croatia, Estonia, Federation of Bosnia and Herzegovina, Germany, Ireland, Italy, Malta, Norway, Sweden. In August 2021, we attempted to further increase participation in our survey by contacting NITAG chairs that had not originally responded, and in so doing we increased the response rate of the survey to 16 NITAGs and integrated the additional responses (from Austria, Denmark, Finland, Portugal, Romania, Slovenia) in the analysis.

The survey questionnaire consisted of 33 questions divided into the following sections:

- Details of the person completing the questionnaire;
- Defining the topics and research questions to be evaluated by NITAGs;
- NITAG budget and costs;
- Outputs;
- Topic A: methods and tools used and costs;
- Topic B: methods and tools used and costs;
- Terms of References (ToRs) and sharing;
- Collaborations with other NITAGs.

Besides describing costs and tools used in two recent evaluations, the survey also aimed to better understand the legal framework of NITAGs, their functioning, how topics and research questions for evaluation are defined, whether the NITAGs have budgets, terms of reference, and whether the latter make any reference to possible collaborations with other NITAGs.

Responses to the questionnaire were analysed using Microsoft Excel.





Results

Review of existing documentation and identification of EU/EEA NITAGs

At the global level, in 2010, the SIVAC Initiative (Supporting Independent Immunization and Vaccine Advisory Committees, funded by the Bill & Melinda Gates Foundation and led by the French Agence de Médecine Préventive (AMP), in partnership with the International Vaccine Institute of Seoul, Republic of Korea and in collaboration with the WHO, to help middle-income and GAVI-eligible countries establish or strengthen NITAGs), developed and launched the NITAG Resource Center (http://www.nitag-resource.org), a platform open to all NITAGs around the world (8, 9). This represented a first step towards a more fruitful and global collaboration between NITAGs. The initial objective was to provide available technical resources to all NITAGs regardless of their status. Following the third international meeting on collaboration between NITAGs in 2015, the platform was completely revamped to serve as the central online interactive platform supporting NITAGs collaboration and facilitating exchanges between NITAGs worldwide. The platform is actively maintained and updated with dedicated person through a network of focal points and partners. Through this platform, it is possible for NITAGs to access different resources, such as NITAG recommendations developed at global, regional and local levels, systematic reviews on immunization topics, scientific publications, technical reports, updates from partners, and upcoming immunization events. The first meeting of the Global NITAG Network (GNN) was held in 2016, and the network was formally inaugurated in Berlin in 2017, during the second GNN meeting. The GNN is open to all NITAGs around the world and is led by a steering committee made up of a chair and NITAG members representing WHO's six regions. (10)

At the **EU/EEA** level, discussions around the issue of strengthening collaboration between NITAGs have been ongoing since 2010 (11, 12). A 2017 report of the "International Stakeholder meeting on collaboration to support National Immunization Technical Advisory Groups in the EU/EEA", carried out in the framework of the Vaccine European New Integrated Collaboration Effort known as the VENICE project (supported by ECDC through a grant until May 2018), found a considerable duplication of work carried out by NITAGs (since each NITAG assesses essentially the same body of evidence) and a need for improved collaboration to utilize more efficiently the limited resources in public health, e.g. by jointly assessing the scientific evidence related to a





specific vaccine which contributes to a considerable extent to the decision-making by each NITAG. Again, there was consensus among all participants that an enhanced collaboration between NITAGs and NITAG secretariats in the EU/EEA would be useful, feasible, and that the next concrete steps should be taken as soon as possible. In the context of the VENICE project, a report entitled "*Roadmap for improving collaboration on data, methodology and resource sharing to support NITAGs in the EU/EEA*" was drafted and shared with all ECDC-appointed NFPs for vaccine-preventable diseases. NFPs are experts designated by the Member States to support ECDC by providing their knowledge of the technical, scientific and administrative structures of one specific field of the national public health system. The report includes a proposal for a network and a hypothetical scenario for collaboration (13).

Collaboration between ECDC and EU-JAV

The inaugural meeting of the NITAG Collaboration Group was held in Stockholm on 12-14 February 2019, focused on further defining the scope of the new collaboration, obtain agreement around the proposed methodologies and structures of the system, and deciding upon the key issues (first topics) to be addressed during a first pilot phase. A session was held with the newly formed EU network of modelling experts to explore potential EU/EEA-level collaboration around disease transmission and vaccine impact models.

To avoid any duplication of efforts between the ECDC supported collaboration and the EU-JAV, several meetings occurred between ECDC representatives and JAV coordinator and task leaders, before and after the launch of the respective projects. Alignment of the two projects was discussed also at the ECDC inaugural meeting in which the EU-JAV coordinator and task leader both participated in person. It was agreed that effective and synergistic collaboration would occur between the two projects with a continuous bidirectional exchange of information. It was also emphasized that the focus for the ECDC collaboration would be on developing evidence to support decision-making in Member States at the EU level. The ECDC would offer a secretariat and a webbased platform to share ideas and documents between the expert groups and fund this support for 2019 - 2021 as a three-year pilot project. The EU-JAV would perform a survey on NITAG costs and tools used.

During the project, collaboration between ECDC and EU-JAV occurred in the following areas:





- Survey development. Reviewing surveys respectively conducted by each group. Sharing of respective survey results. Prior to launching the NITAG collaboration group, ECDC conducted an online survey of all countries interested in the collaboration, to collect up to date information on EU/EEA NITAGs. The EU-JAV provided comments to the survey questionnaire. Likewise, the ECDC provided comments to the EU-JAV questionnaire.
- Attendance at respective meetings. EU JAV coordinator and Task 4.3.2. Leader attended inaugural meeting of the NITAG collaboration group, held in Stockholm in February 2019.
 ECDC attended the EU-JAV kick off meeting in Paris in September 2018 and the first General Assembly meeting in Rome in October 2019.
- Comments on respective reports.

Ongoing communication between ECDC and the EU-JAV occurred throughout the project, to ensure common activities were carefully considered and fully coordinated to maximise the potential benefits for EU/EEA Member States. Regular meetings were held via teleconference to update each other on our respective activities.

Survey on the range of attributable costs and tools used for the most recent MS-NITAG evaluations.

Sixteen of 29 invited NITAGs completed the questionnaire by 15 September 2021 (Table 1). Five respondents were NITAG Chairs, eight were members of the NITAG Secretariat, two were NITAG members, and one a former NITAG member.

Appointment of NITAG Members and Working Groups, defining the workplan, the topics and research questions to be evaluated.

Participants were asked to indicate:

- which institution /person is responsible for appointing the NITAG members;
- which institution/person is responsible for deciding the workplan of the NITAG, including the topics to be evaluated;
- for each topic, which institution/person is responsible for defining the research question(s) to be analysed;





• if applicable, which institution/person is responsible for appointing the NITAG Working Groups.

Responses are shown in Table 2. Table 3 gives more details regarding the process leading to defining the work plan.

Table 1. Survey on the range of attributable costs and tools used for the most recent MS-NITAG evaluations. Study respondents.

Country	Survey respondent
Austria	NITAG member
Belgium	member of NITAG Secretariat, together with NITAG Chair
Bosnia and Herzegovina	member of NITAG Secretariat
Croatia	member of NITAG Secretariat (no NITAG Chair at time of survey)
Denmark	member of NITAG Secretariat
Estonia	member of NITAG Secretariat
Finland	NITAG Chair
Germany	member of NITAG Secretariat
Ireland	NITAG Chair
Italy	NITAG Chair
Malta	NITAG Chair
Norway	NITAG Chair
Portugal	NITAG member
Romania	former NITAG member
Slovenia	member of NITAG Secretariat
Sweden	member of NITAG Secretariat

 Table 2. Institution/person responsible for appointing the NITAG members and NITAG working groups, deciding the work plan of the NITAG and defining research questions





Table 2.	Institution/person responsible for:				
Country	appointing the NITAG members	deciding the work plan of the NITAG	defining research questions	appointing Working Groups	
Austria	Ministry of Health	Ministry of Health Vaccination Department	Ministry of Health/Vaccination Department	Vaccination Department	
Belgium	Superior Health Council	 Superior Health Council Federal Minister of Health NITAG members other administrations 	Superior Health Council	Superior Health Council	
Croatia	Croatian Institute of Public Health	Secretariat (Division of Communicable Disease Epidemiology)	Secretariat (Division of Communicable Disease Epidemiology)	No specific working groups have been appointed so far.	
Denmark	The society or institution that each NITAG member represents	Danish Health Authority (chairmanship)	Group working with a specific topic	No response	
Estonia	Ministry of Social Affairs	Ministry of Social Affairs	Depending on the topic or the question, usually specific research questions are defined by experts (usually medical doctors from different fields), considering the opinion of the experts from the Health Board.	NITAG secretariat, if a specific question needs to be solved. The need for a working group is defined in the meeting.	
Federation of Bosnia and Herzegovina	Ministry of Health	 Ministry of Health NITAG Secretariat (Public Health Institute) NITAG members 	Public Health Institute (PHI)	Ministry of Health and PHI	
Finland	Director General of the Finnish Institute for Health and Welfare (THL)	NITAG The Finnish Institute for Health and Welfare (THL) suggests topics.	NITAG, with help from THL	NITAG	
Germany	Ministry of Health	NITAG At the start of the three- year appointment period, prioritization of upcoming topics is undertaken by the NITAG.	NITAG establishes working groups for a specific vaccination, indication, or problem.	Chair of the respective NITAG working group.	





Ireland	The Royal College of Physicians appoints the chair. Members are nominated by a variety of stakeholders and includes one representative and possible alternate from various institutions / groups. *	Decided either by the committee or at the request of the Department of Health	NIAC	Membership appointed as per the work plan (either by the committee or at the request of the Department of Health). The then working subgroups are convened by the Chair/committee with co-option of outside expertise as considered necessary
Italy	Ministry of Health	NITAG The NITAG decides prorities based on requests from the Ministry of Health and Regional Health Authorities	A member (or a group of members) of the strategic group	Ministry of Health
Malta	Ministry of Health	The committee is advisory to the Superintendent of Public Health	Team of experts	NA
Norway	Norwegian Institute of Public Health, DG.	NITAG secretariat at Norwegian Institute of Public health	NITAG secretariat	Not specified
Portugal	Ministry of Health by proposal of the Directorate-General (DG) of Health	DG of Health, specifically the coordination of the National vaccination program together with the President of the Technical committee on vaccination (NITAG)	Each topic constitutes a working group and the members of this group carry out the research.	NITAG members
Romania	Ministry of Health	NITAG secretariat and the President of NITAG	 Ministry of Health National Institute for Public health Pharmaceutical companies, other institutions 	NITAG secretariat
Slovenia	National Institute of Public Health (NIJZ) (Director)	 National Institute of Public Health (NIJZ) NITAG Chair 	National Institute of Public Health	National Institute of Public Health
Sweden	DG of the Public Health Agency decides on which organizations should be represented in the reference group. The department manager decides on the individual members, who are nominated by the respective organization.	 DG of the Public Health Agency, by decision of the Agency's work plan for the coming year, following a suggestion by the Unit for vaccination programmes (which manages all evaluations in practice). 	Manager of the Unit for vaccination programme**	Manager of the Unit for vaccination programme***

NA= Not applicable (No specific working groups have been appointed).

* (Ireland) namely The Royal College of Surgeons of Ireland, The Royal College of Physicians, The Faculty of Paediatrics, The Faculty of Occupational Health, The National Virus Reference Laboratory, The Faculty of Pathology, The Faculty of Public Health Medicine, The Health Products Regulatory Agency, The Irish Society of Travel Medicine, The Health Protection Surveillance Centre, The National Immunisation Office, The Nursing and Midwifery Board





** (Sweden) For National Vaccination Programmes, 13 criteria should be evaluated, as outlined in the Communicable Disease Act. For recommendations or alterations of existing programmes, the Manager of the Unit for vaccination programme formally decides, based on a suggestion by the project (topic) leader.

*** (Sweden) The Manager of the Unit for vaccination programme, as working groups usually consists mainly of analysts from within that unit, together with analysts from other units within the PHAS, and external experts. Note: Regarding the appointment of NITAG Members, in Sweden, national vaccination programmes are regulated through the Communicable Diseases Act. According to the legislation, the Government decides on which diseases should be covered by national vaccination programmes, and the Public Health Agency of Sweden (PHAS) is responsible for developing evidence-based supporting material for these decisions. In that respect, the PHAS has many of the tasks of a NITAG. To complement and support its mandatory tasks, the PHAS has instituted a reference group for national vaccination programmes, composed of representatives of different agencies, professional associations, and vaccination service providers. The process of deciding on vaccinations is described in the following publication: https://www.folkhalsomyndigheten.se/publicerat-material/publikationsarkiv/v/work-model-for-changing-national-vaccination-programmes-in-sweden/. In this survey, the responses are therefore based on the current system and division of tasks, irrespective of if the tasks are performed by the PHAS or reference group.

Austria	Depends on the set agenda.
Belgium	No response
Croatia	Process not defined. Based on ad hoc needs
Denmark	Internal discussions/wishes, often initiated by scientific developments (e.g., new (types of) vaccines), suggestions from the medical societies, the NITAG members, or the political level.
Estonia	The NITAG meets at least twice a year. Before every meeting, members can suggest topics for the meeting. For specific topics, informal sub-committees are formed. In urgent matters, the members are consulted electronically.
Federation of Bosnia and Herzegovina	Ministry of Health and Public Health Institute propose the work plan, further NITAG members discuss it, and after discussion the work plan is finalized.
Finland	Experts in the Finnish Institute for Health and Welfare (THL) suggest topics, or NITAG members can also suggest topics. NITAG discusses and decides on the work plan.
Germany	STIKO weighs the topics on the task list and decides on the order for topic assessment considering the following aspects: (i) estimate of the burden of disease, (ii) public interest in the vaccination recommendation, (iii) benefits and risks of a respective vaccination program and (iv) Integration of the new vaccine in the national immunization schedule.
Ireland	 Prioritisation of consideration of new vaccines or major change to existing vaccination schedule. Prioritisation will consider the following criteria: Primary Criteria: Availability of a licensed vaccine. For vaccines with a high degree of public interest, NIAC review may need to start prior to licensure. Epidemiology of the disease in Ireland. Secondary Criteria Perception of the disease burden by health professionals and the public. Integration of the new vaccine into the national immunisation schedule. A yearly review of priority issues for consideration is carried out and an outline 2–3-year timetable (Horizon Scanning) agreed. Procedure for discussion of new vaccines or major change to existing vaccination schedule: Agreed membership of subgroup and nominate chair. Subgroup to review the following: Irish disease epidemiology. International disease epidemiology, if relevant. Vaccine information. Experience/guidelines of other countries. Relevant additional scientific evidence. Subgroup to prepare report for discussion at NIAC. NIAC to decide re need for economic evaluation/health technology assessment and, if agreed, seek funding for commissioning of same from the Department of Health.

Table 3. Details, by participating country, regarding the process leading to defining the work plan of NITAGs.





	 Subgroup to produce final report with recommendations for discussion at NIAC. Decisions will be made by consensus whenever possible. If consensus cannot be reached decisions will be by voting with the approval of 50% +1 of voting members required for a majority decision.
Italy	The annual work plan is prepared and approved by the Strategic group of the NITAG. The next main task will be updating of the National Vaccine Action Plan which validity expired at the end of year 2019.
Malta	The team of experts decide the agenda to be discussed depending on current priorities regarding immunisations in Malta.
Norway	Changes to the national vaccination programme should follow a regulated, defined, and open process. System for HTA (Health Technology Assessment) of health interventions in Norway will also include vaccines. The NITAG gives advice to NIPH: Support NIPH to identify needs for changes in national vaccination programmes, suggest for NIPH which evaluations should be done, give advice on reports and recommendations regarding vaccination, support NIPH in identifying improvement in vaccine recommendations. The NITAG secretariat sets up the agenda, suggestions may come both from the NIPH, the NITAG members or others.
Romania	After the topics to be discussed have been established, these being proposed either by the Ministry of Health or by other institutions, the secretariat together with the president approves the agenda and sends it to the members of the committee. Other topics for discussion may be proposed by members.
Slovenia	NIJZ secretariat usually presents proposals for new or updated recommendations to NITAG members or NITAG Chair - which are then included in the work plan.
Sweden	The reference group is presented yearly with a list of possible evaluations that the PHAS could perform. Through discussions a shortlist of evaluations is decided. This is then discussed within the PHAS and incorporated in the work plan for the next year.

Budget and costs

Table 4. Responses to Question "Does your country's NITAG have its own budget?"

Responses	N. NITAGs (N=16) *
Yes (e.g., annual, six-monthly)	6
Yes, for specific topics/activities/assignments	5
No	7

*Total is >16 because two NITAGs reported having both an annual/six-month budget and a budget for specific topics.

Nine of 16 responding NITAGs reported having a budget (either an annual/six-monthly budget or a budget for specific topics/activities/assignments). Two of nine countries reported having both a routine budget and a budget for specific activities.

When a budget was available, it covered expenses mainly pertaining to NITAG functioning (e.g., office space, computers, internet, stationary, meetings, and other services), secretarial staff, scientific staff, travel and subsistence allowances, subcontracting (e.g., of scientific activities: epidemiological studies, systematic reviews, modelling for disease, vaccine impact, and cost-effectiveness studies), training/continuing education of NITAG members/staff. In four countries





the budget was extremely limited, covering exclusively either travel and subsistence allowances, training /continuing education of NITAG members/staff, or NITAG functioning.

Expenses covered	N. NITAGs (N=9)	
NITAG functioning	4	
Secretarial staff	3	
Scientific staff	3	
Travel and subsistence allowances	7	
Subcontracting	4	
Miscellaneous	2	
Training /continuing education of NITAG members/staff	3	
Other	0	

Table 5. Responses to question "What expenses does the budget cover?" (More than one answer was possible).

Details from four countries, of "Other" expenses that the budget covers:

- Belgium. The Belgian NITAG is part of the Superior Health Council (SHC) of Belgium.
 Therefore, a part of the budget of the SHC is used for the NITAG (and other domains of the SHC).
- Germany. NITAG does not have its own budget, but can apply for funding within Robert Koch Institute (RKI) (National Public Health Institute), that hosts the NITAG. RKI funding is provided for the above-mentioned activities. The secretarial and scientific staff are not part of the budget, but provided by the RKI that hosts the secretariat
- Italy. The budget is extremely limited. It covers only travel expenses to Rome (no other destination!). And the total amount is negligible
- Sweden. Overhead costs are covered in other ways, through the PHAS. The routine budget includes time for an analyst to act as Secretary of the reference group, meetings of the reference group and travel costs associated therewith. A specific budget is allocated for each evaluation, including analyst time, modelling, etc.

Portugal (no budget) notes that NITAG members are not remunerated for participating in the commission. There is a request from the Directorate-General of Health to the respective services to make available the participation of members during working hours, when necessary.





The methods/tools for which the budget was used in the previous five years included mainly vaccine impact and disease transmission modelling, followed by health economic assessments and systematic literature reviews (Table 6).

Table 6. In the last five years, for which of the following methods/tools, if any, did you use your budget? (More than one answer was possible)

Methods/tools	N. NITAGS (N=9)	
Expert's opinion	2	
Health economic assessment	3	
Health technology assessment	0	
Systematic literature reviews	3	
Live systematic reviews	0	
Non-systematic literature review	2	
Meta-analysis	1	
Vaccine impact modelling	4	
Disease transmission modelling	4	
Other (please specify)	0	

The source of funding to cover activities of the NITAG was the Ministry of Health in four of nine countries and the national Public Health Institute in four countries (not specified in one country). Table 7 summarizes the responses collected on budgets and tools, by country.

Table 7. Availability of a NITAG budget, expenses covered by the budget, methods/tools for which the budget was used in previous five years, and sources of funding to cover activities of NITAGs, by country.





Country	NITAG Budget	Expenses covered	Methods/tools used in previous five years	Source of funding
Austria	Yes, for specific topics, activities/ assignments	NITAG functioning, secretarial staff, scientific staff, travel and subsistence allowances, subcontracting including scientific activities, miscellaneous	Expert opinion, non- systematic literature review, vaccine impact modelling, Disease transmission modelling	Ministry of Health
Belgium	Yes, both routine budget and additional budget for specific activities	NITAG functioning, secretarial staff, scientific staff, travel and subsistence allowances, subcontracting including scientific activities, miscellaneous, training /continuing education of NITAG members/staff. §	No budget was used for the above methods/tools.	Federal Public Service Health, Food Chain Safety and Environment
Croatia	Yes	Training /continuing education of NITAG members/staff	NS	NS
Denmark	Yes, for specific topics/activities/ assignments	Travel and subsistence allowances, subcontracting including scientific activities	Expert opinion, health economic assessment, systematic literature review, meta-analysis, vaccine impact modelling, disease transmission modelling	Ministry of Health
Estonia	No	NA	NA	NA
Federation of Bosnia and Herzegovina	Yes (e.g., annual, six- monthly)	Travel and subsistence allowances	NS	Ministry of Health
Finland	No			
Germany	Yes (e.g., annual, six- monthly) Note: Permanent budget only for meetings, travel, some training and materials. Also, NITAG can apply for funding within Robert Koch Institute that hosts the NITAG.	NITAG functioning, travel and subsistence allowances, Training /continuing education of NITAG members/staff §	Health economic assessment, Systematic literature review, vaccine impact modelling, disease transmission modelling Note: NITAG payed the above-mentioned activities with RKI funding.	Public Health Institute
Ireland	No			
Italy	Yes (e.g., annual, six- monthly)	Travel (to Rome only) and subsistence allowances §	There is no budget allocation for methods or research.	Ministry of Health
Malta	No			
Norway	No			
Portugal	No	None Note: NITAG members are not remunerated for participating in the commission. There's a request from the Directorate General of Health to the respective services to make available the participation of members during working hours, when necessary.	NA	Directorate General of Health under the Ministry of Health
Romania	No	None	NA	
Slovenia	Yes	NITAG functioning	NS	Public Health Institute
Sweden	Yes, both routine budget and additional budget for specific activities	Secretarial staff, scientific staff, travel and subsistence allowances, subcontracting including scientific activities §	Health economic assessment, systematic literature review, non-systematic review, vaccine impact modelling, disease transmission modelling	Public Health Institute

NS=Not specified





§Comments (what expenses does the budget cover):

- <u>Belgium</u>: The Belgian NITAG is part of the Superior Health Council (SHC) of Belgium. Therefore, a part of the budget of the SHC is used for the NITAG (and other domains of the SHC).
- <u>Germany</u>: The secretarial and scientific staff are not part of the budget but provided by the Robert Koch Institute (National Public Health Institute) that hosts the secretariat. Regarding question 13: Our NITAG does not have an own budget, but we can apply for funding within the Robert Koch Institute (RKI), that hosts the NITAG. With RKI funding we paid the above-mentioned activities. We only have a permanent budget for meetings, travel, some training and materials.
- <u>Italy</u>: The budget is very limited. It covers only travel expenses to Rome (no other destination!) and the total amount is negligible.
- <u>Sweden</u>: Overhead costs are covered in other ways, through the Public Health Agency of Sweden (PHAS). The routine budget includes time for an analyst to act as Secretary of the reference group, meetings of the reference group and travel costs associated therewith. A specific budget is allocated for each evaluation, including analyst time, modelling, etc.

Outputs

Participants were asked to indicate the number of vaccine outputs (e.g., reports, documents/vaccine recommendations for internal use or for external dissemination, peer reviewed scientific articles) that their country's NITAG had produced in the previous five years. Most responding NITAGs (14/16) reported having produced at least one output (Table 8), with seven NITAGs having produced over five outputs. Two countries did not produce any outputs.

N. of outputs	Countries
None	Italy, Romania
1-3	Norway
4 – 5	Croatia, Denmark, Ireland, Malta, Slovenia
> 5	Austria, Belgium, Estonia, Federation of Bosnia and Herzegovina, Finland, Germany, Portugal, Sweden

Table 9 lists the topics selected by NITAGs, the methods/tools used and related costs for each topic. The most frequently covered topic was Human Papillomavirus (HPV) vaccination (Table 9). Most NITAGs used systematic review, meta-analysis, expert opinion, and disease transmission modelling/vaccine impact modelling as methods to produce the outputs. Only two countries specified the costs related to some of these outputs.

Participants were also asked to indicate other costs incurred by NITAGs, more specifically about any fees paid to NITAG member (e.g., token of presence) or to external experts besides those regarding expert opinion, and any travel costs of NITAG members and other external experts. Most NITAGs did not report any fees or travel costs, while four were unable to estimate travel costs for one or more outputs produced. Two NITAGs reported that cost information was confidential.





Methods and tools used and costs in most recent evaluations

NITAGs that had produced at least one output were asked to select two examples of topics (Topic A and Topic B, only one topic if the NITAG had only one output) that had been assessed by the NITAG in the previous five years and to provide some information on each of the topics separately (Table 9).

For each topic, they were asked to specify the year the evaluation was performed, the methods and tools used and the cost (specifying the currency) of each, including subcontracting. Table 9 shows the topics selected by NITAGs for the evaluation, the methods and tools used and the related costs, by country, for the countries who produced at least one output and completed this section (N=12).

Country	Object of the topic	Year of evaluation	Methods/tools used and costs	Fees paid (to NITAG members and external experts) and travel costs
Austria	Topic A: • COVID-19 recommendations	2020	 Tools: Systematic Reviews/ Live Systematic Review, Meta-Analysis, Expert Opinion, Disease Transmission Modelling/Vaccine Impact Modelling Costs: Unable to estimate costs for Systematic Reviews/Live Systematic Review, Meta-Analysis, Expert Opinion Cost information is confidential for disease transmission and vaccine impact modelling. 	None.
	Topic B: • PCV-13 recommendations for children	2019	 Tools: Systematic Reviews/ Live Systematic Review, Meta-Analysis, Expert Opinion Costs: Unable to estimate costs for any of the tools used 	No fees. Unable to estimate travel costs of NITAG members and other external experts.
Belgium	No topics specified.	•		
Croatia	Topic A: • Upper age limit for routine administration of Tdap-IPV- Hib-HepB vaccine	2016-2016	Tools: Expert Opinion, Non-Systematic review of scientific literature and applicable regulations Costs: Zero cost for both tools used	None

Table 9. Topics selected by		methods	/tools used	and related	l costs, b	v country.
Table 3. Toples selected b	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	memous				y country.





	Topic B: • Introducing PCV into the national immunization schedule	2016-2018	Tools:ExpertOpinion,HealthEconomic Assessment,Non-SystematicReviewCosts:Zero cost for expert opinion and for non- systematic review.Unable to estimate costs for health economic assessment.Unable to estimate costs for health economic assessment.Unable to estimate costs for health economic assessment.Unable to estimate costs	None
Denmark	Topic A: • Recommendation on HPV vaccination for boys	2018-2019	Tools Systematic Reviews, Expert Opinion, Disease Transmission Modelling/Vaccine Impact Modelling, Health Economic Assessment Costs: Expert opinion: 30,000 Danish Kroner (about 4,000 Euros according to 22 March 2022 exchange rate). The systematic review, disease transmission/vaccine impact modelling and health economic assessment were all part of a health technology assessment for which the total costs were around 1.2 million Danish kroner (about 161,000 Euros).	Fees: 400,000 Danish kroner (about 54,000 Euros according to March 2022 exchange rate) Unable to estimate travel costs
	Topic B: • Health Technology Assessment for influenza vaccination	2019	Tools: Systematic Reviews, Meta-Analysis, Expert Opinion, Disease Transmission Modelling/Vaccine Impact Modelling, Health Economic Assessment Costs: Expert Opinion (30.000 Danish Kroner) Unable to estimate costs of systematic reviews and meta-analysis, Disease Transmission / Vaccine Impact Modelling, and Health Economic Assessment: cost information is confidential	Unable to estimate fees and travel costs
Estonia	Topic A: • Introducing HPV vaccination in the national immunization programme	2015-2018	Tools: Health Economic Assessment Costs: Unable to estimate costs	Unable to estimate fees and travel costs
	Topic B: • Introduction of vaccination against influenza for residents of nursing homes		Tools:ExpertOpinion,HealthEconomic AssessmentCosts:Unable to estimate costs	None
Federation of Bosnia and Herzegovina	Topic A: • Measles Mumps Rubella (MMR) vaccine during measles outbreak, for children less than 12 months	2019	Tools: Systematic Review, Expert Opinion Costs: Confidential	Confidential





	Topic B: • Number of polio vaccine doses	2019	Tools: Systematic Review, Expert Opinion Costs: Confidential	Confidential
Finland ¹	Topic A: • The phased allocation of Covid-19 vaccines	2020-2021	Tools: Expert Opinion, Disease Transmission Modelling/Vaccine Impact Modelling Impact Impact Costs: Unable to estimate costs. Modelling was done by THL personnel as part of their duties. NITAG members were not paid	None
	Topic B: • Covid-19 vaccinations of children	2021-ongoing	Tools: Expert Opinion, Disease Transmission Modelling/Vaccine Impact Modelling Costs: Unable to estimate costs. Modelling was done by THL personnel as part of their duties. NITAG members were not paid.	None
Germany	Topic A: • HPV vaccination for boys	2016-2018	 Tools: Systematic Review, Meta- Analysis Expert Opinion, Disease Transmission Modelling/Vaccine Impact Modelling, Health Economic Assessment, Assessment of the HPV- associated disease burden Costs: Systematic review was performed by staff of the National Public Health Institute (so no costs for the NITAG budget, but staff time). Unable to estimate costs. Metanalysis was performed as part of the systematic review. Unable to estimate costs. Expert opinion: unable to estimate costs. Modelling and Health economic assessment: Cost information is confidential Assessment of the HPV-associated disease burden: No costs indicated 	No fees. Unable to estimate travel costs
	Topic B: • Herpes Zoster (recombinant vaccine)	2015-2017	Tools:SystematicReview,Meta-AnalysisExpertOpinion,DiseaseTransmissionModelling/VaccineImpactModelling,HealthEconomicAssessment,estimationofdiseaseburdenCosts:SystematicReview andMeta-Analysis:performedperformedwithintheHealthInstitute,onlystaffcostsExpertOpinion:unableto estimatecosts	No fees, unable to estimate travel costs





			Disease transmission modelling / Vaccine Impact Modelling, and Health Economic Assessment: performed within the National Public Health Institute, only staff costs. Estimation of disease burden: no costs indicated	
Ireland ²	Topic A: • HPV vaccination for boys	2014-2019	Tools: Expert Opinion, Health Economic Assessment <td< td=""><td>Fees: HTA for gender neutral HPV was commissioned from HIQA by the DOH and costs not incurred by NIAC.</td></td<>	Fees: HTA for gender neutral HPV was commissioned from HIQA by the DOH and costs not incurred by NIAC.
	Topic B: • Recommendations on the use of BCG in Ireland	2014	Tools:ExpertOpinion,HealthEconomic Assessment.Costs:Unable to estimate costs.ProductionoftheNationalImmunisation Guidelines is mostly donebyvolunteereffortbyvolunteereffortwebhavebeeninappropriate.Costsof placing on thewebhavebeenincorporated inheretofore.heretofore.	No travel costs Fees: Two part-time special advisors hired for a total of about 16 hours/week (unable to calculate cost) No travel costs
Italy	No output in the five years pred	ceding the survey.		
Malta	Topic A: • The introduction of conjugate pneumococcal vaccine on the National Immunisation Schedule	2014/2018	Tools: Systematic Review, Meta-Analysis, Analysis, Expert Opinion, Disease Transmission Modelling/ Vaccine Impact Modelling. Modelling. Costs: Work done by the NITAG members as part of their paid work. Experts within the committee	No fees, no travel costs
	Topic B: • Introduction of multivalent primary vaccinations which include Hepatitis B	2017-2019	Tools: Systematic Review, Meta- Analysis, Expert Opinion. Cost: Work done by the NITAG members as part of their paid work. Experts within the committee	None.
Norway ³	Topic A: • Vaccination of preterm infants against pertussis and pneumococcus	2017-2018	Tools: Systematic Review, Expert Opinion Specific expert groups are performing systematic reviews, HTA, evaluations etc. The NITAG gives comments to a draft report Cost:	No fees. Unable to estimate travel costs
	Topic B: • Vaccination of pregnant women against pertussis	2018-2019	Unable to estimate costs for either tool. Tools: Systematic Review, Expert Opinion, Disease Transmission Modelling/Vaccine Impact Modelling, Health economic assessment. Cost: Cost information is confidential	No fees. Unable to estimate travel costs





Portugal ⁴	Topic A: • HPV vaccination in	2019	Tools : Budget not used for any of the listed tools.	None
	APV vaccination in males		listed tools.	
			Costs: None	
Romania	No output in the five years pre	ceding the survey.		•
Slovenia	Topic A: • Recommendations of HPV vaccination for boys	2018-2019	Tools: Systematic Review, Expert Opinion Cost: Unable to estimate costs for either tool	No fees. No travel costs
	Topic B: • Recommendations for vaccinating children (3 years old) and adults (49 years old) against TBE (3 doses covered)	2016-2018	Tools:SystematicReview,ExpertOpinion,DiseaseTransmissionModelling/VaccineImpact ModellingCost:Unable to estimate costs for any of the tools used	No fees. No travel costs
Sweden ⁵	Topic A: • HPV vaccination for boys	2016-2017	Tools: Expert Opinion, Disease Transmission Modelling/Vaccine Impact Modelling, Health economic assessment, Non-systematic review Cost: Unable to estimate costs	Fees: Language review of reports before publishing, a few thousand SEK per report. Unable to estimate travel costs.
	Topic B: • Timing of first dose of MMR	2016-2018	 Tools: Expert Opinion Other: Non-systematic review. Costs: Unable to estimate costs since expert opinion was employed in the form of a reference group. Non-systematic review: Costs included both time for the review, and costs for individual non-open-access papers. 	Fees: Language review, costs not estimated. Unable to estimate travel costs.

¹ The survey respondent started as the chair only in 2020, so gives examples from this period 2020-2021, which has focused on Covid-19. First task subject is the phased allocation of Covid-19 vaccines (2020).

²NIAC has been totally unfunded, work done is on a voluntary basis. Only in August 2019 were we able to obtain limited once off funding to permit hiring of 2 part-time 'special advisors, to facilitate the work of NIAC. The DOH has accepted the need to transform to a more funded NITAG and this has been provided as interim funding till the final structures are determined. We should receive similar in 2020.

³Specific expert groups are performing systematic reviews, HTA, evaluations etc. The NITAG gives comments to a draft report.

^{<u>A</u>}We do not produce systematic reviews. The members of the NITAG perform extensive literature reviews for each topic. We use systematic reviews/metanalyses that are published. Expert opinion: Other experts are consulted with no costs associated. Our NITAG makes its own vaccine impact modelling work, no costs associated. Health Economic Assessment is not used, generally.

⁵For a list of completed evaluations, please see: https://www.folkhalsomyndigheten.se/smittskydd-

beredskap/vaccinationer/vaccinationsprogram/utredningar-om-nationella-vaccinationsprogram/.

Terms of References and sharing of outputs

Three of 16 participating NITAGS reported having no Terms of Reference (ToRs), one NITAG did not respond. Of the 12 NITAGs that reported having TORs, in ten cases these do not make any reference to possible collaborations with other NITAGs (Table 9). One of 12 NITAGs (Finland) however, pointed out that although there is no direct reference to collaboration, "*it is written in*





the ToRs that our NITAG needs to observe the international developments in vaccinations and immunization programmes."

The two NITAGs that do make reference to collaboration with other NITAGs pointed out:

- Federation of Bosnia and Herzegovina: "It is not precise in the ToR, this option is open with the consent of the Ministry of Health
- Norway: "Since the NITAG members are not doing the systematic reviews themselves,

this is not included in the ToR. But specific expert groups may collaborate with others, in particular with expert Groups in the Nordic countries."

Response	Countries (N=15) *			
No (N=10)	Austria, Denmark, Estonia, Finland, Germany, Ireland, Portugal, Romania, Slovenia, Sweden			
Yes (N=2)	Federation of Bosnia and Herzegovina, Norway			
We do not have ToRs (N=3)	Croatia, Malta, Italy			
*One country did not respond (Belgiu				

Table 9: Responses to question "If your NITAG has Terms of Reference, is there any reference in the
ToRs to possible collaborations with other NITAGs?"*

One country did not respond (Belgium)

Collaborations with other NITAGs

Eleven of 15 NITAGs (one NITAG did not respond) reported not having had any collaborations with other NITAGs in the five years preceding the survey (Table 10) (excluding collaborations that have occurred through the recent ECDC EU/EEA NITAG collaboration). In all four countries that reported some type of collaboration with other NITAGs, this was done without a formal agreement.

Table 10: Responses to question" In the last five years, has your country's NITAG shared (or is it in the process of sharing) any outputs produced regarding vaccines (excluding public results) with other NITAGs? (Excluding collaborations that have occurred through the recent ECDC EU/EEA NITAG collaboration)?"

Responses	Countries (N=15)*
Yes, without a formal agreement	Finland, Germany, Sweden, Norway
No	Austria, Croatia, Denmark, Estonia, Federation of Bosnia and Herzegovina, Ireland, Italy, Malta, Portugal, Romania, Slovenia

*one country did not respond





When asked what the collaboration consisted in, three of four countries provided some details. One country reported having both shared the cost of one or more activities and having jointly prepared the protocol or conducted systematic reviews/meta-analyses/mathematical modelling/cost benefit analyses, another country reported having jointly prepared the protocol or conducted systematic reviews/meta-analyses/mathematical modelling/cost benefit analyses. A third country organized a meeting to compare health economic assessment models developed by two different groups, and shared a draft background paper with other NITAGs before publication. A fourth country did not provide details. Some further details of the collaborations are reported below.

Details of collaborations (NITAGS were asked to specify country (or countries) with whom a collaboration occurred, topics examined, mechanisms for sharing costs)

Germany	Example of models / health economic assessment: We invited two groups who developed a similar model for their NITAG for a meeting and presented/compared the models (HPV vaccination in boys). We shared with other NITAGs our draft background paper before publication.
Norway	Expert Groups in each of the collaborating countries have covered their own costs.
Sweden	A systematic literature review was performed together with Norway to evaluate strategies to prevent pertussis in infants. Another joint collaboration concerns pneumococcal vaccines for the elderly and risk groups. For this, a systematic literature review was performed together with the Public Health Institutes in Norway and Denmark. Costs for salaries and travel were paid by the respective Institute. The institute

took turns in hosting the few physical meetings that were done, but primarily meetings were held by teleconferences.

Finland No details provided

The main reported challenges in collaborating with other NITAGs and lessons learnt are listed in Table 11, while Table 12 shows the institution/person in charge, in each country, for deciding if it is possible to share scientific evidence on vaccines with other NITAGs or international institutions.

Country	Main challenges/obstacles encountered
Austria	Language barriers regarding recommendation outputs, lack of time and resources for collaboration, large differences in policy, legal and health system settings that make it difficult to compare results and recommendations.
Belgium	None
Croatia	Different issues.
Denmark	Lack of time. Often, national circumstances/decisions require your own analyses in different areas and that results can be hard to apply in other countries.
Estonia	We have not had very many contacts with other NITAGs but we are interested in having, so this will be planned in the future.

Table 11. Main challenges reported by NITAGS. in collaborating with other NITAGs.





Federation of Bosnia and Herzegovina	Frameworks to issue recommendations, availability of expertise and human resources.
Finland	Current collaboration on Covid-19 has been productive. Perhaps a challenge is the high number of NITAGs in Europe and differences in their national roles.
Germany	Agreement on the PICO questions of systematic reviews. Agreement on the timing of the prioritized topics. Agreement on methods used.
Ireland	The lack of resources that NIAC/NITAG has (all members have other fulltime commitments). Better resources and support are needed with time allocation to those working on a NITAG.
Italy	Precarious state in which the NITAG operates. So far in Italy it has been considered like a group of experts linked to the Ministry of Health and not like an independent body which needs to operate in autonomy.
Malta	So far there has been no need for this collaboration
Norway	The way NITAGS are organized varies although ToRs are in accordance with WHO/SAGE recommendations. However, collaboration between expert groups may be an option. This can be organized through each NITAG secretariat.
Romania	None indicated
Slovenia	None indicated
Sweden	Timing: both parties must have the same priority at the same time, for a joint evaluation to be possible. Also, most analyses must be adapted to the local context, which makes transferability an issue.

Table 12. Institution/person in charge of deciding if it is possible to share scientific evidence on vaccines with other NITAGs or international institutions. *(N=15; one NITAG did not respond)

Country	Institution/person in charge
Austria	Ministry of Health
Croatia	Not defined
Denmark	Health Authority
Estonia	The institution that owns the evidence in accordance with other NITAG members.
Federation of Bosnia and Herzegovina	Ministry of Health
Finland	NITAG chair together with THL personnel
Germany	Head of the vaccination department at the Robert Koch Institute in consultation with the NITAG Chair
Ireland	Depends on what the information is and who has ownership, and that sharing is compliant with GDPR, etc.
Italy	Ministry of Health
Malta	NITAG Chair
Norway	National Institute of Public Health
Portugal	Directorate General of Health
Romania	Ministry of Health and National Institute of Public Health
Slovenia	National Institute of Public Health
Sweden	Depends on the type of information to be shared: either the manager of the Unit for Vaccination programmes (which conducts the evaluations), or the department manager (both with the Public Health Agency of Sweden).





Conclusions

This report describes the activities conducted in the framework of EU-JAV Task 4.3.2, aimed at exploring the possibility of establishing a strengthened cooperation structure between EU/EEA NITAGS. Importantly, in May 2018, shortly after the launch of the EU JAV project, ECDC initiated a pilot collaboration between EU/EEA NITAGs, denominated "EU/EEA NITAG collaboration network", bringing together experts in the field of public health and immunisation from across the EU/EEA who are working within or supporting national NITAGS. EU-JAV and ECDC have worked closely to create synergies in the two projects.

It is generally agreed among experts in this field that increased collaboration is desirable, not only between individual NITAGs, but also between NITAGs and other EU/EEA competent authorities and their networks (e.g., ECDC, EMA). This could reduce the duplication of efforts that frequently occurs between different NITAGs and different organizations, in the assessment of the evidence for making vaccination-related policy decisions. It would also make possible a more efficient process for making evidence-based decisions, through the sharing of literature reviews and other data, and improve dialogue between EU experts involved in preparing the evidence in the different organizations (e.g., public health, regulatory), and in generating new evidence. Overall, an increased collaboration would strengthen the capacity for decision-making around vaccines through sharing of best practices, technical expertise, and knowledge.

Through our survey, we collected information on how topics and research questions are selected/defined, NITAG's budget and costs, Terms of References (ToRs), and previous collaborations with other NITAGs. A separate task of the EU-JAV (Task 4.3.2.1), led by Spain, has conducted a survey to explore EU/EEA NITAG's decision-making process regarding the inclusion of vaccines in their national immunization schedules. Results of this other task will be published in a separate report.

We found that most European countries have a NITAG and that the institution/person responsible for appointing the NITAG members is usually, with few exceptions, either the Ministry of Health or the national public health institute. Different institutions are involved in deciding the research questions/work plan. We also found that many NITAGs do not have a budget, and when a budget is available, it is limited and mainly covers expenses related to travel or subsistence or NITAG functioning, but not expenses for generation of evidence. This is often performed by staff at





public health institutes, during their working hours. Half of responding NITAGs produced at least five outputs each in the five years preceding the survey, using a range of tools, including estimation of disease burden, systematic and non-systematic reviews, meta-analyses, expert opinion, modelling, and health economic assessments. However, most were not able to quantify the costs for producing the outputs, most likely because of the reasons stated above (work performed by PHI staff during normal working hours). In some cases, cost information was reported to be confidential. However, lack of resources was frequently reported by NITAGs participating in our survey, as one of the main challenges in collaborating with other NITAGs.

It is known that NITAG sustainability and functioning requires secured adequate funding that ensures the availability of at least one full-time secretariat post and the possibility of providing independent, evidence-informed advice to policymakers. A 2017 literature review on NITAGs identified financial sustainability as one of the challenges of NITAGs and highlighted the need to investigate innovative mechanisms to sustain their funding. So far this has been rarely discussed (10). According to a recent report on the role of NITAGs in evidence-informed decision-making, in order to secure this funding, the secretariat must create a work plan based on a national needs assessment, identify potential sources of funding for different activities (which could include national and international sources) and submit proposals for this work (14). The problem of funding is relevant also to collaborations between NITAGs, during which it is necessary to make clear the funding source of any joint work.

Regarding the outputs produced by NITAGs in the previous five years, overlaps were noted; for example, five countries evaluated the question of HPV vaccination in boys. Also, very few examples of previous collaborations were reported (only four NITAGs). The lack of collaboration and communication between NITAGs inevitably leads to duplication of efforts and inefficient use of resources which ideally should be avoided.

All the reported collaborations occurred in an informal manner; no formal agreements were established between NITAGs. Finally, although most NITAGs had ToRs, in only two cases these included a reference to collaboration with other NITAGs. Ideally, collaboration between NITAGs should occur within the context of a formalized network, and the pilot ECDC collaboration initiated





in 2018 is an example of such a network. Implementing collaboration requires that NITAGs be committed to sharing information and documents, that the terms of reference of the collaboration be defined and endorsed by all members. The collaboration may consist in sharing already completed documents and/or in joint work to develop common documents.

Besides lack of resources, other obstacles to collaborating with other NITAGs commonly reported in our survey, were lack of time, heterogeneity in policy, legal and health system settings, lack of agreement on methods, and different priorities. One respondent cited the high number of NITAGs in Europe and differences in their national roles.

During the COVID-19 pandemic, NITAGs faced many challenges in developing recommendations for COVID-19 vaccines. Although the ECDC expert network was created mainly to jointly develop and share scientific products and outputs, such as systematic reviews, new ways of collaboration were implemented during the pandemic, by using webinars to facilitate dissemination and exchange of information on COVID-19 vaccines. Likewise, the WHO Regional Office for Europe, with the support of the Robert Koch Institute, organized a series of webinars, provided materials and remote technical assistance to address the challenges faced by NITAGs (15). This new approach of regular and timely two-way communication helped NITAGs to increase their knowledge and access necessary information, and ultimately develop national recommendations on COVID-19 vaccination. This approach helped the Regional Office tailor support to NITAGs in the challenging COVID-19 environment by using questions, feedback, and requests for direct technical support received during and between webinars, and though poll results. This led to a tailored selection of webinar topics, improvement of webinars' format and development of a guidance tool on using a systematic process to develop recommendations on vaccines.

This innovative approach, used by both ECDC and WHO-Europe, of using webinars to convey and share important information provides new opportunities for more frequent sharing of information and experience, communication, and easier participation of international experts who are not always available for in-person meetings, and should be further built upon.

As highlighted by WHO-Europe, this format can be regularly used in the future also for online trainings which can include all members of NITAGs and their secretariats as well as varied interested colleagues from MoH, public health institutes and others and ultimately may demonstrate more value for money than organizing in-person meetings. This approach may also





facilitate participation of NITAG members in other country's NITAG meetings as observers (i.e., peer-to-peer learning). Besides the above-mentioned webinars, the WHO Regional Office for Europe also convened working groups to develop operational guidance modules to support NITAGs in the Region in preparing for and implementing COVID-19 vaccination (16).

Based on the information collected, we propose some recommendations to strengthen NITAGs collaboration. The implementation of such recommendations could also be taken into account by the ECDC in its efforts to strengthen collaboration across EU/EEA NITAGs in the interest of maximizing the use of platforms, tools and collaborative efforts already in place. The recommendations are as follows:

- Further develop the online webinar format to allow countries to have opportunities to more frequently and directly share experiences, data and technical resources. Besides communication the format can also be used for training.

- Establish an online platform to allow members of the collaboration to interact and share documents and materials. A web platform has been developed by the ECDC in the context of the EU/EEA NITAGs collaboration but has not been fully completed; more work is needed to increase uptake and usage by the members. Of note, the WHO Regional Office for Europe is planning to establish a EURO regional online platform for NITAGs in the entire Region (15).

- To avoid duplication of resources, when deciding the NITAG workplan, choosing or initiating work on a specific research question, NITAGs can, through the online platform, verify what relevant evidence has already been produced by other NITAGs. Consideration may also be given to exploring the possibility of jointly examining the evidence with other NITAGs. Considering our survey results regarding the institutions/persons involved in deciding the NITAG research questions/workplans, consideration can be given to evaluating the possibility of further expanding the existing EU/EEA collaboration network to formally include not only National Focal Points for vaccine-preventable diseases (which only in some cases are also NITAG Chairs or members of NITAG secretariat), but also inviting other relevant experts and representatives of Ministry of Health and public health institutes to participate. In some cases, the latter may already be represented in the collaboration for their role as NFP. Participation should be voluntary and should not hamper NITAG work and independence.





- The cooperation structure should have specific ToRs that describe the framework and terms of the collaboration. This strategic document can be shared and approved by all NITAGs wishing to participate in the network.

- Each NITAG should also include in their own ToRs a reference to possible collaboration with other NITAGs, and the terms of collaboration and sharing with other NITAGs, including opportunities to cross attend respective meetings. Currently, only two respondents in our survey reported making reference to this in the NITAG ToRs.

- Attempts should be made, in individual countries, to quantify the costs incurred for NITAG evaluations. Funding is important to facilitate the work of NITAGs and, as highlighted by our survey results, several countries reported this as an issue at the national level for collaborations between NITAGs, with most work within the individual NITAGs being performed free of charge. Besides national funding, EU funds could also be tapped on for collaborative across-country projects.

- Individual NITAGs and the existing ECDC NITAG collaboration group are encouraged to interact with other NITAG networks (e.g., GNN), as relevant.





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Appendix: Survey Questionnaire

EU-JAV WP4 NITAG Costs & Tools

Thank you for agreeing to participate in this survey on the range of attributable costs and tools used for the most recent MS-NITAG evaluations. This survey is being conducted by the Istituto Superiore di Sanità (Rome, Italy), as part of the activities of WP4 (Task 4.3.2: Explore the possibility to establish an appropriate cooperation structure between EU/EEA NITAGs) of the EU-Joint Action on Vaccination (JAV).

INSTRUCTIONS

The link provided to you is personal but you may share it with your colleagues and collaborators for help with survey completion. Please note however, that we wish to receive a single response from each country. You can fill in the questionnaire at different times, since information entered each time is automatically saved when you change pages. The survey can be reopened by using the same link provided to you initially and you will be able to continue where you left off, and modify previous answers if necessary.

There are no mandatory questions. Please use the fields "comment" when you want to add details and/or explanations to your questions.

You can modify your responses to the questionnaire until 23/09/2019. Once you are sure that the questionnaire is completed, please click on the button "DONE" in the last page.

Thank you very much for completing the questionnaire by 23/09/2019. If you have any questions about the survey, please send an email to antonietta.filia@iss.it

Kind regards,

Antonietta Filia Cristina Rota Andrea Siddu Fortunato "Paolo" D'Ancona

Department of Infectious Diseases Istituto Superiore di Sanità (National Health Institute) Rome, Italy







EU-JAV WP4 NITAG Costs & Tools

Details of the person completing the questionnaire

1. Please provide your name, country and job title

Name

Surname

NITAG (name of Country)

Affiliation

Email

2. May we contact you if we have any questions about your responses? \bigcirc Yes \bigcirc No

- 3. What is your role in your country's NITAG?
- O NITAG Chair
- O NITAG Member
- O Member of NITAG secretariat O
- Other (please specify)
- 4. Comments





EU-JAV WP4 NITAG Costs & Tools

Defining the topics and research questions to be evaluated by NITAGs

5. Which institution /person is responsible for appointing the NITAG members?

- 6. Which institution/person is responsible for deciding the work plan of the NITAG, including the topics to be evaluated?
- 7. For each topic, which institution/person is responsible for defining the research question(s) to be analysed?
- 8. If applicable, which institution/person is responsible for appointing the NITAG Working Groups?

9. Comments

EU-JAV WP4 NITAG Costs & Tools

NITAG's budget and costs

- 10. Does your country's NITAG have its own budget?
- Yes (e.g. annual, six-monthy)
- Yes, for specific topics/activities/assignments
- 0 **No**





EU-JAV WP4 NITAG Costs & Tools

Budget

11. What expenses does the budget cover? (More than one answer is possible)

- NITAG functioning (e.g. office space, computers, internet, stationary, meetings, and other services)
- Secretarial staff
- o Scientific staff
- Travel and subsistence allowances
- Subcontracting, including also scientific activities (e.g. epidemiological studies, systematic reviews, modelling for disease, vaccine impact, and cost-effectiveness).
- o Miscellaneous
- o Training /continuing education of NITAG members/staff

12. Comments.

13. In the last five years, for which of the following methods/tools, if any, did you use your

budget (e.g. for staff, subcontracting)? (More than one answer is possible)

- Expert opinion
- Health economic assessment
- Health technology assessment
- Systematic literature reviews
- Live systematic reviews
- o Non-systematic literature review
- Meta-analysis
- Vaccine impact modelling
- o Disease transmission modelling
- Other (please specify)

14. Comments

- **15.** What is the source of funding to cover activities of the NITAG? (e.g. Ministry of Health, Ministry of Finances, Public Health Institute)
- 16. In the last five years, how many vaccine outputs (e.g. reports, documents/vaccine recommendations for internal use or for external dissemination, peer reviewed scientific articles) has your country's NITAG produced?
 - o None
 - o **1-3**
 - o **4-5**
 - o >5





If you answered "1-3" or "4-5" or ">5", you will be asked to select two examples of topics (Topic A and Topic B) assessed by the NITAG of your country in the last 5 years and to provide some information on each of the topics separately.

TOPIC A

- 17. Object of the topic (e.g. HPV vaccination in males)
- 18. Year evaluation was performed
- 19. Which of the following methods and tools were used and what was the cost (specifying the currency) of each, including subcontracting?

19a. Systematic reviews/ Live systematic review

- o Not used
- o This method was used but the information is confidential
- o This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

19b. Meta-analysis

- $\circ \quad \text{Not used} \quad$
- o This method was used but the information is confidential
- \circ This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

19c. Expert Opinion

- $\circ \quad \text{Not used} \\$
- This method was used but the information is confidential
- o This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

19d. Disease transmission modelling/Vaccine Impact Modelling

- Not used
- This method was used but the information is confidential
- o This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

19e. Health economic assessment

- Not used
- This method was used but the information is confidential
- This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

19f. Other scientific activities (if possible, specify with cost)

20. Which ones of these activities were subcontracted externally to the NITAG?

- o None
- Systematic reviews
- Live systematic review





- o Meta-analysis
- Expert Opinion
- Disease transmission modelling
- Vaccine impact modelling
- o Health economic assessment
- Other (please specify)

20a. If possible, please indicate costs for each subcontracted activity:

21. Other costs incurred for the evaluation

21a. Fees (e.g. token of presence for NITAG members or fees paid to external experts besides those regarding expert opinion)

- No fees
- this information is confidential
- o at this time, unable to estimate costs
- Total cost for fees (in number and currency)

21b. Travel costs of NITAG members and other external experts

- No travel costs
- this information is confidential
- o at this time, unable to estimate costs
- Total travel costs (in number and currency)

21c. Other costs (specify type of costs incurred and total for each cost)

22. Comments

TOPIC B

- 23. Object of the topic (e.g. HPV vaccination in males)
- 24. Year evaluation was performed
- 25. Which of the following methods and tools were used and what was the cost (specifying the currency) of each, including subcontracting?

25a. Systematic reviews/ Live systematic review

- Not used
- o This method was used but the information is confidential
- o This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

25b. Meta-analysis

- o Not used
- \circ This method was used but the information is confidential
- \circ \quad This method was used but at this time we are unable to estimate costs
- \circ This method was used and cost was: (in number and currency)





25c. Expert Opinion

- \circ Not used
- o This method was used but the information is confidential
- \circ $\;$ This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

25d. Disease transmission modelling/Vaccine Impact Modelling

- $\circ \quad \text{Not used} \\$
- o This method was used but the information is confidential
- This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

25e. Health economic assessment

- o Not used
- o This method was used but the information is confidential
- \circ This method was used but at this time we are unable to estimate costs
- This method was used and cost was: (in number and currency)

25f. Other scientific activities (specify with cost)

26. Which ones of these activities were subcontracted externally to the NITAG?

- o None
- Systematic reviews
- Live systematic review
- Meta-analysis
- Expert Opinion
- Disease transmission modelling
- Vaccine impact modelling
- Health economic assessment
- Other (please specify)

26a. If possible, please indicate costs for each subcontracted activity

27. Other costs incurred for the evaluation

27a. Fees (e.g. token of presence for NITAG members or fees paid to external experts besides those regarding expert opinion)

- No fees
- o this information is confidential
- o at this time, unable to estimate costs
- Total costs for fees (in number and currency)

27b. Travel costs of NITAG members and other external experts

- No travel costs
- this information is confidential





- at this time, unable to estimate costs
- Total travel costs (in number and currency)
- **28.** If your NITAG has Terms of Reference is there any reference in the ToRs to possible collaborations with other NITAGs?
 - We do not have ToRs
 - **No**
 - Yes (please describe)
- **29.** In the last five years, has your country's NITAG shared (or is it in the process of sharing) any outputs produced regarding vaccines (excluding public results) with other NITAGs? (excluding collaborations that have occurred through the recent ECDC EU/EEA NITAG collaboration)
 - Yes, with a formal agreement
 - Yes, without a formal agreement
 - o No

30. In what did the collaboration consist in?

- Sharing the cost of one or more activities
- Sharing the protocol prepared by one country
- Sharing the systematic reviews/meta-analyses
- o Sharing the models used
- Sharing the cost-benefit analysis
- Jointly preparing the protocol or conducting systematic reviews/meta analyses/mathematical modelling/cost benefit analyses
- Other (please specify)

31. Please give further details below, by specifying the country (or countries) with whom the collaboration occurred, the topics examined, and the mechanisms for sharing costs.

- **32.** What do you consider the main challenges/obstacles encountered in collaborating with other NITAGs and lessons learnt?
- **33.** Which institution/person is in charge of deciding if it is possible to share scientific evidence on vaccines with other NITAGs or international institutions

The questionnaire ends here.

Once you are sure that the questionnaire is completed, please click on the button "DONE" in this page . Thank you for your participation