TECHNICAL REPORT

Current practices in immunisation policymaking in European countries

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This report of the VENICE III consortium and the European Centre for Disease Prevention and Control (ECDC) was coordinated by Paloma Carrillo Santisteve, Pierluigi Lopalco and Lucia Pastore Celentano.

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NITAG survey respondents:

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Czech Republic	Jitka Castkova, Katerina Fabianova	Luxembourg	-
Cyprus	Maria Koliou	Malta	Victoria Farrugia Santangelo
Denmark	Palle Valentiner-Branth	The Netherlands	Hans Houweling, Leo van Rossum
Estonia	Martin Kadai	Norway	Hanne Nøkleby
Finland	Matti Korppi, Hanna Nohynek	Poland	Iwona Paradowska-Stankiewicz
France	Daniel Floret	Portugal	Graca Freitas, Teresa Fernandes
Germany	Ole Wichmann	Romania	Aurora Stanescu
Greece	Andreas Konstantopoulos	Slovakia	Jan Mikas
Hungary	-	Slovenia	Marta Grgic Vitek
Iceland	Þórólfur Guðnason	Spain	Elena Andradas, Aurora Limia
Ireland	Kevin Connolly	Sweden	Tina Chavoshi
Italy	Stefania Iannazzo, Paolo D'Ancona	United Kingdom	Andrew Pollard

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Abbreviations

AMSTAR	A Measurement Tool to Assess Systematic Reviews
CASP	Critical Appraisal Skills Programme
DALY	Disability-adjusted life year
EEA	European Economic Area
EU	European Union
GRADE	Grading of Recommendations Assessment, Development and Evaluation
MoH	Ministry of health
NIP	National immunisation programme
NITAG	National Immunisation Technical Advisory Group
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY	Quality-adjusted life year
SAGE	Strategic Advisory Group of Experts
VENICE	Vaccine European New Integrated Collaboration Effort
WHO	World Health Organization

Background

With an ever-increasing number of vaccines on the market, making the right choices, both in terms of vaccine effectiveness and budget planning, has become increasingly important. In order to find the ideal balance between cost and quality of (i.e. providing the best possible protection to those who benefit the most in a given population), it is essential to first assess all available evidence before introducing a new vaccine to a national immunisation programme (NIP).

The vaccine recommendation process should always be guided by a standardised and transparent assessment of available evidence. The recommendation process also needs to take into account the risks and benefits of the evaluated vaccine ('context-free' factors, e.g. vaccine effectiveness and safety) as well as local cultural values and preferences on vaccination ('context-specific' factors). In the majority of industrialised countries, national vaccine recommendations are developed by so-called national technical advisory groups (NITAGs) [1]. A NITAG is an independent expert advisory committee, providing 'evidence-based recommendations to the Ministry of Health (MoH), policymakers and programme managers to guide policies and formulate strategies' [2]. However, the role and tasks of NITAGs in the decision-making processes can differ considerably from country to country.

During the 'First international workshop on procedures for the development of evidence-based recommendations' in Berlin in 2010 [3], a working group of international experts involved in vaccine decision-making processes discussed the values of international cooperation in the development of evidence-based vaccine recommendations and how it could be organised. It was pointed out, for example, that NITAGs in several countries conducted systematic reviews of the same body of evidence and that this duplication of efforts could be avoided by sharing reviews and putting them in the public domain. International cooperation in this area, the conference participants agreed, should 'aim at the optimal utilisation of existing resources and the support of the NITAGs in the labor-intensive preparation for evidence-based recommendations'. As a first step leading to international cooperation, the structures and modes of practice of the various NITAGs should be explored.

In a 2013 survey conducted as part of the VENICE II project, Nohynek et al. explored key characteristics of NITAGs in EU/EEA Member States [4]. Twenty-two (85%) of the 27 responding European countries indicated that they had a NITAG in place. Ten NITAGs stated they had a framework for the development of NIP vaccine recommendations. However, the study collected no detailed framework information, e.g. whether NITAGs conduct systematic literature reviews or use results from mathematical modelling in the decision-making processes.

This report describes and summarises the national processes for vaccine policymaking currently implemented, the roles of the Member States' NITAGs and – if applicable – details of the national frameworks, with the aim to assess NITAG collaboration in Europe.

Objectives

The aim of this report is to identify and summarise current practices/frameworks established by NITAGs (or expert groups if no NITAG is in place) involved in the development of national vaccination recommendations in EU/EEA Member States. The rationale was to gain a better understanding of the different decision-making processes in each country and explore the potential for synergy and resource sharing between European NITAGs/expert groups, while also identifying potential barriers and limits to collaboration.

The findings of this report are supplemented by results from a systematic literature review on methodologies/ frameworks used by WHO SAGE (Strategic Advisory Group of Experts) and a number of NITAGs in Europe and North America.

Information collected by this survey is intended to inform a 'roadmap for improving data, methodology and resource sharing between NITAGs in Europe', which, if requested by ECDC, will be developed within the VENICE III project.

Specific objectives of this document are:

- to collect additional basic characteristics from NITAGs/expert groups in EU/EEA Member States, building on information which was collected during the previous NITAG survey in 2013;
- to explore in more detail current practices and, if applicable, framework characteristics of EU/EEA Member States' NITAGs/expert groups;
- to explore the opinions of NITAGs/expert groups on the potential of, or limitations to, collaboration and identify those specific areas within the recommendation process; and

- to conduct a systematic literature review on publications that describe current NITAG methodologies and/frameworks for decision-making processes for vaccine recommendations in Europe, North America and for WHO SAGE.

Methodology

NITAG survey of EU Member States and EEA countries

The survey was designed as a follow-up and supplement of the NITAG survey conducted as part of the VENICE II project in March 2013 [4]. The VENICE gatekeepers in 27 EU Member States and the three EEA countries were asked to name, and provide contact details of, an expert in their respective countries who was involved in the decision-making process for national vaccine recommendations. Ideally, this person should be a member of the NITAG (e.g. the NITAG chairperson) or a staff member of the NITAG executive secretariat. In countries without NITAGs, the VENICE gatekeeper was asked to provide the contact details of an expert involved in the development of national vaccine recommendations.

A questionnaire was developed, sent for evaluation and feedback to the VENICE III consortium members, and pilot-tested by staff members of the executive secretariat of the German NITAG. Due to the short time frame of the project, a more extensive pilot study could not be conducted. On 4 February 2014, the finalised questionnaire (see Annex A) was emailed to the nominated contact persons.

The questionnaire consisted of four sections:

- General part, e.g.: What is the role of the NITAG in the recommendation process? Is a NITAG website available?
- Vaccine recommendation process, e.g.: Does a framework/standard operating procedure exist for the development of a vaccine recommendation? What are the key criteria? Is a systematic literature review required?
- Potential for collaboration between NITAGs in the vaccine recommendation process, e.g.: What areas/aspects lend themselves to collaboration?
- Open section, e.g.: Is there any other important information necessary to better understand the decision-making process for vaccines?

Completed questionnaires were sent back to the Robert Koch Institute, assessed for completeness and consistency. If there were unclear answers or remaining questions, a follow-up telephone interview was scheduled. Requests for minor clarifications were sent by email.

Questionnaire Sections 1 and 2, as well as parts of Section 3, were analysed quantitatively to obtain aggregated results which describe key characteristics of NITAGs/expert groups in Europe. The remaining data retrieved from Section 3 and, if applicable, answers from Section 4 were analysed qualitatively. To protect confidentiality, qualitative answers were kept anonymous. Based on information from Sections 1 and 2 as well as data from the previous NITAG survey by Nohynek et al. [4], a profile (key characteristics) was created for each country. The country profiles were then sent to the respective survey respondents for final validation.

Systematic literature review on methodologies/frameworks of NITAGs in Europe, North America, and WHO SAGE

Literature search and study selection

A systematic literature review to identify publications on methodologies/frameworks of NITAGs in Europe, North America and WHO SAGE was conducted on 6 March 2014, using MEDLINE, Global Health, EMBASE and the Health Technology Assessment Database.

The following search strategy was used:

#1 NITAG
#2 National Immunization Technical Advisory Group
#3 1 OR 2
#4 National Immunization Technical Advisory Groups
#5 3 OR 4
#6 NIP
#7 National Immunization Programme
#8 6 OR 7

#9 5 OR 8
#10 Vaccination
#11 9 AND 10

Restrictions: year of publication: 1990 – 6 March 2014

Species: Human

Snowballing sampling was used to identify additional publications and assessed the methodology/framework references provided by the interviewees in the NITAG survey.

To be eligible for inclusion, the publication had to meet the following inclusion criteria: 1) the publication describes the methodology or framework of a NITAG or expert group involved in the vaccine decision-making process in Europe or North America or describes the methodology or framework of WHO SAGE; 2) the publication was published after 1990.

Publications that were solely describing the structure of the NITAG/expert group or WHO SAGE were not included. Titles and abstracts were screened independently by two reviewers. Potentially eligible publications were reviewed in full text. Disagreements were solved by discussion until agreement was reached.

Results

Responses to the NITAG survey of EU/EEA Member States

By 30 April 2014, 28/30 (93%) countries had responded to the questionnaire. Hungary and Luxemburg did not participate in the survey. Liechtenstein had to be excluded from the survey because the country – not having its own NITAG or expert group – adopts NITAG recommendations without further assessment from Switzerland.

For Cyprus, only data from Section 3 ('Potential for resource collaboration between NITAGs in the vaccine recommendation process') were included in the results section. The Cyprus NITAG was discontinued in 2013. Cyprus plans to establish a new NITAG by 2016; in the meantime, an ad hoc committee assumes all NITAG functions. No country profile was created for Cyprus because the new terms of reference for the future NITAG have not been finalised and data on the temporary committee would skew the analysis.

Follow-up or clarification questions were addressed to 26 countries; 17 (63%) countries were scheduled for an additional telephone interview, eight (30%) countries were contacted through email. For the remaining country, no follow-up interview could be scheduled. No follow-up questions arose for one country.

General characteristics and NITAG functions

All 26 participating countries stated that they have a NITAG or expert group involved in the national vaccine recommendation process; 21 (81%) of them designated themselves as NITAGs. The number of NITAG or expert group members ranged from 7 in Iceland to 35 in Belgium. Table 1 shows further general characteristics of the NITAGs or expert groups.

Table 1: General characteristics of NITAGs/expert groups (n=26)

Characteristics	Countries (n)	Proportion (%)
Years since NITAG/expert group has been established:		
< 5 years	5	19
5–20 years	12	46
> 20 years	9	35
NITAG/expert group members have to declare potential conflicts of interest	20	77
NITAG/expert group chair is:		
Appointed by ministry of health or other/subordinate institution	20	77
Selected by NITAG/expert group members	5	19
No official chair	1	4
NITAG/expert group has voting members from:		
National public health institute (or equivalent)	15	58
Ministry of health	13	50
Neither ministry of health nor national public health institute (or equivalent)	5	19

Table 2 describes the professional expertise represented in NITAGs and expert groups. Information is based on Nohynek et al. [4] and this survey.

Table 2: Professional expertise represented among NITAGs and expert groups (n=26)

Field	Countries (n)	Proportion (%)
Epidemiology	25	96
Paediatrics	24	92
Clinical medicine	22	85
Public health	21	81
Vaccinology	21	81
Immunology	20	77
Microbiology (incl. virology)	17	65
University faculty/various disease specialists	6	23
Health economics	5	19
General practice	5	19
Regulatory authority on medicines	3	12
Evidence-based medicine/systematic reviews	2	8
Non-governmental organisations	2	8

Field	Countries (n)	Proportion (%)
School health medicine	2	8
Social sciences	2	8
Ethics	1	4
Health insurance system	1	4
Lawyer	1	4
Lay members	1	4
Transmission modelling	1	4
Pharmaceutical company[1]	1	4
'Well-baby clinics'	1	4

[1] Representative from the Association of Pharmaceutical Companies

Seventeen (65%) NITAGs/expert groups have an executive secretariat or administrative office. The number of full-time staff in these offices ranged from no full-time staff to a maximum of 3.5 persons. Twenty (77%) NITAGs/expert groups indicated that they have additional persons/institutes scientifically supporting the NITAG/expert group. Those persons belonged to national public health institutes, other federal institutions (e.g. medicine agencies), universities, or were external (disease) specialists/experts.

Eleven (42%) NITAGs or expert groups stated that they owned a website. Four countries provide online materials in English: while the websites in the United Kingdom and Malta offer comprehensive NITAG-specific material, the other two countries offer translations in three areas: a NITAG description (n=1), background material (e.g. recommendations) (n=2), and miscellaneous materials (e.g. advisory reports) (n=1).

The NITAGs' or expert groups' role in the decision-making process of a national vaccine introduction is summarised in Table 3.

Table 3: Role of NITAGs/expert groups (n=26) in the decision-making process for the introduction of new vaccines

Characteristics	Countries (n)	Proportion (%)
NITAG/expert group advises:		
Ministry of health	16	62
National public health institute (or equivalent)	9	35
No advisory function	1	4
Final decision to introduce a new vaccine to the national vaccination schedule/programme:		
Ministry of health	12	46
Ministry of health in combination with other stakeholders (e.g. regional authorities and/or Ministry of finance)	9	35
Parliament or government	3	12
NITAG*	2	8
Funding scheme for vaccinations in the national immunisation schedule		
Tax-funded	19	73
Mixed (tax-funded and social insurance)	4	15
Social insurance	3	12

** Includes one country where the ministry of health is obliged to introduce the vaccine if it is recommended by the NITAG, provided it is also cost-effective.*

It should be noted that information on the national funding scheme sometimes only applies to 'mandatory vaccinations', as opposed to 'recommended vaccinations', which are treated as out-of-pocket medical expenses, e.g. in Poland. Recommended vaccinations (to be paid out-of-pocket) include, but are not limited to, travel vaccinations. See also Annex B.

Frameworks/processes for evidence assessment

Of the 26 countries that participated, 20 (77%) indicated that the NITAG uses a systematic approach (e.g. framework or standard operating procedure). Of those 20 systematic approaches, 13 (65%) contained a fixed list of key criteria (e.g. disease burden in the country, etc.) that need to be addressed. The key elements and key criteria of those systematic approaches are listed in Annex B.

Fifteen (58%) countries indicated that they are required to use systematic literature reviews to answer key questions before they can issue national vaccine recommendation. Although ten countries declared that they are not required to do so, they stated that systematic literature reviews are optional and are often conducted if resources permit doing so. One country does not use systematic reviews. Countries which are not required to use

systematic reviews, gave the following reasons for not conducting literature reviews: 'too much work' (n=4), 'lack of funding/resources' (n=5), 'invited experts in the field already have a good overview of the published literature and can therefore select the most relevant publications' (n=1), and 'lack of local epidemiological data' (n=1). Table 4 further describes elements of the vaccine recommendation process in the surveyed countries.

Table 4: Elements of the vaccine recommendation process from surveyed NITAGs/expert groups (n=26)

Characteristics	Countries (n)	Proportion (%)
NITAG/expert group usually uses:		
Self-conducted systematic reviews and published systematic reviews by others (e.g. Cochrane Collaboration)	17	65
Only published systematic reviews by others	8	31
No reviews	1	4
Mathematical modelling considered as part of the recommendation development process (e.g. transmission modelling)	18	69
Mathematical modelling is:		
Outsourced (e.g. national public health institute or similar institute)	15	58
Developed within NITAG/NITAG executive secretariat	8	31
Experiences exist with adopting existing models to own local setting	7	27
Health economic evaluations considered as part of the recommendation process (e.g. cost-effectiveness studies)	20	77
Level at which the economic evaluation is considered:		
NITAG/expert group	16	62
Ministry of health or government, parliament or ministry of finance (or similar)	14	54
Economic assessment contains cost-effectiveness threshold	5	19
Cost-effectiveness threshold is final/decisive criterion	2	8

Of the 17 NITAGs/expert groups that conduct systematic reviews, 17 (100%) use peer-reviewed data; nine (53%), also use unpublished/non-peer reviewed data in addition to peer-reviewed data. Five (31%) of those 17 countries apply quality appraisal tools for individual studies (e.g. Critical Appraisal Skills Programme (CASP), Cochrane risk of bias tool) or a system to grade the quality of the body of evidence (e.g. the GRADE approach (Grading of Recommendations, Assessment, Development and Evaluation)). Tools or systems named were GRADE (n=4), CASP (n=2) and the Cochrane Risk of Bias Tool (n=1).

Of the 25 NITAGs or expert groups that utilise systematic reviews conducted by other groups, three (12%) stated that they assess the methodological quality of the review using a tool (AMSTAR: n=2; PRISMA: n=1). Eight NITAGs declared that they outsource or are allowed to outsource systematic reviews to a third party (e.g. an institution or private company); of those, five said that they require an evidence assessment to be performed, and five stated that the contract allows them to share the systematic review with other parties, e.g. foreign health agencies.

Table 5 provides information on the number of NITAGs/expert groups that usually publish an explanatory background paper outlining the rationale behind a positive or negative recommendation decision. It has to be noted that the respondents' answers can refer to both peer-reviewed or non-peer reviewed online publications, e.g. on the NITAG's/expert group's own website.

Table 5: NITAGs/expert groups (n=26) that usually publish an explanatory background outlining the rationale behind a positive or negative recommendation decision

	Countries (n)	Percentage (%)
Background paper published with decision rationale	13	50
If yes, the document contains…		
References to used literature	9	69
Narrative summary	8	62
Detailed results of systematic reviews including meta-analysis	6	46
Other materials	6	46
Comprehensive background report (including all items above)	2	15

Country profiles

A listing of the general characteristics and specifics of the vaccine recommendation process by country can be found in Annex B. All country profiles were validated by the respective respondent(s).

Potential for collaboration

Of the 27 countries that participated, 25 (93%) thought that there is 'potential for a collaboration/resource-sharing between NITAGs to support the individual country's process of developing vaccination recommendations'. Two countries believed that there was no potential. Asked for reasons, one country stated 'lack of resources', the other country pointed out that 'the committee is just for recommendation to the Minister of Health'. This could not be explored further because no follow-up phone interview could be scheduled.

When asked in which areas collaboration or resource sharing would be most productive, five (20%) of the 25 countries named systematic literature reviews, and 14 (56%) mentioned collaborating in context-free aspects like vaccine effectiveness, vaccine efficacy or vaccine safety. Of the total of 19 (76%) countries that saw potential for collaboration in the area of systematic literature reviews and/or context-free aspects in particular, twelve had indicated in Section 2 of the questionnaire that they were required to perform systematic reviews during the vaccine recommendation process; of those 12, ten conduct their own reviews.

Nineteen (76%) countries thought it would be beneficial to also collaborate in context-specific aspects. One country stated that 'there is always a value to also share the context-specific aspects', another that 'context-specific material may be illustrative of possible interpretations, assessments and recommendations'. Cost-effectiveness and/or mathematical modelling were mentioned by 15 countries, and disease burden assessment by 11 countries. It was suggested that 'mathematical models and cost-effectiveness models could be shared in order to be adapted to every specific country' and that 'burden assessment templates and mathematical modelling templates [should be shared] in which specific assumptions and country data could be introduced'.

One country mentioned that it was 'unsure about context- and country-specific aspects' and another pointed out that 'context-specific aspects like cost-effectiveness modelling can be difficult as other institutes needed to be included in the collaboration'.

Asked about minimum requirements for joint systematic reviews, mathematical modelling and/or economic models, 18 countries (72%) favoured agreed methodologies and written guidelines. However, while most countries only mentioned that there should be agreed methodologies, some respondents provided more detail: 'Collaborating NITAGs should have the possibility to give input in the beginning of the process, e.g. which outcomes should be considered in the review or inclusion/exclusion criteria of studies'; also, a common methodology should include 'e.g. a search strategy, paper selection, and exclusion criteria of publications', make 'use of the same tools, e.g. GRADE, AMSTAR, etc.' and should 'guarantee high quality of the work, for better comparability and to make the review process more transparent'. Finally, one country mentioned that there should also be 'a plan for peer review/publication' of those collaborative/shared systematic reviews.

Regarding barriers and limitations to collaboration, responses fell into three different categories:

a) Lack of funding and/or lack of (personnel) resources and/or lack of available expertise (n=10)

Most of the countries expressing this barrier/limitation were small countries and/or countries with fewer resources.

b) Possible language barriers and cultural differences (n=5)

Cultural differences and their different values and preferences may lead to a different assessment of available evidence and thus to different recommendations: 'This [vaccination recommendations including assessments of several sub-questions, each of them with their own value judgments], in our opinion, not only precludes grading of the recommendation, it also means that any assessment can only partially rely on a systematic review or an economic model. Although it will be stimulating and useful to participate in any such collaborative effort, that effort will cover only part of the assessment.'

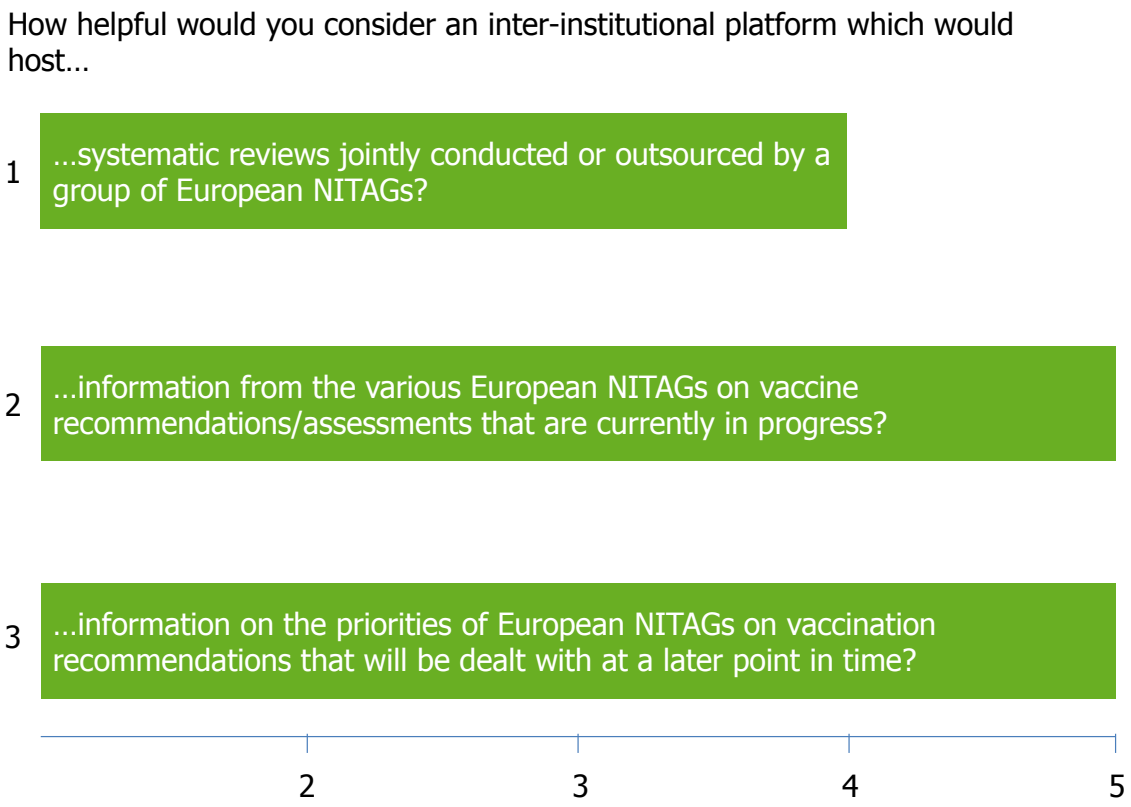
c) Structural concerns (n=16)

Countries mentioned either limiting differences in the countries' healthcare systems/vaccine delivery structures and disease burden/epidemiological situation, or differences among countries regarding the respective role of the NITAG and NITAG (working) structures. Concern was expressed 'when the collaboration exceeds the technical level' or that 'tasks of the vaccination recommendation process can be in different institutions; close collaboration [among those intra-country institutions] would be necessary which is often yet not present'. Furthermore, 'NITAGs/MoH put different value on the methodological requirements in the process of developing NITAG recommendations due to differences in the available resources but also due to different consequences of the NITAG recommendations. … [If the NITAG decision] triggers automatically a coverage decision by health insurances, there is much more of a need to apply rigorous methodologies and be transparent as much as possible.'

Another point raised in the questionnaires was that NITAGs may not always work on the same topic(s): 'countries might be in a different process, one is considering a vaccination while another one is considering another one. However, this should still not hinder collaboration. When a country is considering to assess [a specific] vaccination, a request could be sent out for collaboration. And the result of the assessment should be shared.'

Finally, the survey assessed the countries' interests in sharing information on current NITAG activities and output; respondents were asked to rate the helpfulness of sharing information on a scale from 1 (not necessary at all) to 5 (very helpful). The Figure below depicts the median score for each of the three sub-questions. Answers for sub-question 1 ranged between 2 and 5; for sub-questions 2 and 3 answers ranged between 1 and 5.

Figure: Rated level of interest in NITAG activities or output, as expressed by NITAG's/expert groups (n=26); median rating scores



Systematic literature review regarding methodologies/frameworks of NITAGs in Europe, North America and WHO SAGE

The first search retrieved 299 publications. De-duplication and title screening reduced the number to 31 publications. Applying the snowballing technique generated an additional 20 potentially eligible publications. After a full text screening of a total of 51 publications, eight publications were eligible in accordance with the inclusion criteria. They were supplemented with six additional non-peer reviewed publications which also met the inclusion criteria and were provided by the respondents of the NITAG survey. A list of excluded publications can be found in Annex C.

The identified publications of methodologies/frameworks refer to nine European and the two North American countries; one publication covers WHO SAGE:

Europe

Denmark	Health Technology Assessment. Toolbox. Available from: https://sundhedsstyrelsen.dk/en/health/quality-and-guidelines/centre-for-health-technology-assessment
Finland	Nohynek H. The Finnish decision-making process to recommend a new vaccine: From vaccine research to vaccination policy. J Public Health 2008;16:275-80.
	Systematic approach for development of national vaccine recommendations [in Finnish]. Available from: http://www.thl.fi/fi_FI/web/rokottajankasikirja-fi/kansallinen-rokotusasiantuntijaryhma

Germany	Standing Committee on Vaccination. Standard operating procedures of the German Standing Committee on Vaccination (STIKO) for the development of vaccination recommendations. Version 1.0. Available from: http://www.stiko.de/en
Italy	Ministero della Salute. Piano Nazionale Prevenzione Vaccinale (PNPV). 2012-2014 [in Italian]. Available from: http://www.salute.gov.it/imgs/C_17_pubblicazioni_1721_allegato.pdf
Portugal	Diário da República. Portaria nº 243/2013, 11/04/2013; DR, 2ª série, nº 78, 22/04 [in Portugese]. Available from: http://dre.pt/pdfgratis2s/2013/04/2S078A0000S00.pdf
Spain	Grupo de trabajo criterios 2011, de la ponencia de programa y registro de vacunaciones criterios de evaluación para fundamentar modificationes en el programa de vacunación en españa. comisión de salud pública del consejo interterritorial del sistema nacional de salud. Ministerio de Sanidad, Política, Social e Igualdad. 2011. [in Spanish]. Available from: http://www.msssi.gob.es/ciudadanos/proteccionSalud/vacunaciones/docs/Criterios_ProgramaVacunas.pdf
Sweden	Socialstyrelsen. Modell för framtagande av underlag till regeringen inför beslut om nationella vaccinationsprogram. 2013. [in Swedish]. Available from: http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/19243/2013-11-9.pdf
Switzerland	Masserey Spicher V. The Federal Vaccination Commission in Switzerland: An officially appointed independent commission ensuring evidence-based recommendations and transparent procedures. Vaccine 2010;28S:A48-A53.
The Netherlands	Houweling H, Verweij M, Ruitenberg EJ, on behalf of the National Immunisation Programme Review Committee of the Health Council of the Netherlands. Criteria for inclusion of vaccinations in public programmes. Vaccine 2010;28:2924-31.
	Health Council of the Netherlands. The future of the National Immunisation Programme: towards a programme for all age groups. Report nr. 2007/02E. The Hague: Health Council of the Netherlands, 2007. Available from: http://gr.nl/sites/default/files/200702E_0.pdf
UK (England)	Joint Committee on Vaccination and Immunisation. Code of Practice June 2013. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224864/JCVI_Code_of_Practice_revision_2013_-_final.pdf
North America	
Canada	Ismail SJ, Langley JM, Harris TM, Warshawsky BF, Desai S, FarhangMehr M. Canada's National Advisory Committee on Immunization (NACI): Evidence-based decision-making on vaccines and immunization. Vaccine 2010;28(Suppl.1):A58-63.
	National Advisory Committee on Immunization (NACI). Evidence-based recommendations for immunization – methods of the National Advisory Committee on Immunization. An Advisory Committee Statement (ACS). Can Commun Dis Rep 2009;35(ACS-1):1-10.
	Erickson LJ, De Wals P, Farand L. An analytical framework for immunization programs in Canada. Vaccine 2005;23:2470-76.
United States	Ahmed F, Temte JL, Campos-Outcalt D, Schünemann HJ, for the ACIP Evidence Based Recommendations Work Group (EBRWG). Methods for developing evidence-based recommendations by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention. Vaccine 2011;29:9171-76.
WHO SAGE	
WHO SAGE	Duclos P, Durrheim DN, Reingold AL, Bhutta ZA, Vannice K, Rees H. Developing evidence-based immunization recommendations and GRADE. Vaccine 2012;31:12-19.

Six of the 12 countries had their framework published in a peer-reviewed journal, as did WHO SAGE. Two of these countries also published additional framework information on their NITAG-related websites. The remaining seven frameworks were only published on websites associated with the NITAG/expert group or government. The Finnish peer-reviewed framework publication used a practical example (*Haemophilus influenzae* type b, seven-valent pneumococcal conjugate and human papilloma virus) to illustrate the decision-making process. Information included in the published frameworks for Italy, Portugal, Spain and Sweden was not used because the documents were not available in English.

Publications of the non-surveyed countries Switzerland, Canada and the United States, and also of WHO SAGE, indicate that the decision-making process is preceded by a systematic literature review regarding predefined

outcomes. In Switzerland for example, the following outcomes are considered (in descending importance): mortality, hospitalisations, overall morbidity, epidemic potential, and equity and disability-adjusted life years (DALYs) or quality-adjusted life years (QALYs). The decision-making process is based on a process previously established in Quebec, Canada (described in Eriksen et al.), and later adapted to the Swiss situation. The Canadian NITAG has its own system to assess the quality of evidence ('Schema for ranking individual study design' and 'Quality (internal validity) rating'), followed by a 'Synthesis of the body of evidence' conducted by the respective NITAG Working Group. By contrast, WHO SAGE and the US NITAG require the use of GRADE in their frameworks as a grading system to assess the quality of the body of evidence. The Canadian NITAG uses a system of six criteria (good/fair evidence for/against recommendation of a vaccination, conflicting evidence, insufficient evidence) while the US NITAG assigns three recommendation categories (vaccination recommendation applies to all persons in an age or risk group; vaccination is up to individual clinical decisions; no recommendation/unsolved issue) to categorise evidence-derived vaccination recommendations.

Discussion and conclusions

The survey gathered information on 28 of the 30 EU and EEA countries, thereby allowing for a detailed and representative inventory of NITAGs and expert groups involved in the vaccine recommendation process. All but two of the participating countries have a NITAG or expert group in place. Of those two countries without NITAGs, one is currently restructuring its health system (which led to the discontinuation of its NITAG in 2013; a new NITAG will be implemented by 2016), while the other one directly implements the NITAG recommendations of its bigger neighbouring country.

This survey of NITAGs shows a wide variety of structures, outlines the diverse roles NITAGs play within the decision-making process, and offer some insights in the resources available to NITAGs or expert groups. Although 77% of the NITAGs claim that they use a systematic approach, e.g. a framework or standard operating procedure, an analysis of the key elements and key criteria of these frameworks showed that the range of approaches used by the various NITAGs within those systematic approaches is large and differs between countries. Only nine (45%) of the countries with a framework chose to publish it, and only two of those countries published their framework in a peer-reviewed journal, offering the added advantage of easy access via Pubmed. The remaining frameworks were published on websites associated with the NITAG/expert group or government, which makes access rather difficult. To complicate matters even further, four of those seven frameworks were only available in the local language.

Nearly all (96%) NITAGs/expert groups in our survey indicated the use of systematic reviews. While some NITAGs only user their own systematic reviews, others also used reviews by a third party (e.g. Cochrane Collaboration) or relied on both options. The use of a tool or grading system to assess the quality of evidence is not very common: five respondents claimed they used grading systems for single studies, while three declared they used such tools to evaluate bodies of evidence. Only eight (31%) of the surveyed countries are entitled to outsource systematic reviews. Of those who do, five are allowed to share the results with other parties.

Health economic assessments were part of most vaccine recommendation processes (n=20; 77%). Five countries indicated to have a cost-effectiveness threshold. However, only two countries use exceeding this threshold as a criterion against a vaccine. Mathematical modelling as part of the recommendation process was conducted in 18 (69%) countries. Seven countries have adapted models from third countries to their local situation. However, the fact that more countries cited health economic assessments than mathematical modelling (mathematical modelling is indispensable for cost-effectiveness studies) might indicate that respondents interpreted the two terms different from their intended meaning.

Nearly all NITAGs and expert groups (93%) believed that the development of evidence-based vaccination recommendations had a potential for collaboration and resource sharing. A high percentage (76%) of NITAGs wanted to collaborate in the field of systematic reviews, covering both context-free and context-specific aspects. The context-free areas mentioned were vaccine effectiveness, vaccine efficacy, vaccine safety; context-specific areas included cost-effectiveness, mathematical modelling and the assessment of disease burden. With regard to joint systematic reviews, 72% favoured agreed methodologies and written guidelines as a minimum requirement. A small number of countries suggested a number of concrete requirements (probably based on national prerequisites in their systematic approaches), including predefinitions for search strategies, inclusion/exclusion criteria for publications, and the application of tools or grading systems (e.g. GRADE, AMSTAR) to make the review process more transparent.

Regarding barriers and limitations for collaboration, responses could be grouped into three categories: lack of resources and expertise in the country (concerns voiced to a large degree from smaller countries or countries with less resources), possible language barriers and cultural differences, and barriers due to structural concerns, either based on structural differences in the NITAGs' role in the decision making process, framework requirements and working structures or based on differences in the countries' health care systems, vaccine delivery structures and epidemiological situations/disease burdens.

In what could be seen as a potential first step towards collaboration, respondents generally considered it very helpful to receive information on recent output from other NITAGs/expert groups. They showed great interest in an institutional platform organising joint systematic reviews, which would either be conducted by a group of EU/EEA NITAGs or outsourced by them; other topics for joint activities could include information on vaccine recommendations and vaccine assessments performed by the various NITAGs/expert groups in the EU, as well as information on NITAGs'/expert groups' priorities for vaccine recommendations that needed to be dealt with in the near future. Information on the last two points has already been collected under Work Package 4 of this project.

Information collected in this survey provides baseline data which make it possible to further explore
a) collaboration at the individual NITAG/expert group level (see information provided in the country profiles), and
b) collaboration at the EU level by establishing structures for broader resource-sharing, e.g. providing an inter-institutional exchange platform. Such collaboration would most likely require an agreement on a number of

practical issues, e.g. data protection, a code of conduct for considering unpublished data, concrete guidelines for systematic reviews, and a decision where such an inter-institutional platform would be hosted.

This survey could therefore serve as a starting point for developing a roadmap for improved data, methodology and resource sharing among European NITAGs.

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[3] Matysiak-Klose D, Ahmed F, Duclos P, Falck-Ytter Y, Forland F, Houweling H, et al. Report on the first international workshop on procedures for the development of evidence-based vaccination recommendations, Berlin, Germany, 22–23 November 2010. Vaccine 2012;30(14):2399-404.

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Appendix A. Questionnaire

I. General part

1. Does your country have a National Immunization Technical Advisory Group (NITAG)?
☐ Yes ☐ No (please go to question 3)

2. **If a NITAG is in place:**
2.1 Are experts from the following institutions voting-members of your NITAG?
Ministry of Health ☐ Yes ☐ No
National Public Health Institute/equivalent ☐ Yes ☐ No
☐ Not applicable
2.2 How /by whom is the NITAG chair selected or appointed?
Answer:
2.3 Does your NITAG have an Executive Secretariat/administrative office?
☐ Yes ☐ No
2.3.1 If **yes**: How many full-time staff are on the secretariat?
Answer:
2.3.2 Are there additional persons that scientifically support the NITAG in its work?
☐ Yes ☐ No
2.3.2.1 If **yes**: From which institutions?
Answer:

3. **If no NITAG is in place:**
3.1 Is any other expert group involved in the decision-making process?
☐ Yes ☐ No (please go to question 3.1.2)
3.1.1 If **yes**: Of whom does the expert group consist? Who choses/appoints them? How are they chosen? Is it a standing group or do the experts change depending on the topic/question?
Answer:
3.1.2 If **no**: Who is the key decision-making driver in your country?
Answer:

4. Could you briefly explain the decision making process of a national vaccine introduction in your country by answering the following questions:
4.1 Which institutions /expert groups are involved (e.g. NITAG, Ministry of Health, Parliament) and in what order?
Answer:
4.2 Which institution/ministry or the like is the NITAG (or expert group making the national vaccine recommendation) attached to/part of?
Answer:
4.3 Who does the NITAG (or expert group making the national vaccine recommendation) advise (e.g. ministry of health)?
Answer:
4.4 Who takes the final decision on the introduction of a new vaccine in the national vaccine schedule (e.g. ministry of health, ministry of finance, parliament)?
Answer:
4.5 Who pays for the vaccination adopted in the national immunisation schedule of your country? (e.g. public-funded program, reimbursement etc.)
Answer:

5. Does your NITAG or the expert group making the national vaccine recommendations has/have a website?
☐ Yes ☐ No (please go to question 6)
5.1 If **yes**: Please provide the address:
Answer:
5.2 If **yes**: Does you provide English translations of NITAG-specific material on that website?
☐ Yes ☐ No (please go to question 6)
5.2.1 If **yes**: Which parts are translated?
☐ NITAG description ☐ Background materials (e.g. recommendations)
☐ All ☐ Other:
6. Who is the contact person for the NITAG or the expert group making the national vaccine recommendations in your country (to be included in the report)?
Answer:

II. Vaccine recommendation process

7. Does your NITAG/the expert group developing the national vaccine recommendations use a systematic approach (in the sense of a framework or standard operating procedure) that is adhered to during the development of a vaccine recommendation?
☐ Yes ☐ No (please go to question 8)
7.1 If **yes**: Could you briefly describe this framework? What are the key elements?
Answer:
7.2 If **yes**: Is that systematic approach set out in writing?
☐ Yes ☐ No (please go to question 7.3)
7.2.1 If **yes**: Has it been published?
☐ Yes ☐ No
7.2.2 If **yes**: Can you provide us with the document or the URL?
☐ Yes ☐ No
7.2.3 If **yes**: Document is sent per email ☐ Yes ☐ No
or URL:

7.3 If **yes**: Does it contain a fixed list of key criteria (e.g. disease burden in the country etc.) that needs to be addressed?
☐ Yes ☐ No (please go to question 8)
7.3.1 If **yes**: What are they?
Answer:

8. Is your NITAG or the expert group required to use systematic literature reviews to answer key questions for a national vaccine recommendation?
☐ Yes (please go to question 8.4) ☐ No (please go to question 8.1)
8.1 If **no**: What procedure do you use instead?
Answer:

8.2 If **no**: What are the reasons that you do not conduct/use systematic reviews?
☐ Too much work
☐ Language barriers
☐ Limited/no access to certain journals
☐ Lack of funding/resources
☐ Other:
8.3 Would you consider it helpful to be provided with a systematic review for the respective topic by an independent body?
☐ Yes ☐ No (please go to question 9)
8.4 If **yes**: Do you usually use published systematic reviews (conducted by others such as the Cochrane Collaboration) or do you conduct the systematic literature reviews yourself?
☐ own product (please go to question 8.4.1)
☐ conducted by others (please go to question 8.4.4)
☐ both (please explain):
8.4.1 If NITAG/NITAG Secretariat conducts **own reviews**: Who conducts them? (e.g. NITAG members, secretariat staff or outsourced)?
Answer:
8.4.2 If NITAG/NITAG Secretariat conducts **own reviews**: Do you only include peer-reviewed evidence or also unpublished data in your reviews?
☐ only peer-reviewed ☐ peer-reviewed and unpublished/non-peer reviewed
8.4.2.1 If **unpublished/non-peer-review data**: Where is the data usually coming from? (e.g. from industry or European Public Assessment Reports)?
Answer:
8.4.3 If NITAG/NITAG Secretariat conducts **own reviews**: Do you apply **q**uality **a**ppraisal **t**ools (QATs) for individual studies or systems to grade the quality of the body of evidence (e.g. GRADE)?
☐ Yes ☐ No (please go to question 9)
8.4.3.1 If **yes**: Which one do you usually apply?
Answer:
8.4.4 If you use **reviews conducted by others** (e.g. published in peer-reviewed journals or outsourced): Do you assess the methodological quality of the review?
☐ Yes ☐ No (please go to question 8.5)
8.4.4.1 If **yes**: How is it assessed (e.g. AMSTAR)?
Answer:
8.5 Do you outsource systematic reviews to a third party (e.g. institution, private company)?
☐ Yes ☐ No (please go to question 9)
8.5.1 If **yes**: Is there a guideline that has to be followed when you outsource reviews (in the sense: are there criteria that have to be fulfilled in the final product)?
☐ Yes ☐ No (please go to question 8.5.2)
8.5.1 If **yes**: What are they?
Answer:
8.5.2 If **yes**: Do you require an evidence grading system to be used to assess the quality of the body of gathered literature (e.g. GRADE)?
☐ Yes ☐ No (please go to question 8.5.3)
8.5.2.1 If **yes**: Which one?
Answer:
8.5.3 If **yes**: Does the contract (usually) allow you to share the systematic review with other parties, e.g. foreign national health agencies?
☐ Yes ☐ No

9. Do you include results of own/outsourced/published mathematical modelling (e.g. transmission modelling) in your vaccine recommendation process if applicable?
☐ Yes ☐ No (please go to question 10)
9.1. If **yes**: Do you usually develop such models yourself or outsource such work?
☐ Own models ☐ Outsource (please go to question 10)
9.2. If **own models**: Do you have experiences in adopting existing models from other countries to your own local setting (e.g. through a collaborative effort)?
☐ Yes ☐ No

10. Are at any stage health economic evaluations (e.g. cost-effectiveness studies) part of the vaccine recommendation process?
☐ Yes ☐ No (please go to question 11)
10.1 If **yes**: At what decision level of the vaccine recommendation process are health economic assessments considered (e.g. within the NITAG, later at Ministry of Health or Parliament)?
Answer:
10.2 If **yes**: Does the economic assessment contain a cost-effectiveness threshold that should not be exceeded (e.g. 30,000 € per avoided QALY)?
☐ Yes ☐ No (please go to question 11)
10.2.1 If **yes**: Is the excess of the cost-effectiveness threshold a final/definite criterion against the vaccine introduction?
☐ Yes ☐ No

11. After a decision has been made regarding the positive or negative recommendation of a vaccine: Do you usually publish (peer-reviewed or online, e.g. own website) a background paper with a decision rationale?

☐ Yes ☐ No (please go to question 12)

11.1 If **yes**: What does it include?

☐ Narrative summary

☐ Detailed results of systematic reviews including meta-analysis

☐ References of used literature

☐ Other:

III. Potential for resource collaboration between NITAGs in the vaccine recommendation process

12. Do you think there is potential for collaboration/resource-sharing between NITAGs to support the individual country's process of developing vaccination recommendations?

☐ Yes ☐ No (please go to question 12.2)

12.1 If **yes**: In which areas/aspects of the vaccination recommendation development process (e.g. context-free aspects (such as review of vaccine efficacy/effectiveness data) or context-specific aspects (such as country-specific modelling of cost-effectiveness, mathematical modelling or disease burden assessment))?

Answer:

12.1.1 If the interviewee believes that **joint systematic reviews or joint use/development of mathematical/economic models are possible**: What would be minimum requirements for a collaboration in conducting such work (e.g. agreed guidelines, methodologies)?

Answer:

12.2 If **no**: For what reasons?

Answer:

13. What barriers or limitations do you see in general for collaboration between NITAGs?

Answer:

14. Would you consider an institutional platform as helpful that would host:

14.1 systematic reviews jointly conducted or outsourced by a group of European NITAGs?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

(not necessary at all) (very helpful)

14.2 information on vaccine recommendations/assessments currently in progress of the different European NITAGs?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

(not necessary at all) (very helpful)

14.3 information on European NITAGs' priorities for vaccine recommendations that need to be dealt with?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

(not necessary at all) (very helpful)

IV Supplemental information

15. Is there any other important information that can be shared with us to better understand the immunization decision-making process in your country and potential modes of NITAG collaboration?

Answer:

Appendix B. Validated country profiles

AUSTRIA (validated) As of 30 April 2014

General facts	
Name of recommending body	Nationales Impfgremium (NIG) English: National Vaccination Committee
Self-designation as National Immunization Technical Advisory Group (NITAG)	Yes
Contact	National Vaccination Committee Prof. Ursula Wiedermann, NITAG chair
Year established	2011 (previous committee: 1984–2010)
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	No
NITAG or expert group receives (additional) scientific support from:	If applicable, representatives of topic-related specialties
Number of NITAG or expert group members	10
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists/infectiologists
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises:	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health after negotiation with the Ministry of Finance, the Federal States Governments and social insurance
Funding scheme for vaccinations in the national immunisation schedule	Mixed (4/6 Ministry of Health, 1/6 Federal State Governments, 1/6 social insurance)

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	• Formulation of question: PICO approach for interventions, flexible approach for other cases • Systematic literature research (definition of inclusion/exclusion criteria, data bases and/or other sources) • Data/study selection • Assessment of the data/studies: modified GRADE for interventions, individually adapted/chosen criteria for other cases
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	Primary criteria: • Availability of vaccine • Vaccines of special public health importance • Epidemiology • Data on efficacy and safety of the vaccine Secondary criteria: • Opportunities and risks of vaccination programme • Expected acceptability • Compatibility with existing vaccination schedule • Vaccines in the existing vaccination schedule
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes

Vaccine recommendation process	
Data source(s)	Peer-reviewed Unpublished/non-peer reviewed (European Public Assessment reports, EMA authorisation reports)
Evidence assessment performed with tool/system	Yes
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Modified GRADE (e.g. observational studies start as 'high quality')
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	Yes
Name of tool(s) (e.g. AMSTAR)	PRISMA guidelines
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	NITAG Outsourced
Experience with adopting existing models from other countries to own setting	No
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Annual update of vaccination recommendation (national vaccine schedule)

BELGIUM (validated) As of 30 April 2014

General facts	
Name of recommending body	Hoge Gezondheidsraad – Conseil Supérieur de la Santé English: Superior Health Council
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Superior Health Council Dr Veerle Mertens, Scientific Collaborator
Year established	1991
Website	www.hgr-css.be
Website material in English	No
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from::	Federal and regional institutions and universities
Number of NITAG or expert group members	35
NITAG or expert group chair is elected/appointed by	NITAG members
Voting-member composition	Clinicians, epidemiologists, health economists, immunologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists, general practitioner, school health medicine specialist, 'well baby clinics' specialist
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	> 5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health/Social Affairs
Final decision-maker for vaccine introduction in the national programme	National Ministry of Health/Social Affairs and Regional Ministries of Health
Funding scheme for vaccinations in the national immunisation schedule	Mixed (children: tax-funded; adults: social insurances)

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	No
Key elements of the systematic approach	Not applicable
Fixed list of key criteria which need to be addressed during the development process	Not applicable
List of criteria	Not applicable
Systematic approach published	Not applicable
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed Unpublished/non-peer reviewed (country-specific surveillance data, hearing of vaccine companies)
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable

Vaccine recommendation process	
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	No
Developed by	Not applicable
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Not required – asked for at the Ministry-of-Health level (performed by Belgian Health Care Knowledge Center)
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	Regional
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	References of used literature Further information as vaccination sheets and advisory reports

BULGARIA (validated) 30 April 2014

General facts	
Name of recommending body	Експертен съвет по надзор на заразните болести, имунопрофилактика и противоепидемичен контрол English: Expert Committee for Communicable Disease Surveillance, Immunoprophylaxis and Control
Self-designation as National Immunisation Technical Advisory Group (NITAG)	No
Contact	Dr. Radosveta Filipova, Expert Committee member, country EPI manager
Year established	2002
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	No
NITAG or expert group receives (additional) scientific support from::	No
Number of NITAG or expert group members	13
NITAG or expert group chair is elected/appointed by	Chair is the Deputy Minister of Health (member of the Expert Committee, but with no voting rights), Co-Chair is the Chief State Health Inspector
Voting-member composition	Clinicians, epidemiologists, paediatricians, vaccinology experts, virologists/microbiologists, lawyer
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	No
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Minister of Health
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	No
Key elements of the systematic approach	Not applicable
Fixed list of key criteria which need to be addressed during the development process	Not applicable
List of criteria	Not applicable
Systematic approach published	Not applicable
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	No
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	No

Vaccine recommendation process	
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	Not applicable
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	expert group Outsourced
Experience with adopting existing models from other countries to own setting	No
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	No
Contains cost-effectiveness threshold	Not applicable
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes (annual)
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

CZECH REPUBLIC (validated) As of 30 April 2014

General facts	
Name of recommending body	Národní imunizační komise (NIKO) English: National Immunisation Board
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Vladimír Valenta, chief hygienic officer
Year established	2010
Website	http://www.mzcr.cz/Verejne/obsah/cile-a-zamereni_1984_5.html
Website material in English	No
NITAG or /expert group executive secretariat/administrative office	No
NITAG or expert group receives (additional) scientific support from:	Czech Medical Association of JEP (Jan Evangelista Purkyně) and the Scientific Societies belonging to it, e.g. Vaccinological Society, Epidemiological and Microbiological Society, Society of Infectious Disease Specialists, Paediatric Society, General Practitioners Society, Czech Pneumological and Phthisiological Society, National Institute of Public Health, State Institute for Drug Control, Health Care Insurance Companies etc.
Number of NITAG or expert group members	11
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, general practitioners
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	Yes
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Parliament
Funding scheme for vaccinations in the national immunisation schedule	Mixed (Social insurances for mandatory vaccinations; Ministry of Health for extraordinary vaccinations – for example for selected risk groups in selected areas e.g. in case of floods or infectious diseases outbreaks)

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	• Epidemiological situation • Safety of vaccination • Consultation with relevant specialties
Fixed list of key criteria which need to be addressed during the development process	No
List of criteria	Not applicable
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by NITAG or expert group/Executive Secretariat itself	No
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable

Vaccine recommendation process	
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	No
Developed by	Not applicable
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Narrative summary References of used literature

DENMARK (validated) As of 30 April 2014

General facts	
Name of recommending body	Sundhedsstyrelsens Vaccinationsudvalg English: The National Vaccine Committee
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Dr Palle Valentiner-Branth, EPI manager and head of the national vaccine-preventable diseases surveillance group, Statens Serum Institut
Year established	At least from 1980
Website	https://sundhedsstyrelsen.dk/da/sundhed/vaccination/vaccinationsudvalg
Website material in English	No
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	When necessary experts from relevant organisations such as infectious disease specialists, paediatricians, health economists
Number of NITAG or expert group members	14
NITAG or expert group chair is elected/appointed by	Danish Health and Medicines Authority
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, representative from Association of pharmaceutical companies
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	Yes
Number of meetings per year	2
Meetings open to public	No
Minutes published online	Yes
NITAG or expert group advises	Danish Health and Medicines Authority
Final decision-maker for vaccine introduction in the national programme	Parliament
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes – if a Medical Health Technology Assessment (MTA) is carried out (but no predefined criteria when to do an MTA)
Key elements of the systematic approach	For MTA: • Different sections of technology (methodology, e.g. a systematic literature review, efficacy of the vaccine, impact on morbidity on the population level after vaccination, side effects, interactions with other vaccines) • Perspectives of citizens and patients • Organisation (e.g. experiences from other countries who have used this vaccine, planning of the vaccination programme, number and timing of doses, catch-up programme, procurement of the vaccine) • Health economics
Fixed list of key criteria which need to be addressed during the development process	No
List of criteria	Not applicable
Systematic approach published	Yes
URL	https://sundhedsstyrelsen.dk/en/health/quality-and-guidelines/centre-for-health-technology-assessment
Systematic literature review	
Recommendation development process requires systematic literature review	Yes – if an MTA is carried out
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed Unpublished/non-peer reviewed (national surveillance data for estimate of disease burden)
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	Yes (but only to e.g. universities, no commercial companies)

Vaccine recommendation process	
Evidence assessment required to be performed	Yes
Contract allows sharing of systematic review with other parties	Yes
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	NITAG Outsourced
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Entire report is made public Including: • Narrative summary • Detailed results of systematic reviews including meta-analysis • References of used literature

ESTONIA (validated) As of 30 April 2014

General facts	
Name of recommending body	Immunoprofülaktika ekspertkomisjon English: Expert Committee on Immunoprophylaxis
Self-designation as National Immunisation Technical Advisory Group (NITAG)	No
Contact	Dr Martin Kadai, Expert Committee member
Year established	2006
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Estonian Health Board
Number of NITAG or expert group members	15
NITAG or expert group chair is elected/appointed by	Minister of Social Affairs
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, virologists/microbiologists, representatives from the Estonian Health Insurance Fund, State Agency of Medicine, Estonian Union for Child Welfare and Estonian Association of Family Doctors
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Social Affairs (incorporates Health)
Final decision-maker for vaccine introduction in the national programme	Ministry of Social Affairs, if additional financing is needed the Government
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	1. Disease burden; 2. Vaccine effectiveness, efficacy and safety; 3. Cost-effectiveness; 4. Availability of alternative public health measures; 5. Availability of financial resources; 6. Acceptance and expectations of and adherence to vaccination.
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	1. Disease burden; 2. Vaccine effectiveness, efficacy and safety; 3. Cost-effectiveness; 4. Availability of alternative public health measures; 5. Availability of financial resources; 6. Acceptance and expectations of and adherence to vaccination.
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	No
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No

Vaccine recommendation process	
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	Estonian Health Board Outsourced
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

FINLAND (validated) As of 30 April 2014

General facts	
Name of recommending body	Kansallinen rokotusasiantuntijatyöryhmä (KRAR) English: National Vaccination Expert Working Group
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Prof Matti Korppi, NITAG chair Dr Hanna Nohynek, NITAG secretary
Year established	2001
Website	http://www.thl.fi/fi_FI/web/rokottajankasikirja-fi/kansallinen-rokotusasiantuntijaryhma
Website material in English	No
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	National Institute for Health and Welfare (THL)
Number of NITAG or expert group members	13
NITAG or expert group chair is elected/appointed by	National Institute for Health and Welfare
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	National Institute for Health and Welfare (that advises the Ministry of Health)
Final decision-maker for vaccine introduction in the national programme	Parliament after recommendation from Ministry of Finance as part of annual financial budget package for NIP immunisations
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	1. Considerable disease burden 2. Vaccine safety on individual level 3. Vaccine safety on population level 4. Reasonable cost effectiveness
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	1. Considerable disease burden 2. Vaccine safety on individual level 3. Vaccine safety on population level 4. Reasonable cost effectiveness
Systematic approach published	Yes
URL	http://www.thl.fi/fi_FI/web/rokottajankasikirja-fi/kansallinen-rokotusasiantuntijaryhma
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	• Peer-reviewed • Unpublished/non-peer reviewed (own research, manufacturers, European Medicines Agency and Fimea reports)
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No

Vaccine recommendation process	
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	National Institute for Health and Welfare
Experience with adopting existing models from other countries to own setting	No
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	Yes
Cost-effectiveness threshold (e.g. per QALY)	No formal absolute threshold
Cost-effectiveness threshold definite criterion for/against vaccine introduction	No
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	• Narrative summary • Detailed results of systematic reviews including meta-analysis • References of used literature • Model details and assumptions used

FRANCE (validated) As of 30 April 2014

General facts	
Name of recommending body	Comité Technique des Vaccination English: Vaccine Technical Committee
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Prof Daniel Floret, NITAG chair Corinne Le Goaster, NITAG Executive Secretariat
Year established	1985
Website	www.hcsp.fr
Website material in English	No
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Institut de veille sanitaire (French Institute for Public Health Surveillance), Agence Nationale de Sécurité des Médicaments
Number of NITAG or expert group members	17
NITAG or expert group chair is elected/appointed by	NITAG members
Voting-member composition	Clinicians, epidemiologists, health economists, immunologists, paediatricians, public health experts, social scientists, vaccinology experts, virologists/microbiologists
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	Yes
Number of meetings per year	> 5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme for vaccinations in the national immunisation schedule	Mixed (tax-funded and social insurance)

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	No
Key elements of the systematic approach	Not applicable
Fixed list of key criteria which need to be addressed during the development process	Not applicable
List of criteria	Not applicable
Systematic approach published	Not applicable
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed
Evidence assessment performed with tool/system	Yes
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	GRADE
Systematic literature review is/can be outsourced by the NITAG or expert group	Yes
Evidence assessment required to be performed	Yes
Contract allows sharing of systematic review with other parties	No
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes

Vaccine recommendation process	
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	NITAG Outsourced
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	• Detailed results of systematic reviews including meta-analysis • References of used literature • Cost-effectiveness evaluation (if conducted)

GERMANY (validated) As of 30 April 2014

General facts	
Name of recommending body	Ständige Impfkommission (STIKO) English: German Standing Committee on Vaccination
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	NITAG Executive Secretariat
Year established	1972
Website	www.stiko.de/en
Website material in English	Yes
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	National Public Health Institute (Robert Koch Institute)
Number of NITAG or expert group members	12–18
NITAG or expert group chair is elected/appointed by	NITAG members
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, vaccinology experts, virologists/microbiologists, expert in evidence-based medicine
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	Yes
Number of meetings per year	≥ 2
Meetings open to public	No
Minutes published online	Yes (since 2013)
NITAG or expert group advises	No advisory function. The STIKO recommendations serve as the basis for the • reimbursement decision (making the reimbursement of the respective vaccine compulsory for all statutory health insurances in Germany), and • official vaccination recommendations of the German federal states (which is needed for vaccines to be considered by the federal states' vaccine injury compensation system)
Final decision-maker for vaccine introduction in the national programme	NITAG
Funding scheme for vaccinations in the national immunisation schedule	Social insurance

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	1. Prioritisation process of topic 2. Identification of relevant questions, using PICO format 3. Conduct of systematic reviews for each critical and important efficacy/safety outcome 4. Application of GRADE for grading the quality of the body of evidence for efficacy/safety outcomes 5. Address all other relevant questions according to a standard list of key criteria
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	Questions related to: a) pathogen b) target disease c) vaccine characteristics d) immunisation strategy e) implementation of a vaccination recommendation
Systematic approach published	Yes
URL	www.stiko.de/en >> STIKO methodology
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed
Evidence assessment performed with tool/system	Yes

Vaccine recommendation process	
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	For RCTs: Cochrane risk of bias tool For observational studies: CASP tool For body of evidence: GRADE
Systematic literature review is/can be outsourced by the NITAG or expert group	Yes
Evidence assessment required to be performed	Yes
Contract allows sharing of systematic review with other parties	Yes
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	Yes
Name of tool(s) (e.g. AMSTAR)	AMSTAR
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	Robert Koch Institute Outsourced
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	In some federal states (for selected vaccines)
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Narrative summary Detailed results of systematic reviews including meta-analysis References of used literature

GREECE (validated) As of 30 April 2014

General facts	
Name of recommending body	Εθνική Επιτροπή Εμβολιασμών English: National Committee on Immunisations
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Prof. Andreas Konstantopoulos, Head of the National Immunisation Committee
Year established	1991
Website	www.diavgeia.gov.gr
Website material in English	No
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	National Public Health Institute
Number of NITAG or expert group members	11
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	No
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	No
Key elements of the systematic approach	Not applicable
Fixed list of key criteria which need to be addressed during the development process	Not applicable
List of criteria	Not applicable
Systematic approach published	Not applicable
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes

Vaccine recommendation process	
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	No
Developed by	Not applicable
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	No
Contains cost-effectiveness threshold	Not applicable
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

ICELAND (validated) As of 30 April 2014

General facts	
Name of recommending body	Sóttvarnaráð English: National Committee on Communicable Diseases
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Haraldur Briem, State Epidemiologist Ólafur Guðlaugsson, NITAG chair
Year established	1998
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Icelandic State Epidemiologist
Number of NITAG or expert group members	7
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Clinicians, epidemiologists, public health experts, virologists/microbiologists
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	No
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	No
Key elements of the systematic approach	Not applicable
Fixed list of key criteria which need to be addressed during the development process	Not applicable
List of criteria	Not applicable
Systematic approach published	Not applicable
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes

Vaccine recommendation process	
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	NITAG
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

IRELAND (validated) As of 30 April 2014

General facts	
Name of recommending body	National Immunisation Advisory Committee (NIAC)
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	National Immunisation Advisory Committee
Year established	1996
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Health Protection Surveillance Centre, National Centre for Pharmacoeconomics
Number of NITAG or expert group members	18
NITAG or expert group chair is elected/appointed by	Royal College of Physicians of Ireland
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	> 5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Department of Health (=Ministry of Health)
Final decision-maker for vaccine introduction in the national programme	Department of Health
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	- Quality/safety/efficacy of the vaccine - Burden of disease - Economic sustainability - Integration in the existing schedule
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	- How common and how serious is the disease? - Is there any other way, apart from a vaccine, of protecting people from the disease? - Is the vaccine safe, does it work, and can the country afford it? - Can the vaccine easily be added to the existing vaccine programmes? - How will the vaccine be accepted by those for whom it is recommended?
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed
Evidence assessment performed with tool/system	Yes
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	CASP
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable

Vaccine recommendation process	
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	National Centre for Pharmacoeconomics
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	Yes
Cost-effectiveness threshold (e.g. per QALY)	EUR 45 000/QALY
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Yes
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

ITALY (validated) As of 30 April 2014

General facts	
Name of recommending body	Gruppo Istruttorie Vaccini English: Group of experts for investigations on vaccines
Self-designation as National Immunisation Technical Advisory Group (NITAG)	No
Contact	Stefania Iannazzo, MD PHD, Medical Officer, Infectious Diseases Unit – Ministry of Health Silvia Declich, Chief of the Epidemiology of Infectious Diseases Unit – National Centre for Epidemiology/ISS
Year established	2013
Website	No
Website material in English	Not applicable
NITAG or expert group Executive Secretariat/administrative office	Not applicable
NITAG or expert group receives (additional) scientific support from:	Not applicable
Number of NITAG or expert group members	10
NITAG or expert group chair is elected/appointed by	Director of National Centre for Epidemiology/ISS
Voting-member composition	No voting takes place Member composition: Experts in infectious disease epidemiology, systematic reviews, pharmaco-epidemiology
Voting member(s) from Ministry of Health	No/Not applicable
Declaration of conflict of interest	Yes
Number of meetings per year	Not applicable
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health and Regional Health Authorities
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	According to the key elements defined in the WHO guidelines (WHO/IVB/05.18: http://www.who.int/immunization/documents/WHO_IVB_05.18/en/) • Identification of relevant questions • Systematic review
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	According to the criteria defined in the WHO guidelines (WHO/IVB/05.18, see above): The expert group analyses • Disease burden • Efficacy, quality and safety • Alternative interventions (including other vaccines) • Vaccine presentation Economic and financial issues are kept in consideration for the final decision of inclusion in the national immunisation plan.
Systematic approach published	Yes
URL	http://www.salute.gov.it/imgs/C_17_pubblicazioni_1721_allegato.pdf
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed Unpublished/non-peer reviewed (e.g. regional/national surveillance data and coverage data, documents from foreign NPHIs)

Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	expert group
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National, regional and local
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

LATVIA (validated) As of 30 April 2014

General facts	
Name of recommending body	Imunizācijas valsts padome English: The State Immunisation Advisory Council
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Dr. Jurijs Perevoscikovs, NITAG chair Dr. Irina Lucenko, NITAG Secretary
Year established	2000
Website	http://www.spkc.gov.lv/imunizacijas-valsts-padome/
Website material in English	No
NITAG or /expert group executive secretariat/administrative office	No
NITAG or expert group receives (additional) scientific support from:	Centre for Diseases Prevention and Control of Latvia – infectious diseases surveillance, immunisation monitoring and Adverse Events Following Immunisation (AEFI) data, secretary functions
Number of NITAG or expert group members	15
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Clinicians, epidemiologists, health economists, immunologists, paediatricians, public health experts, vaccinology experts, Ministry of Health, National Regulatory Authority on Medicines, NGO, academics
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	No
Number of meetings per year	≥2
Meetings open to public	Yes
Minutes published online	Yes
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health, then by the Cabinet of Ministers
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	- Disease burden - Severity of disease - Vaccine effectiveness - Vaccine safety - Experience of other countries - Financial opportunities - Possibility to include new vaccine in immunisation schedule - Existence of combined vaccines
Fixed list of key criteria which need to be addressed during the development process	No
List of criteria	Not applicable
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	No
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable

Vaccine recommendation process	
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	No
Developed by	Not applicable
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	No
Contains cost-effectiveness threshold	Not applicable
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

LITHUANIA (validated) As of 30 April 2014

General facts	
Name of recommending body	Nacionalines imunoprofilaktikos programos koordinavimo taryba English: Coordinating Council of National Immunisation Programme
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Prof. Daiva Razmuviene, Head of Immunoprophylaxis Division, Centre for Communicable diseases and AIDS
Year established	1999
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	No
NITAG or expert group receives (additional) scientific support from:	No
Number of NITAG or expert group members	11
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	- Disease burden - Severity of disease - Vaccine effectiveness - Experience of other countries - Financial opportunities
Fixed list of key criteria which need to be addressed during the development process	No
List of criteria	Not applicable
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	No
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable

Vaccine recommendation process	
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	No
Developed by	Not applicable
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	No
Contains cost-effectiveness threshold	Not applicable
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

MALTA (validated) As of 30 April 2014

General facts	
Name of recommending body	Advisory Committee on Immunisation Policy (ACIP)
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Dr Charmaine Gauci, Director Health Promotion and Disease Prevention
Year established	2007
Website	https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/regulatory_councils_list.aspx
Website material in English	Yes
NITAG or /expert group executive secretariat/administrative office	No
NITAG or expert group receives (additional) scientific support from:	Not applicable
Number of NITAG or expert group members	8
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Clinicians, epidemiologists, paediatricians, public health experts, virologists/microbiologists
Voting member(s) from Ministry of Health	Yes (all NITAG members are employed by the Ministry of Health; the National Public Health Institute is a department of the Ministry of Health)
Declaration of conflict of interest	Yes
Number of meetings per year	> 5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Superintendent of Public Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health (discussed with Ministry of Finance whether funding is available)
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	Health Technology Assessment (includes epidemiological data) Cost-effectiveness analysis
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	• Cost-effectiveness • Impact of decrease in disease burden • Priority
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	No
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable

Vaccine recommendation process	
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	Existing literature
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

NETHERLANDS (validated) As of 30 April 2014

General facts	
Name of recommending body	Gezondheidsraad English: Health Council in the Netherlands – Committee on Vaccinations
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Leo van Rossum PhD, NITAG Executive Secretariat Hans Houweling MD PhD, NITAG Executive Secretariat
Year established	1902
Website	www.healthcouncil.nl
Website material in English	Yes
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	National Institute of Public Health (RIVM)
Number of NITAG or expert group members	About 20
NITAG or expert group chair is elected/appointed by	The President of the Health Council
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists, ethicist
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	Yes
Number of meetings per year	> 5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Minister of Health
Final decision-maker for vaccine introduction in the national programme	Minister of Health
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	• Seriousness and extent of disease burden • Effectiveness and safety of vaccination • Acceptability of vaccination • Efficiency of vaccination • Priority of vaccination
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	• Seriousness and extent of disease burden • Effectiveness and safety of vaccination • Acceptability of vaccination • Efficiency of vaccination • Priority of vaccination
Systematic approach published	Yes
URL	• http://gr.nl/sites/default/files/200702E_0.pdf • Houweling H, Verweij M, Ruitenberg EJ. Criteria for inclusion of vaccinations in public programmes. Vaccine 2010; 28: 2924-2931.
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	Yes
Evidence assessment required to be performed	No

Vaccine recommendation process	
Contract allows sharing of systematic review with other parties	Yes
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	NITAG Outsourced
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No formal threshold
Cost-effectiveness threshold (e.g. per QALY)	Informally EUR 20 000/QALY
Cost-effectiveness threshold definite criterion for/against vaccine introduction	No
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Narrative summary Detailed results of systematic reviews including meta-analysis References of used literature

NORWAY (validated) As of 30 April 2014

General facts	
Name of recommending body	Names differ as the recommending bodies are ad hoc, topic-related expert group(s)
Self-designation as National Immunisation Technical Advisory Group (NITAG)	No
Contact	Britt Wolden, Director, Department of Vaccines, Norwegian Institute of Public Health
Year established	First expert group active in 1991
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Not applicable
Number of NITAG or expert group members	8–12 (including Norwegian Institute of Public Health experts)
NITAG or expert group chair is elected/appointed by	Usually appointed by Norwegian Institute of Public Health
Voting-member composition	No voting takes place Member composition: Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists, other medical specialties when relevant (gynaecologists, pathologists), public health nurses
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	Yes
Number of meetings per year	No fixed number of meetings
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Norwegian Institute of Public Health (that advises the Ministry of Health)
Final decision-maker for vaccine introduction in the national programme	Ministry of Health (Parliament in case of large economic impact)
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	• Literature search • Country-specific epidemiology and burden of disease • Feasibility/possibility for implementation in the vaccination programme • Attitudes in the population • Cost-effectiveness analysis
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	• Literature search • Country-specific epidemiology and burden of disease • Feasibility/possibility for implementation in the vaccination programme • Attitudes in the population • Cost-effectiveness analysis
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	Yes
Evidence assessment required to be performed	Yes

Vaccine recommendation process	
Contract allows sharing of systematic review with other parties	Yes
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	Norwegian Public Health Institute Outsourced
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	Yes
Cost-effectiveness threshold (e.g. per QALY)	No fixed number
Cost-effectiveness threshold definite criterion for/against vaccine introduction	No
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Narrative summary References of used literature

POLAND (validated) As of 30 April 2014

General facts	
Name of recommending body	(1) Rada Sanitarno-Epidemiologiczna i (2) Pediatryczny Zespół Ekspertów do Spraw Programu Szczepień Ochronnych English: (1) Sanitary- Epidemiology Advisory Board (2) Pediatric Group of Experts on Immunisation Program
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	1) Chief Sanitary Inspectorate and 2) Department of Mother and Child
Year established	2003
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	No
NITAG or expert group receives (additional) scientific support from:	Experts from The National Institute of Public Health – National Institute of Hygiene (NIPH-NIH) and Polish Medical Societies (e.g. Pediatrics, Vaccinology, Epidemiology), institutes and universities
Number of NITAG or expert group members	(1) 17 (2) 10
NITAG or expert group chair is elected/appointed by	(1) Ministry of Health (2) Ministry of Health at request of Sanitary Inspector
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	No
Number of meetings per year	3–5 (additional meetings if necessary)
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded (for mandatory vaccines, recommended vaccines are paid by individual)

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	• Burden of disease • Efficacy • Effectiveness • Safety of the vaccine • Pharmacoeconomics analysis
Fixed list of key criteria which need to be addressed during the development process	No
List of criteria	Not applicable
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	No
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable

Vaccine recommendation process	
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	Outsourced
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

PORTUGAL (validated) As of 30 April 2014

General facts	
Name of recommending body	Comissão Técnica de Vacinação English: National Vaccination Committee
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Dr. Graça Freitas, NITAG
Year established	1998
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Mainly from the Directorate-General of Health (DGS) but also other experts, depending of the subjects
Number of NITAG or expert group members	19
NITAG or expert group chair is elected/appointed by	Director-General of Health, representing the Ministry of Health
Voting-member composition	Experts in Public health, pediatrics, epidemiology, infectiology, family practice, modeling, immunology, nursing, pharmacy, biology
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	≥ 3
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Director-General of Health (advising the Ministry of Health)
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	1. Evaluation of available vaccines (quality, safety, efficacy/effectiveness, duration of immunity, herd immunity, impact on pathogen and on disease epidemiology, compatibility with the NIP vaccines, applicability and acceptability) 2. Disease burden (incidence, prevalence, severity, fatality ratio, occurrence of the microorganism, others) 3. Cost-effectiveness studies
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	1. Evaluation of available vaccines (quality, safety, efficacy/effectiveness, duration of immunity, herd immunity, impact on pathogen and on disease epidemiology, compatibility with the NIP vaccines, applicability and acceptability) 2. Disease burden (incidence, prevalence, severity, fatality ratio, occurrence of the microorganism, others) 3. Cost-effectiveness studies
Systematic approach published	Yes
URL	http://dre.pt/pdfgratis2s/2013/04/2S078A0000S00.pdf
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed Unpublished/non-peer reviewed
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable

Vaccine recommendation process	
Systematic literature review is/can be outsourced by the NITAG or expert group	Yes
Evidence assessment required to be performed	No
Contract allows sharing of systematic review with other parties	Yes
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	NITAG Outsourced
Experience with adopting existing models from other countries to own setting	Yes
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	No
National/regional/local	Not applicable
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Narrative summary Detailed results of systematic reviews including meta-analysis

ROMANIA (validated) As of 30 April 2014

General facts	
Name of recommending body	Comitetul National de Vaccinologie English: National Commitee of Vaccinology
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	National Centre for Communicable Diseases Surveillance and Control, NITAG Executive Secretariat
Year established	2008
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Various experts
Number of NITAG or expert group members	15
NITAG or expert group chair is elected/appointed by	NITAG members
Voting-member composition	Clinicians, epidemiologists, immunologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	Yes
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Ministry of Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	Epidemiological data/disease burden
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	• Assessment of epidemiological context • Age group most exposed • Recommended vaccination schemes • Implementation/logistical issues
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable

Vaccine recommendation process	
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	No
Developed by	Not applicable
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	No
Contains cost-effectiveness threshold	Not applicable
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

SLOVAKIA (validated) As of 30 April 2014

General facts	
Name of recommending body	Pracovná skupina pre imunizáciu (PSPI) English name: Working Group for Immunisation (WGFI)
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	RN Dr Jan Mikas, NITAG Chair
Year established	2006
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	No
NITAG or expert group receives (additional) scientific support from:	No
Number of NITAG or expert group members	9
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Clinicians, epidemiologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists, pharmaceutists, infectologists, general practitioners
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	Yes
Number of meetings per year	3–5
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Chief Hygienist
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme for vaccinations in the national immunisation schedule	Social insurance

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	• Epidemiological situation in the country • WHO recommendations
Fixed list of key criteria which need to be addressed during the development process	No
List of criteria	Not applicable
Systematic approach published	No
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes
Data source(s)	Peer-reviewed Unpublished/non-peer reviewed evidence
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes

Vaccine recommendation process	
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	Outsourced
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	No
National/regional/local	Not applicable
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

SLOVENIA (validated) As of 30 April 2014

General facts	
Name of recommending body	Posvetovalna skupina za cepljenje (PSC) English: Advisory Group on Immunisation (AGI)
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Marta Grgic Vitek, NIPH, Centre for Communicable Diseases
Year established	2011
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	National Institute of Public Health
Number of NITAG or expert group members	9
NITAG or expert group chair is elected/appointed by	NITAG members
Voting-member composition	Infectious disease specialists, immunologist, paediatricians, pulmonologist, allergologist, school doctor, medicinal regulatory scientist
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	Yes
Number of meetings per year	3–5
Meetings open to public	Yes
Minutes published online	Yes
NITAG or expert group advises	National Institute of Public Health
Final decision-maker for vaccine introduction in the national programme	Ministry of Health
Funding scheme for vaccinations in the national immunisation schedule	Social insurance

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	No
Key elements of the systematic approach	Not applicable
Fixed list of key criteria which need to be addressed during the development process	Not applicable
List of criteria	Not applicable
Systematic approach published	Not applicable
URL	Not applicable
Systematic literature review	
Recommendation development process requires systematic literature review	Yes
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	No
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes

Vaccine recommendation process	
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	No
Developed by	Not applicable
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	Yes
Cost-effectiveness threshold (e.g. per QALY)	EUR 30 000/QALY
Cost-effectiveness threshold definite criterion for/against vaccine introduction	No
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	No
Rationale includes	Not applicable

SPAIN (validated) As of 30 April 2014

General facts	
Name of recommending body	Ponencia de Programa y Registro de Vacunaciones English: Immunisation Advisory Committee (IAC)
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Subdirection of Health Promotion and Epidemiology
Year established	1991
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Health Institute Carlos III (National Center for Epidemiology and National Center for Microbiology), Spanish Medicines Agency
Number of NITAG or expert group members	19+4
NITAG or expert group chair is elected/appointed by	Ministry of Health
Voting-member composition	Epidemiologists, paediatricians, public health experts, vaccinology experts, virologists/microbiologists
Voting member(s) from Ministry of Health	Yes
Declaration of conflict of interest	No
Number of meetings per year	>2
Meetings open to public	No
Minutes published online	No
NITAG or expert group advises	Commission of Public Health (advising the Interterritorial Council of the National Health System)
Final decision-maker for vaccine introduction in the national programme	Interterritorial Council of the National Health System (consists of the national Minster of Health and the regional Ministers of Health)
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	Three consecutive steps: (Step 2 is evaluated after criteria of step 1 are considered important from a public health perspective, and step 3 after a positive assessment of step 2) 1. Burden of disease, effectiveness and safety of the vaccine 2. Impact of modifications in the immunisation programme and ethical aspects 3. Economic evaluation
Fixed list of key criteria which need to be addressed during the development process	Yes
List of criteria	1. Burden of disease 2. Effectiveness and safety of the vaccine 3. Impact of modifications in the immunisation programme 4. Ethical aspects 5. Economic evaluation
Systematic approach published	Yes
URL	http://www.msssi.gob.es/ciudadanos/proteccionSalud/vacunaciones/docs/Criterios_ProgramaVacunas.pdf
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes (in most cases)
Data source(s)	Peer-reviewed Published documents from recognised institutions (ECDC, WHO, and other NITAGs)
Evidence assessment performed with tool/system	No
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	Yes (when needed)

Vaccine recommendation process	
Evidence assessment required to be performed	Yes
Contract allows sharing of systematic review with other parties	No
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Not specifically
Developed by	Not applicable
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	No
National/regional/local	Not applicable
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Entire rationale Including: Narrative summary References of used literature

SWEDEN (validated) As of 30 April 2014

General facts	
Name of recommending body	Expertgrupp and Sakkunniggrupp (assessment of scientific and organisational aspects, established for each topic/vaccination) Socialstyrelsen (makes recommendation based on scientific assessment) English: Expert group and assessment group (scientific basis) National Board of Health and Welfare (recommendation)
Self-designation as National Immunisation Technical Advisory Group (NITAG)	No
Contact	Tina Chavoshi, programme officer
Year established	2014
Website	No
Website material in English	Not applicable
NITAG or /expert group executive secretariat/administrative office	The scientific groups are supported by the National Board of Health and Welfare
NITAG or expert group receives (additional) scientific support from:	Expert advice from Swedish Public Health Agency, Medical Products Agency, consultants for cost-effectiveness analysis
Number of NITAG or expert group members	expert group: 4 Assessment group: 5–10 (The number of members might differ depending on the topic/vaccination being assessed)
NITAG or expert group chair is elected/appointed by	Expert group and assessment group: No official chair
Voting-member composition	Expert groups include: Clinicians, epidemiologists, health economists, immunologists, paediatricians, vaccinology experts, virologists/microbiologists, other medical specialties when relevant
Voting member(s) from Ministry of Health	Expert group and assessment group: No
Declaration of conflict of interest	Expert group and assessment group: Yes
Number of meetings per year	Expert group and assessment group: need of meetings depends on topic/vaccination addressed
Meetings open to public	Expert group and assessment group: No
Minutes published online	Expert group and assessment group: No
NITAG or expert group advises	The expert and assessment groups produce the scientific basis/analysis for a recommendation. Based on their assessment reports, the National Board of Health and Welfare gives a recommendation to the government.
Final decision-maker for vaccine introduction in the national programme	Government
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	Two prerequisites that have to be fulfilled: • A vaccine should be available that can be given without prior diagnosis of the disease • The vaccine should induce more than short-time immunity against the disease If the two prerequisites are met the vaccination should be encompassed by the National Immunisation Program if the vaccination is expected to: • effectively prevent the spread of the disease within the population • if it is cost effective • if it is sustainable as regards ethical and humanitarian standpoints. The framework consists of the assessment of three criteria and 13 aspects regulated by law (see List of criteria).
Fixed list of key criteria which need to be addressed during the development process	Yes (if applicable)

Vaccine recommendation process	
List of criteria	Criteria: 1. Does it effectively prevent the spread of the disease within the population? 2. Is it cost-effective? 3. Is it sustainable from ethical and humanitarian standpoints? Aspects: 1. Disease burden in society, health care and for the individual 2. Expected impact of the vaccination regarding disease epidemiology 3. Number of doses needed to reach the desired effect 4. Groups that should be offered vaccination 5. Safety of the vaccine 6. Expected outcome/effect of the vaccination on the operation of the counties, municipalities and private caregivers 7. Suitability of the vaccine to combine with vaccinations already part of the National Immunisation Program 8. Public acceptance of the vaccination and its influence on attitudes towards vaccinations in general 9. Other measures or treatments that can be given as an alternative to a national immunisation programme 10. Socioeconomic assessment of the cost-effectiveness of the vaccination and an assessment of the costs and incomes to the states, counties, municipalities 11. Possibilities for follow-up regarding the effect of the vaccination in regard to the 10 above mentioned aspects as well as the costs for follow-up/surveillance 12. Need for information campaigns towards the public and the caregivers and the costs thereof 13. Medical ethical and humanitarian considerations
Systematic approach published	Yes
URL	http://www.socialstyrelsen.se/publikationer2013/2013-11-9
Systematic literature review	
Recommendation development process requires systematic literature review	Yes, if possible
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	Yes, if possible
Data source(s)	Peer-reviewed Unpublished/non-peer reviewed
Evidence assessment performed with tool/system	Yes, when applicable and possible
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	GRADE (when applicable and possible)
Systematic literature review is/can be outsourced by the NITAG or expert group	No
Evidence assessment required to be performed	Not applicable
Contract allows sharing of systematic review with other parties	Not applicable
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	Yes
Name of tool(s) (e.g. AMSTAR)	AMSTAR
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes – if available
Developed by	Outsourced
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	No

Vaccine recommendation process	
Cost-effectiveness threshold (e.g. per QALY)	Not applicable
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Not applicable
Tender system in place	Yes
National/regional/local	Regional and local
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Narrative summary References of used literature Results of assessment without meta-analysis (not conducted)

UNITED KINGDOM (validated) As of 30 April 2014

General facts	
Name of recommending body	Joint Committee on Vaccination and Immunisation (JCVI)
Self-designation as National Immunisation Technical Advisory Group (NITAG)	Yes
Contact	Joint Committee on Vaccination and Immunisation
Year established	1963
Website	https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation
Website material in English	Yes
NITAG or /expert group executive secretariat/administrative office	Yes
NITAG or expert group receives (additional) scientific support from:	Public Health England, commissioned academic groups
Number of NITAG or expert group members	18-20
NITAG or expert group chair is elected/appointed by	Department of Health (= Ministry of Health)
Voting-member composition	Clinicians, epidemiologists, health economists, immunologists, paediatricians, public health experts, social scientists, vaccinology experts, virologists/microbiologists, lay members
Voting member(s) from Ministry of Health	No
Declaration of conflict of interest	Yes
Number of meetings per year	3 (of the main committee plus subcommittee meetings as necessary)
Meetings open to public	No
Minutes published online	Yes
NITAG or expert group advises	Department of Health (= Ministry of Health)
Final decision-maker for vaccine introduction in the national programme	The Minister of Health is obliged to introduce the vaccine if it is recommended by the JCVI and is cost-effective
Funding scheme for vaccinations in the national immunisation schedule	Tax-funded

Vaccine recommendation process	
Systematic approach	
NITAG or expert group uses systematic approach for the development of national vaccine recommendations	Yes
Key elements of the systematic approach	• Case of need • Efficacy • Effectiveness • Safety data • Cost-effectiveness
Fixed list of key criteria which need to be addressed during the development process	No
List of criteria	Not applicable
Systematic approach published	Yes
URL	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224864/JCVI_Code_of_Practice_revision_2013_-_final.pdf
Systematic literature review	
Recommendation development process requires systematic literature review	No
Systematic literature review is conducted by the NITAG or expert group/Executive Secretariat itself	No (but can be if sufficient resources)
Data source(s)	Not applicable
Evidence assessment performed with tool/system	Not applicable
Name of applied risk of bias tool(s) (e.g. CASP) or grading system(s) (e.g. GRADE)	Not applicable
Systematic literature review is/can be outsourced by the NITAG or expert group	Yes
Evidence assessment required to be performed	Process in development
Contract allows sharing of systematic review with other parties	Process in development

Vaccine recommendation process	
Systematic literature reviews conducted or published by others (e.g. Cochrane Collaboration) are/can be considered by NITAG or expert group/Executive Secretariat	Yes
Methodological quality of the review assessed by NITAG or expert group/Executive Secretariat using tool/assessment system	No
Name of tool(s) (e.g. AMSTAR)	Not applicable
Mathematical modelling (e.g. transmission modelling)	
Recommendation development process includes consideration of results from mathematical modelling	Yes
Developed by	Outsourced
Experience with adopting existing models from other countries to own setting	Not applicable
Health economic evaluations (e.g. cost-effectiveness studies)	
Recommendation development process includes consideration of results from health economic evaluations	Yes
Contains cost-effectiveness threshold	Yes
Cost-effectiveness threshold (e.g. per QALY)	GBP 20 000 to GBP 30 000/QALY
Cost-effectiveness threshold definite criterion for/against vaccine introduction	Yes
Tender system in place	Yes
National/regional/local	National
Decision communication	
Rationale for vaccine recommendation published	Yes
Rationale includes	Narrative summary References of used literature

Appendix C. List of studies excluded from the systematic literature review

The below list of studies excluded from the systematic literature review includes 43 titles. These publications were excluded because they made no reference to NITAG/expert group frameworks/methodologies or to NITAGs/expert groups outside of Europe/North America, or WHO SAGE.

Andreae MC. Switalski K, Abraham L. Freed GL. National immunization advisory committees of the World Health Organization's European Region. Vaccine 2009;27:3131-36.

Al Awaidy S. The National Committee for Vaccines Regulation and Surveillance of Vaccine-Preventable Diseases in the Sultanate of Oman: Evidence-based approach and consensus decision-making. Vaccine 2010;28S:A39-A41.

Blau J, Faye PC, Senouci K, Dagnan SN, Douba A, Tagliante Saracino J, Gessner BD. Establishment of a National Immunization Technical Advisory Group in Cote d'Ivoire: Process and lessons learned. Vaccine 2012;30:2588-93.

Blau J, Sadr-Azodi N, Clementz M, Abeysinghe N, Cakmak N, Duclos P, Janusz C, Jauregui B, Mihigo R, Mosina L, Takashima Y, Senouci K. Indicators to assess National Immunization Technical Advisory Groups (NITAGs). Vaccine 2013;31:2653–57.

Bryson M, Duclos P, Jolly A. Global immunization policy making process. Health Policy 2010;96:154-59.

Bryson M, Duclos P, Jolly A, Bryson J. A systematic review of national immunization policy making processes. Vaccine 2010;28S:A6-A12.

Bryson M, Duclos P, Jolly A, Cakmak N. A global look at national Immunization Technical Advisory Groups. Vaccine 2010;28S:A13-A17.

Burns JE, Mitrovich RC, Jauregui B, Ruiz Matus C, Andrus JK. Descriptive analysis of immunization policy decision making in the Americas. Pan Am J Public Health 2009;26(5):398-404.

Ceyhan M. Recent improvements in the Turkish childhood national immunization program. Turk J Pediatr 2010;52:563-69.

Chocarro L, Duclos P, Senouci K, Southern J. Consultation on interactions between National Regulatory Authorities and National Immunization Technical Advisory Groups. Expert Rev Vaccines 2011;10(9):1265-70.

Cho HY, Kim CH, Go UY, Lee HJ. Immunization decision-making in the Republic of Korea: The structure and functioning of the Korea Advisory Committee on Immunization Practices. Vaccine 2010;28S:A91-A95.

Duclos P. National Immunization Technical Advisory Groups (NITAGs): Guidance for their establishment and strengthening. Vaccine 2010;28S:A18-A25.

Duclos P, Dumolard L, Abeysinghe N, Adjagba A, Janusz CB, Mihigo R, Mosina L, Takashima Y, Öztürk MH. Progress in the establishment and strengthening of national immunization technical advisory groups: Analysis from the 2013 WHO/UNICEF joint reporting form, data for 2012. Vaccine 2013;31:5314-20.

Duclos P, Okwo-Bele JM, Salisbury D. Establishing global policy recommendations: the role of the Strategic Advisory Group of Experts on Immunization. Expert Rev Vaccines 2011;10(2):163-73.

Duclos P, Ortynsky S, Abeysinghe N, Cakmak N, Bess Janusz C, Jauregui B, Mihigo R, Mosina L, Sadr-Azodi N, Takashima Y, Dumolard L, Gacic-Dobo M. Monitoring of progress in the establishment and strengthening of national immunization technical advisory groups. Vaccine 2012;30:7147-52.

Floret D, Deutsch P. The French Technical Vaccination Committee (CTV). Vaccine 2010;28S:A42-A47.

Freed GL. The structure and function of immunization advisory committees in Western Europe. Human Vaccines 2008;4:292-97.

Gessner BD, Duclos P, DeRoeck D, Nelson EAS. Informing decision makers: Experience and process of 15 National Immunization Technical Advisory Groups. Vaccine 2010;28S:A1-A5.

Hall AJ. The United Kingdom Joint Committee on Vaccination and Immunisation. Vaccine 2010;28S:A54-A57.

John TJ. India's National Technical Advisory Group on Immunization. Vaccine 2010;28S:A88-A90.

Kimman TG, Boot HJ, Berbers GAM, Vermeer-de Bondt PE, de Wit GA, de Melker HE. Developing a vaccination evaluation model to support evidence-based decision making on national immunization programs. Vaccine 2006;24:4769-78.

Le Gargasson JB, Breugelmans JG, Mibulumukini B, Da Silva A, Colombini A. Sustainability of National Immunization Programme (NIP) performance and financing following Global Alliance for Vaccines and Immunization (GAVI) support to the Democratic Republic of the Congo (DRC). Vaccine 2013;31:1886-91.

Matysiak-Klose D, Ahmed F, Duclos P, Falck-Ytter Y, Forland F, Houweling H, Kramarz P, Langley JM, Mertens T, Schünemann H, Senouci K, Temte J, Wichmann O. Report on the 1st international workshop on procedures for the development of evidence-based vaccination recommendations, Berlin, Germany, 22-23 November 2010. Vaccine 2012;30(14):2399-404.

Molina-Aguilera IB, Mendoza-Rodríguez LO, Palma-Rios MA, Valenzuela-Castillo R. An overview of the National Consultative Council of Immunization in Honduras. Vaccine 2010;28S:A64-A67.

Muangchana C, Thamapornpilas P, Karnkawinpong O. Immunization policy development in Thailand: The role of the Advisory Committee on Immunization Practice. Vaccine 2010;28S:A104-A109.

Ngcobo NJ, Cameron NA. The decision making process on new vaccines introduction in South Africa. Vaccine 2012;30S:C9-C13.

Nohynek H, Wichmann O, D'Ancona F and VENICE National Gatekeepers. National Advisory Groups and their role in immunization policy-making process in European countries. Clin Microbiol Infect 2013;19(12):1096-105.

Nolan TM. The Australian model of immunization advice and vaccine funding. Vaccine 2010;28S:A76-A83.

Piso B, Wild C. Decision support in vaccination policies. Vaccine 2009;27:5923-28.

Reed G, Galindo MA. Cuba's National Immunization Program. MEDICC Review 2007;9:5-7.

Ricciardi WG, Duvillard R, Dankó D, Duru G, Picazo J, Poland J, Poland G, Weil-Olivier G, Toumi M. National Immunization Technical Advisory Group (NITAG) decision-making process for vaccine recommendation: overview and analysis. Value Health 2012;15:A277-A575.

Saitoh A, Okabe N. Current issues with the immunization program in Japan: Can we fill the 'vaccine gap'? Vaccine 2012;30:4752-56.

Schoub BD, Mphahlele MJ, Ngcobo NJ, Hoosen AA, Meheus A. Introducing new vaccines into the South African national immunization programme – A case study. Vaccine 2012;30S:C1-C2.

Schoub BD, Ngcobo NJ, Madhi S. The National Advisory Group on Immunization (NAGI) of the Republic of South Africa. Vaccine 2010;28S:A31-A34.

Senouci K, Blau J, Nyambat B, Faye PC, Gautier L, Da Silva A, Favorov MO, Clemens JD, Stoeckel P, Gessner BD. The Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative: A country-driven, multi-partner program to support evidence-based decision making. Vaccine 2010;28S:A26-A30.

Soeung SC, Grundy J, Kamara L, McArthur A. Developments in immunization planning in Cambodia – rethinking the culture and organization of national program planning. Rural Remote Health 2007;7:630.

Smith JC. The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). Vaccine 2010;28S:A68-A75.

Tapia-Conyer R, Betancourt-Cravioto M, Saucedo-Martínez R, Motta-Murguía L, Gallardo-Rincón H. Strengthening vaccination policies in Latin America: An evidence-based approach. Vaccine 2013;31:3826-33.

Van Lier A, Oomen P, de Hoogh P, Drijfhout I, Elsinghorst B, Kemmeren J, Conyn-van Spaendonck M, de Melker H. Praeventis, the immunization register of the Netherlands: a tool to evaluate the National Immunisation Programme. Euro Surveill 2012;17(17):pii 20153.

Wijesinghe PR, Palihawadana P, Peiris TSR. Participatory decision-making through the Advisory Committee on Communicable Diseases: The Sri Lankan experience. Vaccine 2010;28S:A96-A103.

Zahraei SM, Marandi A, Sadrizadeh B, Gouya MM, Rezaei P, Vazirian P, Yaghini F. Role of the National Immunization Technical Advisory Group on improvement of immunization programmes in the Islamic Republic of Iran. Vaccine 2010;28S:A35-A38.

Zheng J, Zhou Y, Wang H, Liang X. The role of the China Experts Advisory Committee on Immunization Program. Vaccine 2010;28S:A84-A87.