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EU JAV

Work Package 4 - Sub-task 4.3.2.1.

Report on:

D4.6. Methodology and plan for pilot study and draft plan for extended study

30.04.21

This project has received co-funding from the European Union's Health Programme under Grant Agreement no. 801495

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WP number Deliverable number Title	WP4 D20 Methodology and plan for pilot study and draft plan for extended study
Responsible partner No. Organization Name E-mail address	19 FMS (UB&UA) Angela Domínguez & Jose Tuells angela.dominguez@ub.edu and tuells@ua.es
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LIST OF ABBREVIATIONS AND ACRONYMS

NITAG: National immunization technical advisory groups

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I. OVERVIEW OF THE PROCESS

a. Context

In 2011, the World Health Organization (WHO) recommended that National Immunization Technical Advisory Groups (NITAGs) be established in each member country. NITAGSs are envisioned as independent, multidisciplinary expert groups within the national immunization framework, tasked with providing evidence-based evaluations and recommendations to governmental decision-makers about specific vaccines, vaccine-dosing, vaccine program development and immunization policy and practice more generally. As of 2020, 171 WHO countries have formed NITAGs. Within the scope of WP4 of the EU Joint Action on Vaccination, we have developed an online survey to characterize the decision-making process of NITAGs of different European countries regarding the inclusion of vaccines in their national immunization schedules.

b. Scope and objective

Characterize the decision-making process of different NITAGs countries regarding the inclusion of vaccines in their national immunization schedules.

Specific objectives

- Related to NITAGs: Map their structure and characteristics.
- Related to Immunization schedules: Description, type, age dimension, geographic dimension (country, regions)
- Decision-making framework for the introduction of vaccines in each country. Overview of the history of recommendations.

c. General methodology

The survey will collect information from NITAG members based on national data or on literature review.

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II. PHASE I. Methodology and plan for pilot study

a. Questionnaire design

To identify NITAG decision-making process and multi-criteria decision analysis on vaccines, we performed a literature review on MEDLINE with the following algorithm:

("nitag"[All Fields] OR "nitags"[All Fields]) AND ("decision making"[MeSH Terms] OR ("decision"[All Fields] AND "making"[All Fields]) OR "decision making"[All Fields]) AND ("process"[All Fields] OR "processe"[All Fields] OR "processed"[All Fields] OR "processes"[All Fields] OR "processing"[All Fields] OR "processings"[All Fields]) AND ("vaccin"[Supplementary Concept] OR "vaccin"[All Fields] OR "vaccination"[MeSH Terms] OR "vaccination"[All Fields] OR "vaccinable"[All Fields] OR "vaccinal"[All Fields] OR "vaccinate"[All Fields] OR "vaccinated"[All Fields] OR "vaccinates"[All Fields] OR "vaccinating"[All Fields] OR "vaccinations"[All Fields] OR "vaccination s"[All Fields] OR "vaccinator"[All Fields] OR "vaccinators"[All Fields] OR "vaccine s"[All Fields] OR "vaccined"[All Fields] OR "vaccines"[MeSH Terms] OR "vaccines"[All Fields] OR "vaccine"[All Fields] OR "vaccins"[All Fields])

Finally, the search obtained 34 selectable articles, of which 10 were considered to guide the survey items. (summarized below).

1. Kimman TG, Boot HJ, Berbers GA, Vermeer-de Bondt PE, Ardine de Wit G, de Melker HE. Developing a vaccination evaluation model to support evidence-based decision making on national immunization programs. Vaccine. 2006 ;24(22):4769-78. doi: 10.1016/j.vaccine.2006.03.022

2. Piso B, Wild C. Decision support in vaccination policies. Vaccine. 2009;27(43):5923-8. doi: 10.1016/j.vaccine.2009.07.105

3. Munira SL, Fritzen SA. What influences government adoption of vaccines in developing countries? A policy process analysis. Soc Sci Med. 2007;65(8):1751-64. doi: 10.1016/j.socscimed.2007.05.054

4. Andrus JK, Toscano CM, Lewis M, Oliveira L, Ropero AM, Dávila M, Fitzsimmons JW. A model for enhancing evidence-based capacity to make informed policy decisions on the introduction of new

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vaccines in the Americas: PAHO's ProVac initiative. Public Health Rep. 2007;122(6):811-6. doi: 10.1177/003335490712200613.

5. Jauregui B, Garcia AG, Bess Janusz C, Blau J, Munier A, Atherly D, Mvundura M, Hajjeh R, Lopman B, Clark AD, Baxter L, Hutubessy R, de Quadros C, Andrus JK. Evidence-based decision-making for vaccine introductions: Overview of the ProVac International Working Group's experience. Vaccine. 2015;33 Suppl 1(0 1):A28-33. doi: 10.1016/j.vaccine.2014.10.090

6. Houweling H, Verweij M, Ruitenberg EJ; National Immunisation Programme Review Committee of the Health Council of the Netherlands. Criteria for inclusion of vaccinations in public programmes. Vaccine. 2010;28(17):2924-31. doi: 10.1016/j.vaccine.2010.02.021.

7. Burchett HE, Mounier-Jack S, Griffiths UK, Mills AJ. National decision-making on adopting new vaccines: a systematic review. Health Policy Plan. 2012;27 Suppl 2:ii62-76. doi: 10.1093/heapol/czr049.

8. Bryson M, Duclos P, Jolly A, Bryson J. A systematic review of national immunization policy making processes. Vaccine. 2010;28 Suppl 1:A6-12. doi: 10.1016/j.vaccine.2010.02.026.

9. Wonodi CB, Privor-Dumm L, Aina M, Pate AM, Reis R, Gadhoke P, Levine OS. Using social network analysis to examine the decision-making process on new vaccine introduction in Nigeria. Health Policy Plan. 2012;27 Suppl 2:ii27-38. doi: 10.1093/heapol/czs037

10. Nohynek H, Wichmann O, D Ancona F; VENICE National Gatekeepers. National Advisory Groups and their role in immunization policy-making processes in European countries. Clin Microbiol Infect. 2013 ;19(12):1096-105. doi: 10.1111/1469-0691.12315

After reviewing the scientific literature, multiples teleconferences have been held between Dr. Domínguez, Dr. Tuells and the INSERM team to design the draft of the questionnaire. Three sections were included according to the results of the bibliographic search:

- Characteristics of the NITAG
- Decision-making process
- Specific questions about vaccines:
    - *In the first draft, 4 vaccines were included (HPV, Pneumococcus, MenB and Zoster)*

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- *In the pilot version, 5 vaccines were included (HPV, Pneumococcus, MenB, Zoster and COVID-19)*

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Selected Results of the Bibliographic Review

Table 1. Results on compliance with the six basic criteria of the NITAGs for the 4 countries of the initial pilot study (SP, FR, IT, NL)

NITAGs					
Criteria		Country			
		SP	FR	IT	NL
Criteria 1	Legislative / administrative basis	✓	✓	✓	✓
Criteria 2	Formal terms of reference	✗	✓	✓	✓
Criteria 3	Conflict of interest policy implemented	✓	✓	✓	✓
Criteria 4	At least 5 expertise areas	✓	✓	✓	✓
Criteria 5	Meets at least once a year	✓	✓	✓	✓
Criteria 6	Circulation of the agenda & background documents a week before meeting	✓	✓	✓	✓

Source: http://www.nitag-resource.org/

Table 2. Some characteristics of the NITAGs of the countries of the initial pilot study (SP, FR, IT, NL)

NITAGs				
Characteristics	**Country**			
	SP	FR	IT	NL
Year when NITAG was established	1991	1985	¿?	1902
Number of NITAG members	19+4	17		20
External experts temporary specific topics	✓	✓		✓
Pharmaceutical companies occasional invited	✗	✓		✗
Conflicts of interests Declaration	✗	✓		✓
Framework for systematic development recommendations	✓	✗		✓
Economic evaluation routinely considered for recommendations	✓	✓		✓

Source: Nohynek, 2013

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Table 3. Developing a vaccination evaluation model to support evidence-based decision making on national immunization programs. (source Kimman, 2006)

An evaluation model to support decision making on NIPs	
The Disease	
Burden of disease	What is the incidence of infection? How reliable are surveillance data?
	Is there a social impact of the disease?
	What are risks for infection? What is the size of groups at risk for infection?
	What is the percentage of symptomatic vs. asymptomatic infections?
	What are risk factors (age, sex, and ethnicity) for symptomatic infection?
	What part of the infections results in carriership?
	What are risk factors (age, sex, and ethnicity) for carriership?
	What is short- and long-term mortality? How reliable are surveillance data?
	What are short- and long-term consequences of infection (morbidity)? What is their frequency?
	Are there any sub-populations (age, sex, and co-morbidity) with more severe forms of disease?
	What is the short- and long-term quality of life after infection?
	What is the burden of disease expressed in DALYs?
	Is there a difference between real and presumed burden of disease? What is the public's perception of the burden of disease?
Use and costs of health care	What is the short- and long-term use of health care (incl. treatments and hospitalization)?
	What are the costs associated with short- and long-term health care (treatments and hospitalization)?
School and work absenteeism	What is the magnitude of school absenteeism of infected individuals?
	What is the magnitude of work absenteeism of infected individuals?
	What is the magnitude of work absenteeism of parents and caretakers of infected individuals?
	What are the costs associated with school and work absenteeism?
	Will there be economic benefits for companies if they offer vaccination to their employees? Can these economic benefits be quantified?
Alternative preventive measures	Are there any alternative preventive measures (e.g., health education, better hygiene, vector control) that are preferred because of effectiveness, costs, and practicality?
	What is the effectiveness of alternative preventive measures?
	What are the costs of these alternative preventive measures?

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The Vaccine	
Availability of vaccine(s)	Which vaccines, monovalent or in combination, are available?
	Which vaccines have been registered?
	For which indications have the vaccines been registered?
	What is the target population for vaccination (age, sex, specific target populations)?
Effectiveness	What is the (type-specific) protection afforded?
	What are critical determinants of the immune response associated with protection?
	What is the optimal vaccination schedule (dosage, age) to protect the vaccinated individual? Are alternative vaccination schedules possible, for example, to accommodate the present NIP's infrastructure?
	What is the frequency of vaccine failure (despite optimal vaccination)?
	What is the frequency of vaccine failure when using alternative vaccination schedules?
	What are risk groups for vaccine failure?
	Is there any interference, regarding protection or immunity, with other vaccines or vaccine components? E.g., regarding humoral and cellular immunity
	Are there any contra-indications for vaccination? In what proportion of the target population?
	What proportion of the target population will accept the vaccine, or has already been vaccinated?
	Is the expected vaccination rate sufficient to reach herd immunity to stop transmission?
	What is the expected duration of protection? Consider humoral and cellular immunity
	What is the effect of waning immunity?
	Will reduced pathogen transmission under vaccine pressure lead to enhanced vulnerability of specific sub-populations?
	Are repeated vaccinations necessary on the short or long-term?
	What is the expected vaccination coverage of repeated vaccinations?
Adverse events following vaccination, safety considerations	What is the nature and frequency of short- and long-term adverse events following vaccination?
	Are there risk groups or risk factors for adverse events? What is the frequency of these risk factors?
	What are the consequences of adverse events on the short- and long-term, and in which frequency do these occur? (Illness, absence from school, use and costs of health care, QALYs)?
	Is there any difference between true, observed disease burden of disease due to adverse events and presumed disease burden (perception of the population)?
	For live attenuated vaccines: is there any chance on reversion to virulence?
Costs of the vaccine and the vaccination program	What are the costs of available vaccines?
	What are the once-only costs to implement the vaccine (education, administration)?
	What are the yearly costs to administer the vaccine?
	What are the costs to monitor safety and effectiveness of the vaccine?

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The Pathogen	
Pathogenicity	Which part of the population comes in contact with the pathogen?
	What is the incidence of infection in the general population and in sub-populations?
	Is there any variation in pathogenicity, for example, serotype-dependent?
	Are there (synergistic or antagonistic) interactions with other pathogens?
	Will there be any ecological consequences after implementation of vaccination (e.g., filling of an ecological niche)?
	Which part of the population comes in contact with the pathogen?
Infectiveness and transmissibility	What is the infectiveness during various stages of infection (incubation period, symptomatic infection, carriership)?
	What are routes and mechanisms of transmission?
	What is the relative importance of different transmission routes?
Antigenic variation	Does antigenic variation occur?
	Does vaccination exert evolutionary pressure leading to the emergence of antigenic or virulence variants?
	What are the consequences of the emergence of antigenic or virulence variants on the vaccine's effectiveness?
Cost-effectiveness	
How many infections can be prevented by vaccination (using different vaccination schedules)?	
What are savings on costs of health care by vaccination?	
Are the benefits of vaccination gained by those who carry the costs?	
How many years of life (QALYs) are saved by vaccination?	
What is the time interval between vaccination and realization of health effects?	
How many infections can be prevented by alternative preventive measures?	
What are savings on costs of health care by alternative preventive measures?	
What is the cost-effectiveness ratio of vaccination compared with alternative preventive measures?	
Is it possible to select individuals eligible for vaccination because of enhanced risk of infection (e.g., by antibody screening)? What would be the cost-effectiveness of such an approach?	

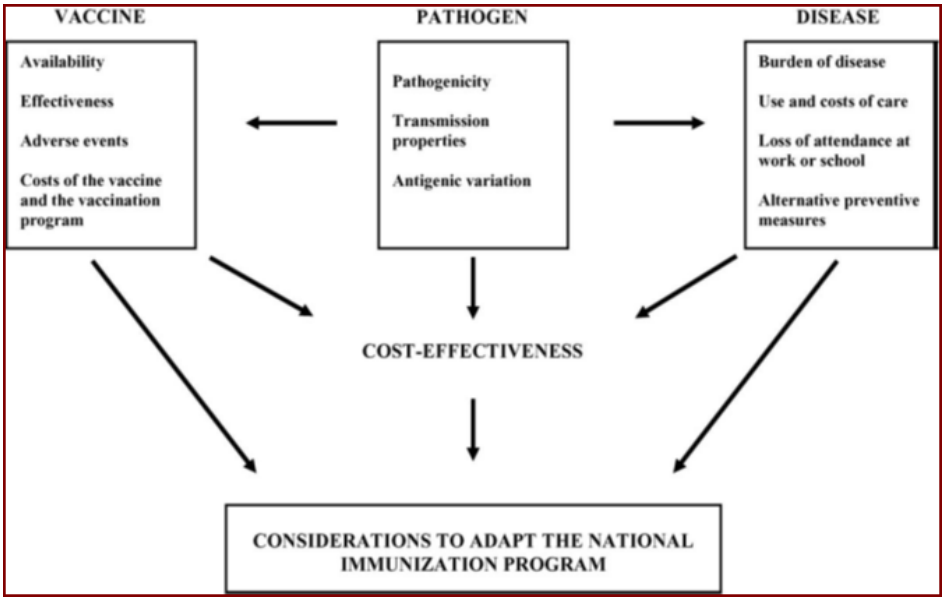

Figure 1. Considerations to adapt the National Immunization Program . (source Kimman, 2006)

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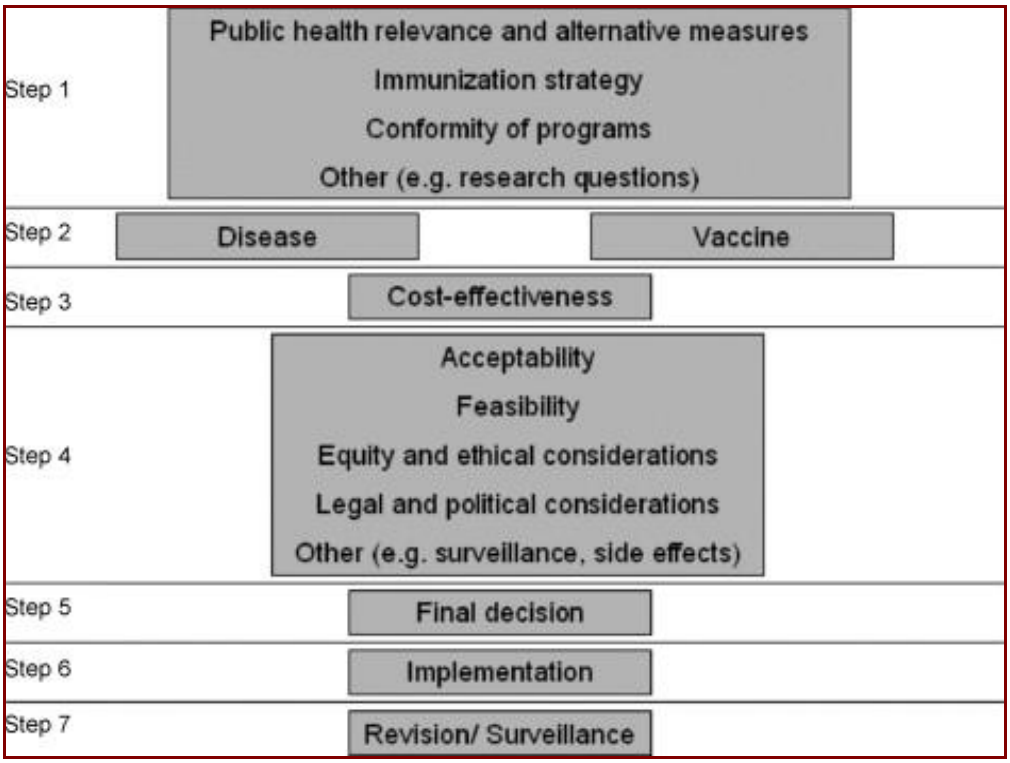

Figure 2. Proposed model of analytical steps in the decision-making process. (source Piso, 2009)

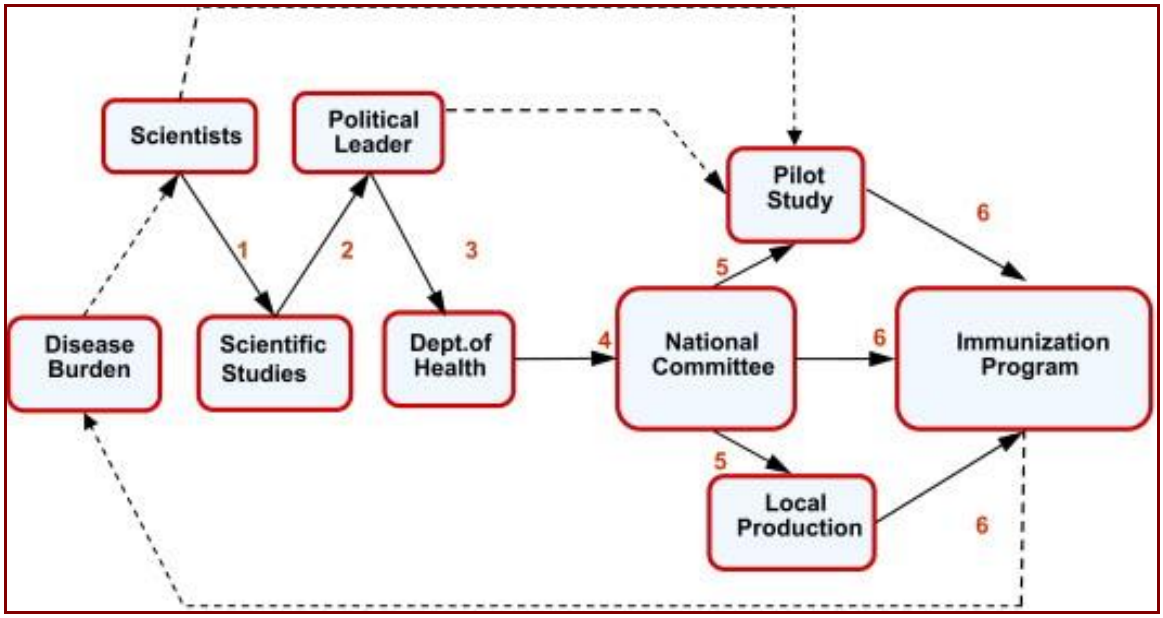

Figure 3. Taiwan's process prior to introduction (compiled from expert interviews and literature review). (source Munira , 2007)

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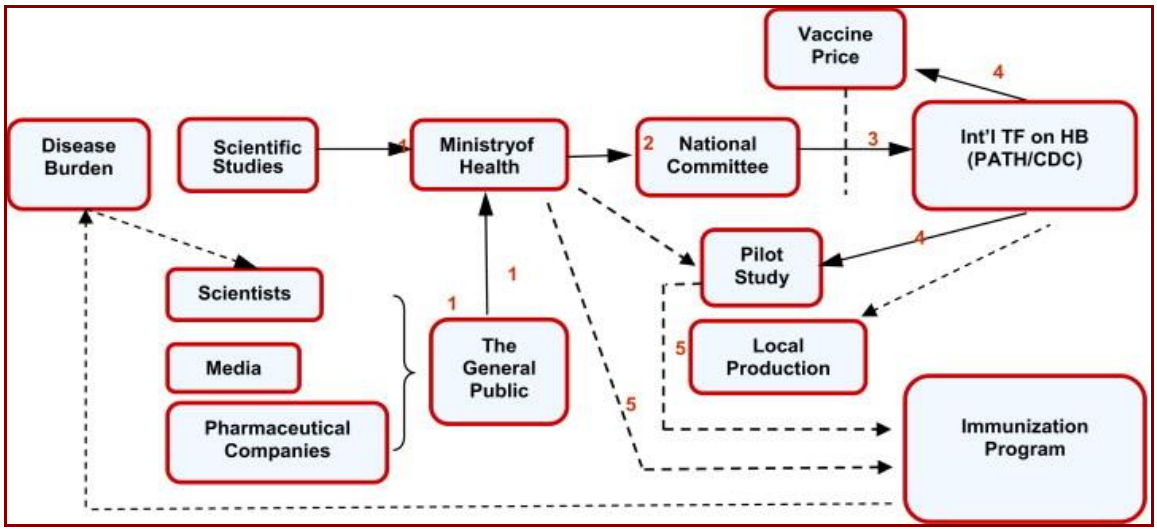

Figure 4. Thailand's process prior to introduction (compiled from expert interviews and literature review). (source Munira , 2007)

Table 4. Hypothesized factors influencing government decision to introduce vaccine into immunization program. (source Munira, 2007)

Factors influencing government decision to introduce vaccine into immunization program	
High disease burden	
Programmatic feasibility	
Pilot studies	
Scientific evidence	
Important role played by	a. Role of the medical associations
	b. Local manufacturers
	c. International support
	d. Role of media
Sensitivity to price	
Policy entrepreneurs	
Other countries already using the vaccine?	

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Table 5. Framework to Vaccine Introduction Decision-Making. (source Andrus, 2007)

Framework Vaccine Introduction Decision-Making	
Technical criteria	Disease burden
	Characteristics of the vaccine
	Adverse events and post-marketing surveillance
	Cost-effectiveness and other economic evaluations
Programmatic and operational criteria	Vaccine supply
	Logistical and operational issues
	Financing strategies
	Partnerships
Social criteria	Perception of risk
	Political will
	Equity

Table 6. Evidence-based decision-making for vaccine introductions: Overview of the ProVac International Working Group's experience. (source Jáuregui, 2015)

Strategy
Analyze the country's existing decision-making process for introducing new vaccines
Identify stakeholders and their roles in the decision process
Identify relevant evidence that should be used to properly inform the decision
Address common questions about cost-effectiveness and its role in the decision-making on new vaccine introduction
Create concise and effective technical presentations based on data from the economic analysis performed
Construct key messages and provide supporting evidence to accompany the results of the economic analyses
Draft policy briefs that include the national economic analysis and other relevant criteria for decision-making
Draft technical reports, including more detailed information about the economic evaluation that was conducted

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Table 7. Criteria for inclusion of vaccinations in public programmes. (source Houwelling, 2010)

Criteria for inclusion of vaccinations in public programmes	
Seriousness and extent of the disease burden	1. The infectious disease causes considerable **disease burden** within the population; the infectious disease is serious for individuals; and the infectious disease affects or has the potential to affect a large number of people.
Effectiveness and safety of the vaccination	2. Vaccination may be expected to considerably **reduce the disease burden** within the population; the vaccine is effective for the prevention of disease or the reduction of symptoms; the necessary vaccination rate is attainable (if eradication/elimination or the creation of herd immunity is sought).
	3. Any adverse effects associated with vaccination are not sufficient to substantially diminish the public health benefit.
Acceptability of the vaccination	4. The inconvenience or discomfort that an individual may be expected to experience in connection with his/her personal vaccination is not disproportionate in relation to the health benefit for the individual concerned and the population as a whole.
	5. The inconvenience or discomfort that an individual may be expected to experience in connection with the vaccination programme as a whole is not disproportionate in relation to the health benefit for the individual concerned and the population as a whole.
Efficiency of the vaccination	6. The balance between the cost of vaccination and the associated health benefit compares favourably to that associated with other means of reducing the relevant disease burden.
Priority of the vaccination	7. Relative to other vaccinations that might also be selected for inclusion, provision of this vaccination serves an urgent public health need at reasonable individual and societal costs

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Table 8. Criteria for decision-making. (source Burchett, 2012)

Criteria for decision-making	
Category	**Criteria**
The importance of the health problem	Burden of disease (e.g. prevalence)
	Political priority
	Costs of disease
	Perceptions of importance (e.g. in terms of perceived severity or vulnerability)
Vaccine characteristics	Efficacy/effectiveness
	Vaccine safety
	Delivery issues (e.g. vaccine schedule)
	Other characteristics
Programmatic considerations	Feasibility
	Vaccine supply
Acceptability	Acceptability of vaccine
Accessibility, equity and ethics	Accessibility, equity and ethics
Financial/economic issues	Economic evaluation
	Incremental costs
	Funding sources
	Vaccine price
	Financial sustainability
	Other (including affordability)
Impact of vaccination	Impact on health outcomes
	Impact on non-health outcomes
	Effect of co-administration
	Risks of serotype replacement
	Other impact
Consideration of alternative interventions	Cost-effectiveness of alternatives
	Effectiveness of alternatives
	Other considerations
Decision-making process	Evidence sources/quality of evidence
	Actors involved
	Procedures
	Cues to action (e.g. disease outbreaks)

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Table 9. Factors considered when making recommendations. (source Bryson, 2010)

Factors considered when making recommendations	
Burden of disease	Netherlands, Spain
Economic evaluation	Netherlands
Feasibility of local vaccine production	
Recommendations of other countries	
Feasibility of recommendation	
Public perception	
Vaccine safety	Spain
Vaccine effectiveness	Spain

Table 10. Characteristics of policy processes and National Immunization Technical Advisory Group (NITAG) by country with information available on immunization policy development. (source Bryson, 2010)

Characteristics of policy processes and National Immunization Technical Advisory Group (NITAG) by country with information available on immunization policy development[a].

Country	NITAG	Core members	Defined term limit for members (years)	Declare conflicts of interest	Meetings per year	Nature of meetings	Meeting minutes published on the internet	Method of final decision making	Other group that makes immunization recommendations [b]
Australia	Yes				3	Closed	Yes		
Austria	Yes	16	3		3		No		
Belgium									Yes
Brazil	Yes								
Bulgaria									Yes
Cambodia									Yes
Canada	Yes	12	4	Yes	3	Closed	Yes	Vote	
Denmark									Yes
France	Yes	16			6–8	Closed	No		
Germany	Yes	17			2				
Greece									Yes
Ireland	Yes		No		6	Closed	No	Consensus	
Italy	Yes								
New Zealand	Yes								
Luxembourg									Yes
Norway									Yes
Papua New Guinea									Yes
Portugal									Yes
Spain	Yes		No					Consensus	
Slovakia									Yes
Slovenia									Yes
Sweden									Yes
Switzerland	Yes	15	4		5	Closed	No	Vote	
Thailand									Yes
The Netherlands	Yes								
UK	Yes	16	4	Yes	3	Closed	Yes	Vote	
USA	Yes	15	4	Yes	3	Open	Yes	Vote	

[a] Blank fields indicate that information was not available—also limited information was available on Argentina, China, Finland, Iceland, Mali, and Poland but not related to the information in this table.
[b] Unknown if these groups are NITAGs as defined in this paper.

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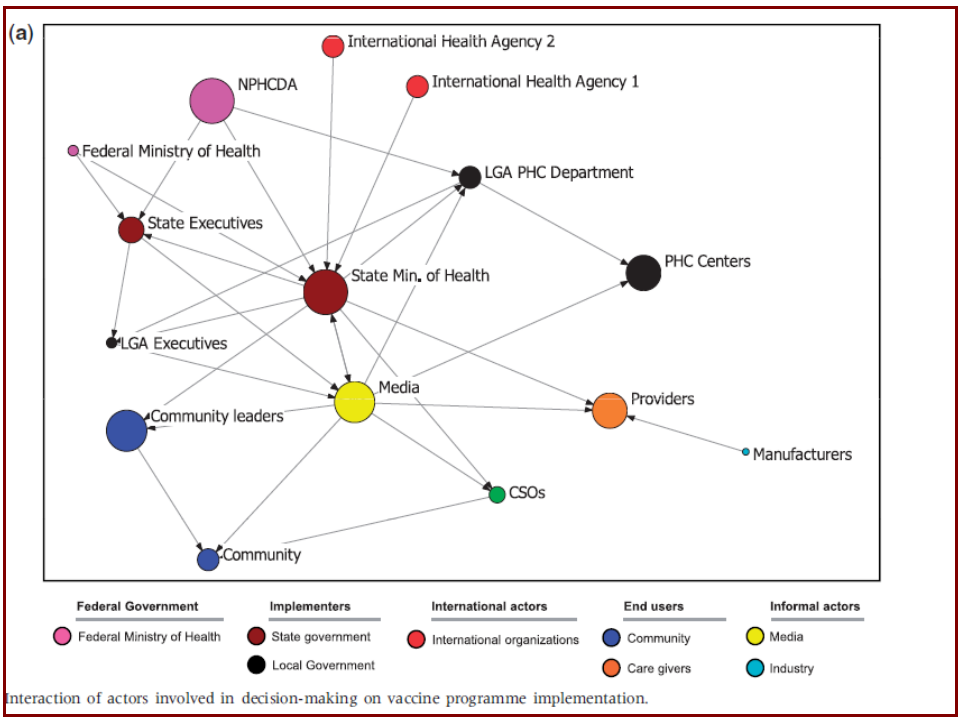
Table 11. Vaccine programme implementation decision-makers network: organizations involved and node-level statistics. (source Wonodi, 2012)

Table 3 Vaccine programme implementation decision-makers network: organizations involved and node-level statistics

Type of organization	Actor[a]	Total no. of ties	No. of nodes that actor influences (outdegrees)	No. of nodes that influence actor (indegrees)	Influence score (range: 0–10)
Federal Government of Nigeria					
Federal Ministry of Health	NPHCDA	3	3	0	10
	FMoH	2	2	0	2
Implementers					
State Government	SMoH	11	7	5	10
	State Executive	5	2	3	5
Local Government	LGA PHC Dept	5	2	3	4
	LGA Executive	4	1	4	2
	CSO	3	1	2	3
International actors					
International orgs	International health agency 1	1	1	0	5
	International health agency 2	1	1	0	5
End users					
Community	Community leader	3	1	2	9
	Community	3		3	–
Care givers	Providers	3		3	8
	PHC centres	2		2	8
Informal actors					
Media	Media	9	9	3	9
Industry	Manufacturers	1	1	0	1
Total		**56**	**31**	**30**	

Notes: [a]Conceptually, the terms 'node' and 'actor' are used interchangeably. In this table, actor = index node.
NPHCDA = National Primary Health Care Development Agency; FMoH = Federal Ministry of Health; SMoH = State Ministry of Health; LGA = Local Government Area; PHC = Primary Health Care; CSO = civil society organization.



Interaction of actors involved in decision-making on vaccine programme implementation.

Figure 4. Interaction of actors involved in decision-making on vaccine programme implementation.. (source Wonodi, 2012)

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Table 12. Key factors considered in the decision-making process of adopting vaccines in the NITAGs. (source Nohynek, 2013)

Key factors considered in the decision-making process of adopting vaccines in the NITAGs
Disease burden in home country
Severity of disease
Vaccine efficacy/effectiveness
Vaccine safety at population level
Vaccine safety at individual level
Feasibility of recommendation
Guidance document from WHO
Priority among other vaccine-preventable diseases
Results from economic evaluations
Guidance document from ECDC
Recommendations of other countries
Method of vaccine administration
Priority of vaccination compared with all other possible health interventions
Results from mathematical modelling
Public perception about the disease
Disease burden in neighbouring country
Feasibility of local vaccine production

Table 13. Professional expertise represented among National Immunization Technical Advisory Group (NITAG) members in 22 countries with NITAGs. (source Nohynek, 2013)

Professional expertise represented among NITAGs		
Clinical medicine	Epidemiology	Paediatrics
Public health	Immunology	Microbiology (incl. Virology)
Vaccinology	Ethics	Health economics
General practice	Lay members	Regulatory Authority on Medicines
Ministry of Health	Medicine School	Social sciences
University faculty	Travel medicine	Well-baby clinics
Occupational health	Non-governmental organizations	Health insurance system

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The questionnaire was developed considering the objectives of the study and collecting part of the items and ideas from the review that we have summarized above.

b. Pilot Survey:

The pilot survey was scheduled to take place in France, the Netherlands, Italy and Spain in October / November 2020, but was delayed until March 2021.

An invitation was sent out in early March to one member of each NITAG from the four countries. At the end of March, a response was only received from Spain and France.

Survey Decision-Making Process (SDMP)			
NITAG Some features of NITAGs			
Year NITAG established			
Number NITAG voting members			
Number and composition of NITAG scientific secretariat members			
NITAG replay based on: ☐ National data ☐ Literature review			
	Answer		
	YES	**NO**	**NK/NA**
All members have declared their conflicts of interest (if any)			
Official legislative/administrative basis for the advisory group			
Formal written Terms of Reference			
At least 5 expertise areas			
Meets at least once a year			
Circulation of the agenda & background paper a week before meeting			
Framework for systematic development recommendations			
Economic evaluation routinely considered for recommendations			
External experts temporary specific topics (working groups, partnership,..)			
Pharmaceutical industry occasionally invited			
Your NITAG makes recommendations regarding off-label vaccine use			
NITAG uses the systematic review methodology (PRISMA)			

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NITAG uses the GRADE methodology				
CATEGORY	**CRITERIA**	**Answer**		
		YES	**NO**	**NK/NA**
Factors influencing government decision (MoH)	Programmatic Feasibility			
	NITAG Recommendation			
	Pilot studies			
	Vaccine coverage			
	Scientific evidence			
	Role of patient representatives			
	Role of the medical associations			
	Local manufacturers			
	Role of media			
	Sensitivity to price			
	Foreign recommendations / Other countries already using the vaccine			
	WHO recommendations			
Professional expertise represented among NITAG members	Clinical medicine			
	Public health			
	Vaccinology			
	General practice			
	Ministry of Health			
	Ethics			
	Occupational health			
	Others Ministries			
	Epidemiology			
	Immunology			
	Social sciences			
	Lay members			
	Health/ Medicine School			
	Travel medicine			
	Paediatrics			
	Microbiology / Virology			

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	Health economics			
	Regulatory Authority on Medicines			
	Social sciences			
	Health insurance system			
	Non-governmental organizations			
	Patients representatives			

You can add specific comments

CRITERIA DECISION MAKING

Different categories and criteria for decision-making in the adoption of new vaccines.

Please give weight between 1 (less important) to 10 (more important) for the following criteria. Write 'not considered' if the criteria was not considered.

CATEGORY	CRITERIA	Answer
Burden of disease	Incidence/ prevalence of infection	
	Risks for infection/ developing a severe form	
	Size of groups at risk for infection	
	Percentage of symptomatic vs. asymptomatic infections	
	Risk factors (age, sex, and ethnicity) for symptomatic infection	
	Risk factors (age, sex, and ethnicity) for carriership	
	Incidence of hospitalization	
	Short- and long-term disease mortality	
	Short- and long-term consequences of infection : incidence of disease (morbidity)	
	Short- and long-term quality of life after infection	
	Burden of disease expressed in DALYs	
	Burden of disease expressed in YPLL (years of potential life lost)	
	The real burden of disease is different from the burden of disease usually considered	
	Public's perception of the burden of disease	
Costs of disease	Short- and long-term use of health care	

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	Costs associated with short- and long-term health care	
	Magnitude of school absenteeism of infected individuals	
	Magnitude of work absenteeism of infected individuals	
Vaccine Efficacy/ effectiveness	Type-specific protection afforded	
	Vaccine targeted population (general, at risk, size)	
	Critical determinants of the immune response associated with protection	
	Optimal vaccination schedule (dosage, age) to protect the vaccinated individual	
	Vaccine efficacy	
	Expected vaccine impact	
	Foreign impact if other countries already using the vaccine	
	Frequency of vaccine failure	
	Vaccine failure in risk groups	
	Contra-indications for vaccination	
	Expected vaccination rate sufficient to reach herd immunity	
	Expected duration of protection	
	Effect of waning immunity: need for booster dose	
	Vaccinations necessary on the short or long-term	
	Expected vaccination coverage of repeated vaccinations	
Cost-effectiveness	An important proportion of infection can be prevented by vaccination	
	Savings on costs of health care by vaccination	
	Benefits of vaccination gained /disease can be prevented by vaccination	
	Quality adjusted life years (QALYs) are saved by vaccination	
	Vaccine costs Saving	
	Cost-effectiveness ratio of vaccination compared with alternative preventive measures	
Safety Vaccine	Nature and frequency of short-term adverse events following vaccination	
	Nature and frequency of long-term adverse events	

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Adverse events following vaccination	following vaccination	
	Risk groups or risk factors for adverse events	
	Consequences of adverse events on the short- and long-term	
Costs of the vaccine and the vaccination program	Costs of available vaccines	
	Yearly costs to administer the vaccine	
	Costs to monitor safety and effectiveness of the vaccine	
	Efficiency studies before the prize of the vaccine was fixed	
Programmatic considerations	Delivery issues	
	Feasibility	
	Vaccine supply	
	Plans for shortages	
	Plans in case of outbreaks	
Financial/economic issues	Incremental costs	
	Funding sources	
	Vaccine price	
	Financial sustainability	
	Affordability	
Decision-making process	Evidence sources/quality of evidence	
	Actors involved	
	Procedures	
	Cues to action (e.g. disease outbreaks)	
Social Criteria	Acceptability of vaccine :Perception of Benefit/risk	
	Vaccine hesitancy	
	Equity	
	Ethics	
Political issues **(open question)**	Political priority	
Uncertainties	Uncertainties are mentioned	
	It is planned how to answer uncertainties	
You can add specific comments		

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Newly Incorporated Vaccines New vaccines have been added to immunization schedules in the past decade. Have the decision-making processes been different?	
Human Papilloma Vaccine (HPV). Vaccination for girls.	
Year of introduction into the official immunization schedule for girls	
Recommendation	
Target population adolescent girls (age range)	
NITAG published a document with the recommendation	Yes / No
Significant burden of disease	High/Medium/Low
Specific concerns about SAE	Yes / No
Costs of vaccination were discussed	Yes / No
Costs of benefits of vaccination were discussed	Yes / No
Results for mathematical modelling or cost-effectiveness modelling (country-specific)	Yes / No
Level of Grade recommendation if used	
Contextual concerns	
Political priority	Yes / No
There were positive pressures from the medical professionals	Yes / No
There were negative pressures from the medical professionals.	Yes / No
There were pressures from the pharmaceutical industry	Yes / No
Social concerns: acceptability, equity, ethic	
Supply problems	Yes / No
You can add specific comments about this vaccine	

Human Papilloma Vaccine (HPV). Vaccination for boys.	
Year of introduction into the official immunization schedule for boys	
Recommendation	
Target population adolescent boys (age range)	
NITAG published a document with the recommendation	Yes / No
Significant burden of disease	High/Medium/Low
Specific concerns about SAE	Yes / No
Costs of vaccination were discussed	Yes / No
Costs of benefits of vaccination were discussed	Yes / No

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Results for mathematical modelling or cost-effectiveness modelling (country-specific)	Yes / No
Level of Grade recommendation if used	
Contextual concerns	
Political priority	Yes / No
There were positive pressures from the medical professionals	Yes / No
There were negative pressures from the medical professionals.	Yes / No
There were pressures from the pharmaceutical industry	Yes / No
social concerns: acceptability, equity, ethic	
Supply problems	Yes / No
You can add specific comments about this vaccine	

Pneumococcal conjugate vaccine (**PCV**). Prevenar 13-valent.	
Year of incorporation into the official immunization schedule for pediatrics' populations	
Recommendation	
Target population: specify	
NITAG published a document with the recommendation	Yes / No
Significant burden of disease	High/Medium/Low
Specific concerns about SAE	Yes / No
Costs of vaccination were discussed	Yes / No
Costs of benefits of vaccination were discussed	Yes / No
Results for mathematical modelling or cost-effectiveness modelling: (country-specific)	Yes / No
Level of Grade recommendation if used	
Contextual concerns	
Political priority	Yes / No
There were positive pressures from the medical professionals	Yes / No
There were negative pressures from the medical professionals.	Yes / No
There were pressures from the pharmaceutical industry	Yes / No
Social concerns: acceptability, equity, ethic	
Supply problems	Yes / No
You can add specific comments about this vaccine	

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Meningococcal B (MenB) **Bexsero**	
Year of introduction into the official immunization schedule	
Recommendation	
Target population: specify	
NITAG published a document with the recommendation	Yes / No
Significant burden of disease	High/Medium/Low
Specific concerns about SAE	Yes / No
Costs of vaccination were discussed	Yes / No
Costs of benefits of vaccination were discussed	Yes / No
Results for mathematical modelling or cost-effectiveness modelling: (country-specific)	Yes / No
Level of Grade recommendation if used	
Contextual concerns	
Political priority	Yes / No
There were positive pressures from the medical professionals	Yes / No
There were negative pressures from the medical professionals.	Yes / No
There were pressures from the pharmaceutical industry	Yes / No
Social concerns: acceptability, equity, ethic	
Supply problems	Yes / No
You can add specific comments about this vaccine	

Meningococcal B (MenB) **Trumenba**	
Year of introduction into the official immunization schedule	
Recommendation	
Target population: specify	
NITAG published a document with the recommendation	Yes / No
Significant burden of disease	High/Medium/Low
Specific concerns about SAE	Yes / No
Costs of vaccination were discussed	Yes / No
Costs of benefits of vaccination were discussed	Yes / No
Results for mathematical modelling or cost-effectiveness modelling: (country-specific)	Yes / No

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Level of Grade recommendation if used	
Contextual concerns	
Political priority	Yes / No
There were positive pressures from the medical professionals	Yes / No
There were negative pressures from the medical professionals.	Yes / No
There were pressures from the pharmaceutical industry	Yes / No
Social concerns: acceptability, equity, ethic	
Supply problems	Yes / No
You can add specific comments about this vaccine	

Herpes Zoster Vaccine **Zostavax**	
Year of introduction into the official immunization schedule	
Recommendation	
Target population: specify	
NITAG published a document with the recommendation	Yes / No
Significant burden of disease	High/Medium/Low
Specific concerns about SAE	Yes / No
Costs of vaccination were discussed	Yes / No
Costs of benefits of vaccination were discussed	Yes / No
Results for mathematical modelling or cost-effectiveness modelling: (country-specific)	Yes / No
Level of Grade recommendation if used	
Contextual concerns	
Political priority	Yes / No
There were positive pressures from the medical professionals	Yes / No
There were negative pressures from the medical professionals.	Yes / No
There were pressures from the pharmaceutical industry	Yes / No
Social concerns: acceptability, equity, ethic	
Supply problems	Yes / No
You can add specific comments about this vaccine	

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Herpes Zoster Vaccine Shingrix	
Year of introduction into the official immunization schedule	
Recommendation	
Target population: specify	
NITAG published a document with the recommendation	Yes / No
Significant burden of disease	High/Medium/Low
Specific concerns about SAE	Yes / No
Costs of vaccination were discussed	Yes / No
Costs of benefits of vaccination were discussed	Yes / No
Results for mathematical modelling or cost-effectiveness modelling: (country-specific)	Yes / No
Level of Grade recommendation if used	
Contextual concerns	
Political priority	Yes / No
There were positive pressures from the medical professionals	Yes / No
There were negative pressures from the medical professionals.	Yes / No
There were pressures from the pharmaceutical industry	Yes / No
Social concerns: acceptability, equity, ethic	
Supply problems	Yes / No
You can add specific comments about this vaccine	

c. Pilot Survey analysis:

The responses received were analyzed considering two aspects, on the one hand, the comments regarding the structure and design of the questionnaire itself were observed. The suggestions of the participants who had responded were collected. Some referred to its length and doubts about the relevance of any of the questions. On the other hand, the contents of the responses have been studied, which have given us a good perspective to further analyze the final result of the entire survey when we have received the reports from the different European NITAGs.

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Results of the questionnaires received from the NITAGs of Spain and France in the pilot study

		SPAIN	FRANCE
Some features of NITAGs	Year NITAG established	1991	1985
	Number NITAG voting members	20	28
	Number and composition of NITAG scientific secretariat members	6	6
	NITAGs decission is based on: National data	Yes	Yes
	NITAGs decission is based on: Literature review	Yes	Yes
	All members have declared their conflicts of interest (if any)	Yes	Yes
	Official legislative/administrative basis for the advisory group	Yes	Yes
	Formal written Terms of Reference	Yes	Yes
	At least 5 expertise areas	Yes	Yes
	Meets at least once a year	Yes	Yes
	Circulation of the agenda & background paper a week before meeting	Yes	Yes, but the delay of circulation is often shorten
	Framework for systematic development recommendations	Yes	Yes
	Economic evaluation routinely considered for recommendations	Yes	Yes, not systematically
	External experts temporary specific topics (working groups, partnership,...)	Yes	Yes
	Pharmaceutical industry occasionally invited	No	Yes
	Your NITAG makes recommendations regarding off-label vaccine use	Yes	Yes
	NITAG uses the systematic review methodology (PRISMA)	No	Yes
	NITAG uses the GRADE methodology	No	No

Factors influencing government decision (MoH)	Programmatic Feasibility	Yes	Yes
	NITAG Recommendation	Yes	Yes
	Pilot studies	Yes	No
	Vaccine coverage	Yes	Yes
	Scientific evidence	Yes	Yes
	Role of patient representatives	Yes	Yes
	Role of the medical associations	Yes	Yes
	Local manufacturers	Yes	Yes
	Role of media	Yes	Yes
	Sensitivity to price	Yes	Yes
	Foreign recommendations / Other countries already using the vaccine	Yes	Yes
Professional expertise represented among NITAG members	WHO recommendations	Yes	Yes
	Clinical medicine	Yes	Yes
	Public health	Yes	Yes
	Vaccinology	Yes	Yes
	General practice	Yes	Yes
	Ministry of Health	Yes	Yes
	Ethics	No	No
	Occupational health	No	Yes
	Others Ministries	Yes	Yes
	Epidemiology	Yes	Yes
	Immunology	No	Yes
	Social sciences	No	Yes
	Lay members	No	No
	Health/ Medicine School	No	No
	Travel medicine	Yes	No

	Paediatrics	Yes	Yes
	Microbiology / Virology	Yes	Yes
	Health economics	No	Yes
	Regulatory Authority on Medicines	Yes	Yes
	Health insurance system	Yes	Yes
	Non-governmental organizations	No	No
	Patients representatives	No	Yes
	You can add specific comments:	**The professional expertise is complemented with external advisers in the working groups on specific topics.**	**The composition of the Committee was revised on 2017. The committee is now composed with 28 voting members including 2 patients representatives and additionnal 9 ex officio members who represent French public health agency, regulatory agency for drugs , Ministry of Health and other ministries (education, army medical corps) and others representatives such as the Heath insurance system.**

CRITERIA DECISION MAKING

		SPAIN	FRANCE
Burden of disease	Incidence/ prevalence of infection	1	10
	Risks for infection/ developing a severe form	2	10
	Size of groups at risk for infection	6	5
	Percentage of symptomatic vs. asymptomatic infections	4	3
	Risk factors (age, sex, and ethnicity) for symptomatic infection	9	9
	Risk factors (age, sex, and ethnicity) for carriership		8
	Incidence of hospitalization	3	10
	Short- and long-term disease mortality	5	10
	Short- and long-term consequences of infection : incidence of disease (morbidity)	7	10
	Short- and long-term quality of life after infection	8	7
	Burden of disease expressed in DALYs		3
	Burden of disease expressed in YPLL (years of potential life lost)		2
	The real burden of disease is different from the burden of disease usually considered		1
	Public's perception of the burden of disease	10	2
Costs of disease	Short- and long-term use of health care	1	6
	Costs associated with short- and long-term health care	2	6
	Magnitude of school absenteeism of infected individuals		1
	Magnitude of work absenteeism of infected individuals	3	1

Vaccine Efficacy/ effectiveness	Type-specific protection afforded	5	7
	Vaccine targeted population (general, at risk, size)	6	10
	Critical determinants of the immune response associated with protection	13	8
	Optimal vaccination schedule (dosage, age) to protect the vaccinated individual	10	9
	Vaccine efficacy	2	10
	Expected vaccine impact	1	10
	Foreign impact if other countries already using the vaccine	14	8
	Frequency of vaccine failure	3	5
	Vaccine failure in risk groups	11	7
	Contra-indications for vaccination	7	6
	Expected vaccination rate sufficient to reach herd immunity	5	7
	Expected duration of protection	4	5
	Effect of waning immunity: need for booster dose	12	6
	Vaccinations necessary on the short or long-term	8	7
	Expected vaccination coverage of repeated vaccinations	9	3
Cost-effectiveness	An important proportion of infection can be prevented by vaccination	3	5
	Savings on costs of health care by vaccination	5	4
	Benefits of vaccination gained /disease can be prevented by vaccination	1	7
	Quality adjusted life years (QALYs) are saved by vaccination	2	4
	Vaccine costs Saving	6	4
	Cost-effectiveness ratio of vaccination compared with alternative preventive measures	4	5

Safety Vaccine Adverse events following vaccination	Nature and frequency of short-term adverse events following vaccination	2	8
	Nature and frequency of long-term adverse events following vaccination	3	10
	Risk groups or risk factors for adverse events	4	9
	Consequences of adverse events on the short- and long-term	1	8
Costs of the vaccine and the vaccination program	Costs of available vaccines	1	3
	Yearly costs to administer the vaccine	2	2
	Costs to monitor safety and effectiveness of the vaccine	3	1
	Efficiency studies before the prize of the vaccine was fixed		4
Programmatic considerations	Delivery issues	3	2 (not a problem in France -except COVID vaccines)
	Feasibility	1	3
	Vaccine supply	2	2
	Plans for shortages	5	6
	Plans in case of outbreaks	4	3
Financial/economic issues	Incremental costs	4	4
	Funding sources		1
	Vaccine price	3	3
	Financial sustainability	2	4
	Affordability	1	4
Decision-making process	Evidence sources/quality of evidence	1	10
	Actors involved	4	4
	Procedures	2	7
	Cues to action (e.g. disease outbreaks)	3	3

Social Criteria	Acceptability of vaccine :Perception of Benefit/risk	3	7
	Vaccine hesitancy	4	5
	Equity	1	3
	Ethics	2	3
Political issues (open question)	Political priority		8
Uncertainties	Uncertainties are mentioned	2	6
	It is planned how to answer uncertainties	1	4
Recommendation	**You can add specific comments**	The grade of the different categories has not been responded in an exhaustive form, as it is not graded in the NITAG´S framework.	Some remarks on the questionnaire: It seems that some criteria mentioned in the questionnaire are very close and interdependent. For example: long term consequences of disease and disease morbidity; price of vaccine and costs of vaccination program. It would be useful to shorten the number of criteria. Maybe it could be useful to shorten the number of criteria

Newly Incorporated Vaccines

Human Papilloma Vaccine (HPV). Vaccination for girls.

		SPAIN	FRANCE
Year of introduction into the official immunization schedule for girls		2008	2007
Recommendation	Target population adolescent girls (age range)	12-26y	2007: 14 yo + catch up campaign 15-23 y.o in the year after the sexual life beginning 2012: 11-14 and catch-up until 20 yo.
	NITAG published a document with the recommendation	Yes	Yes
	Significant burden of disease	High	Medium
	Specific concerns about SAE	No	No (initially) but concerns raised rapidly after the start of the vaccination program due to occurrence of unexplained deaths, and of autoimmune diseases.
	Costs of vaccination were discussed	Yes	Yes
	Costs of benefits of vaccination were discussed	Yes	Yes
	Results for mathematical modelling or cost-effectiveness modelling (country-specific)	Yes	Yes
	Level of Grade recommendation if used	A	Not applicable

Contextual concerns	Political priority	Yes	Yes
	There were positive pressures from the medical professionals	Yes	Yes
	There were negative pressures from the medical professionals.	Yes	No
	There were pressures from the pharmaceutical industry	Yes	No
	Social concerns: acceptability, equity, ethic	Yes	Yes
	Supply problems	No	No (initially)

You can add specific comments about this vaccine		The Committee recommended in 2007 that priority be given to the establishment of an organized cervical cancer screening program at national level before the introduction of the vaccination program. At the beginning of the program, the Committee also highlighted specific concerns about the emergence of new HPV genotypes and vaccine pressure (HPV genotypes selection) and about the long term impact of the vaccination program on the compliance to the individual cervical screening. A political pressure was observed since the reimbursement of the vaccine was announced by the MoH as the recommendations of the NITAG had not yet be provided

Human Papilloma Vaccine (HPV). Vaccination for boys.

	Year of introduction into the official immunization schedule for girls		2021
Recommendation	Target population adolescent girls (age range)		11-14yo. + immunocompromised With catch-up until 20yo + specific catch up for MSM until 26 yo.
	NITAG published a document with the recommendation		Yes
	Significant burden of disease		
	Specific concerns about SAE		Yes due to a French study that identified a increase risk of GBS but this signal wad not confirmed in others studies
	Costs of vaccination were discussed		No
	Costs of benefits of vaccination were discussed		Yes
	Results for mathematical modelling or cost-effectiveness modelling (country-specific)		Yes An analysis for France was not conducted, instead economic evaluations from other countries were assessed for their applicability to the French situation
	Level of Grade recommendation if used		No

Contextual concerns	Political priority		Yes
	There were positive pressures from the medical professionals		Yes
	There were negative pressures from the medical professionals.		No
	There were pressures from the pharmaceutical industry		No
	Social concerns: acceptability, equity, ethic		Yes
	Supply problems		Yes, delay of implementation of one year
You can add specific comments about this vaccine			In this recommendation, the Committee pay an attention to enhance the vaccination program including for girls. The better acceptability of vaccination of a non-gendered program was highlighted as well as ethical consideration and equity access of vaccination to all susceptible individuals irrespective of their gender.

Pneumococcal conjugate vaccine (PCV). Prevenar 13-valent.

	Year of incorporation into the official immunization schedule for pediatrics' populations	2015	2009
Recommendation	Taerget population: specify	2,4,11m	All infants under 2yo. Premature neonates, + infants at higher risk of IIP with a catch-up until 59 months

	NITAG published a document with the recommendation	Yes	Yes
	Significant burden of disease	Medium	High
	Specific concerns about SAE	No	No
	Costs of vaccination were discussed	Yes	No
	Costs of benefits of vaccination were discussed	Yes	No
	Results for mathematical modelling or cost-effectiveness modelling (country-specific)	Yes	No
	Level of Grade recommendation if used	A	no
Contextual concerns	Political priority	Yes	No
	There were positive pressures from the medical professionals	Yes	No
	There were negative pressures from the medical professionals.	No	No
	There were pressures from the pharmaceutical industry	Yes	No
	Social concerns: acceptability, equity, ethic	Yes	No
	Supply problems	No	No

You can add specific comments about this vaccine		The Committee highlighted the importance to move from the 7-valent vaccine to the 13-valent vaccine due to epidemiological concerns regarding the dramatical decrease of IIP due to vaccine serotypes and the increase of infection of non vaccine serotypes (including those were less sensitive to antibiotics) due to vaccine pressure.

Meningococcal B (MenB)

Bexsero	Year of introduction into the official immunization schedule		2013
Recommendation	Target population: specify		Individuals aged 2 months old and above, at increased risk of invasive meningococcal disease caused by serogroup B
	NITAG published a document with the recommendation		Yes
	Significant burden of disease		Low
	Specific concerns about SAE		Yes, high reactogenicty with risk of hospitalization
	Costs of vaccination were discussed		Yes
	Costs of benefits of vaccination were discussed		Yes

	Results for mathematical modelling or cost-effectiveness modelling: (country-specific)		Yes
	Level of Grade recommendation if used		No
Contextual concerns	Political priority		No
	There were positive pressures from the medical professionals		Yes
	There were negative pressures from the medical professionals.		No
	There were pressures from the pharmaceutical industry		No
	Social concerns: acceptability, equity, ethic		No
	Supply problems		No

You can add specific comments about this vaccine	The place of the BEXSERO vaccine in the meningococcal vaccination strategy in France was first evaluated in 2013 by the HCSP. At that time the Committee decided not to recommend a generalised vaccination programme for all infants, children or adolescents and to instead recommend vaccination only to individuals at-risk of invasive meningococcal disease caused by serogroup B (be that due to the presence of specific comorbidities, receiving certain treatments or being in the entourage of a confirmed case). The reasons for this were the lack of data concerning duration of protection; the absence of heard immunity resulting in a low impact of the vaccination on the burden of the disease difficulties envisaging how to fit 4 doses of the vaccine into the existing infant vaccination calendar; and the unfavourable cost-effectiveness analysis results . Following updated European marketing authorisations in 2018 and 2020, the Commission reviewed the policy and updated the risk-groups eligible for vaccination, but again declined to introduce a generalised vaccination programme due to the evolution of the incidence of the disease since the 2013 recommendation. Intermediate recommendations were published for consultation in January 2021, with the final recommendations due to be published in May 2021.

Meningococcal B (MenB)

Trumenba	Year of introduction into the official immunization schedule		2021
Recommendation	Target population: specify		Individuals ≥10 years old, at increased risk of invasive meningococcal disease caused by serogroup B
	NITAG published a document with the recommendation		Yes
	Significant burden of disease		Low
	Specific concerns about SAE		No
	Costs of vaccination were discussed		Yes
	Costs of benefits of vaccination were discussed		Yes
	Results for mathematical modelling or cost-effectiveness modelling: (country-specific)		Yes
	Level of Grade recommendation if used		No
Contextual concerns	Political priority		No
	There were positive pressures from the medical professionals		No
	There were negative pressures from the medical professionals.		No
	There were pressures from the pharmaceutical industry		No
	Social concerns: acceptability, equity, ethic		No
	Supply problems		No

You can add specific comments about this vaccine		The Commission published intermediate recommendations for TRUMENBA in January 2021, and final recommendations are due to be published in May 2021. The Commission recommends vaccination with TRUMENBA to those individuals in at-risk groups and will not publish a generalised recommendation to all adolescents and adults due to the observed decrease in the incidence of the disease over the last 15 years.

Herpes Zoster Vaccine

Zostavax	Year of introduction into the official immunization schedule		2014
Recommendation	Target population: specify		Adults of 65 to 74 yo. With a catch-up program during the first year for older adults (75 to 79 yo).
	NITAG published a document with the recommendation		Yes
	Significant burden of disease		Medium
	Specific concerns about SAE		No
	Costs of vaccination were discussed		Yes
	Costs of benefits of vaccination were discussed		Yes
	Results for mathematical modelling or cost-effectiveness modelling: (country-specific)		Yes
	Level of Grade recommendation if used		no
Contextual concerns	Political priority		No
	There were positive pressures from the medical professionals		No

	There were negative pressures from the medical professionals.		No
	There were pressures from the pharmaceutical industry		No
	Social concerns: acceptability, equity, ethic		No
	Supply problems		No
You can add specific comments about this vaccine			The Committee examined the VZV vaccine for the first time in 2006 and did not recommend it for a vaccination program due to : -the availability of a vaccine frozen presentation only; -the lack of evidence of duration of protection, - the lack of correlate of protection and regarding the potential risk that vaccination could delay the occurrence of zoster infection at older age.

Herpes Zoster Vaccine

Shingrix	Year of introduction into the official immunization schedule		Not available yet
Recommendation	Target population: specify		
	NITAG published a document with the recommendation		
	Significant burden of disease		
	Specific concerns about SAE		
	Costs of vaccination were discussed		
	Costs of benefits of vaccination were discussed		
	Results for mathematical modelling or cost-effectiveness modelling: (country-specific)		

	Level of Grade recommendation if used		
Contextual concerns	Political priority		
	There were positive pressures from the medical professionals		
	There were negative pressures from the medical professionals.		
	There were pressures from the pharmaceutical industry		
	Social concerns: acceptability, equity, ethic		
	Supply problems		
You can add specific comments about this vaccine			The Committee planned to review this vaccine and update the vaccination program in 2020 but in the context of Covid-19, the workplan has been modified and this assessment had to be delayed. Furthermore, GSK did not yet consider the availability of the vaccine in France.

COVID-19 Vaccine

Recommendation	Pfizer BioNTech COVID-19	Yes	Yes
	Vaccination Start date	27/12/2020	25/12/2020
	Moderna COVID-19 vaccine	Yes	Yes
	Vaccination Start date	12/1/2021	9/1/2021
	AstraZeneca's COVID-19 vaccine	Yes	Yes
	Vaccination Start date	6/2/2021	5/2/2021
	Janssen's (Johnson&Johnson) COVID-19 vaccine	No	No (but pending)
	Vaccination Start date		
	Novavax's COVID-19 vaccine	No	No
	Vaccination Start date		
	Curevac COVID-19 vaccine	No	No

	Vaccination Start date		
	Others		
Has NITAG produced a document on possible priority groups?		Yes	Yes on 30th November (list below) and updated on 3rd march
If yes, please indicate the first eight groups selected		1. Residents and staff in centers for the elderly and care for large dependent people.	1. Phase 1 residential care homes for older adults: Nursing home and long term services residents
		2. First-line health and social-health personnel.	2. Phase 1: Health care professionals in nursing home at high risk (>65 yo or with underling medical conditions
		3. Other health and social health personnel.	3. Phase 2: People older than 75 y.o.
		4. Large non-institutionalized dependent people.	4. Phase 2: Heath and social care workers older then 50 y.o.
		5. People >80	5. Phase 2: all those 65 years of age and over with underlying conditions
		6. Other health and social health personnel <56 (Astra Zeneca)	6. Phase 3: all those 50 years of age and over or all people with underlying conditions
		7. Workers with an essential social function <56 (Astra Zeneca)	7. Phase 3: all heath and social care workers

	8. People between 70-79	8. Phase 3: all essential workers
NITAG published a document with the recommendation on pregnant women	No	Yes
Specific concerns about distribution and transport condition	Yes	No
NITAG published a document with pharmacovigilance items	Yes	No
Costs of vaccination were discussed	No	No
Costs of benefits of vaccination were discussed	Yes	No
There were positive pressures from the medical professionals	Yes	Yes
There were negative pressures from the medical professionals.	Yes	Yes
There were pressures from the pharmaceutical industry	No	No
Social concerns: acceptability, equity, ethic	Yes	Yes
Concerns about cultural differences between clinical trials population and citizen	No	No
Supply vaccine problems	Yes	Yes
There were positive pressures from the medical professionals	Yes	

You can add specific comments about this vaccine	The committee is working with high constraints of delay responses and with significant Political pressure due to the Covid-19 vaccination program priority The Committee also produces specific recommendation on the vaccination for people already infected by the Covid-19, on the need to delay the second dose whatever the vaccine to fasten the vaccination program and the vaccine rule-out, on the vaccination for people living in area with high level of VOC circulation

III. Draft plan for extended study

The Spanish team (UB and UA) and the MoH-FR team has held meetings to discuss the modifications made in the final survey that is presented below:

- In May 2021, a videoconference was organized between the UB, UA and MoH-FR to discuss the new version of the questionnaire and the methodology of the extended study. The final survey is presented below:
- The launch of the extended study was planned to be distributed to 22 countries on 21 June 2021. NITAG members have been asked to submit their responses by July 20 2021.
- The survey is planned to be resubmitted in the first week of September 2021 to NITAG members who have not responded.

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Inserm

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