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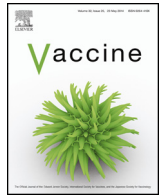
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Comparison of NITAG policies and working processes in selected developed countries



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ABSTRACT

Background: Vaccines are specific medicines characterized by two country-specific market access processes: (1) a recommendation by National Immunization Technical Advisory Group (NITAG), and (2) a funding policy decision.

Objectives: The objective of this study was to compare and analyze NITAGs of 13 developed countries by describing vaccination committees' bodies and working processes.

Methods: Information about NITAGs bodies and working processes was searched from official sources from June 2011 to November 2012. Retrieved information was completed from relevant articles identified through a systematic literature review and by information provided by direct contact with NITAGs or parent organizations. An expert panel was also conducted to discuss, validate, and provide additional input on obtained results.

Results: While complete information, defined as 100%, was retrieved only for the UK, at least 80% of data was retrieved for 9 countries out of the 13 selected countries. Terms of references were identified in 7 countries, and the main mission for all NITAGs was to provide advice for National immunization programs. However, these terms of references did not fully encompass all the actual missions of the NITAGs. Decision analysis frameworks were identified for 10 out of the 13, and all NITAGs considered at least four criteria for decision-making: disease burden, efficacy/effectiveness, safety and cost-effectiveness. Advices were published by most NITAGs, but few NITAGs published meeting agendas and minutes. Only the United States had open meetings.

Conclusions: This study supports previous findings about the disparities in NITAGs processes which could potentially explain the disparity in access to vaccinations and immunization programs across Europe. With NITAGs recommendations being used by policy decision makers for implementation and funding of vaccine programs, guidances should be well-informed and transparent to ensure National Immunization Programs' (NIP) credibility among the public and health care professionals.

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1. Introduction

Vaccines follow country-specific market access paths that differ from traditional registration processes. Vaccines' market

access processes are characterized first by the development of recommendations, and are followed by the executive policy-decision, which includes funding and which is usually based on the recommendations.

Expert committees, referred as National Immunization Technical Advisory Group (NITAG), are in charge of developing recommendations that are ultimately used by policy-makers to make evidence-based decisions on immunization-related policies

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and programs, such as the inclusion of the new vaccine in the national immunization program (NIP) [1].

NITAGs are country-specific, thus varying greatly from one country to another. Indeed, Lopalco et al. concluded in their study that NITAGs' policy, including analysis framework and decisions processes, were heterogeneous across European Union (EU) member states [2]. Piso et al. performed a Delphi panel of 14 immunization experts and drew similar conclusions about the heterogeneity of decision-making criteria and processes within European NITAGs [3].

Immunization policy development processes were also studied by Bryson et al. who presented the results of a global survey performed in 2008 with the World Health Organization (WHO) [4]. Duclos et al. performed an update of the same global survey, reporting impressive progress in NITAGs establishment and performance and proposing general guidelines for the NITAGs [5,6]. More recently, a collaborative project, Vaccine European New Integrated Collaboration Effort II (VENICE II), involving 29 EU countries, was implemented to collect and share information on immunization programs through a network of professionals to improve the overall performance of the immunization systems [7].

While Duclos and Piso's work provided valuable input on NITAGs processes, there is still need for up-to-date information about NITAGs' policies and recommendations in developed countries. Indeed, understanding vaccination recommendation processes is crucial for health policy decision makers, public health specialists, and civil society. Furthermore, a comparison between several NITAGs would allow the identification of both good practices and shortcomings, and thus pinpoint areas in need of improvement. Therefore, the objective of this study was to compare and analyze NITAGs of a selected number of developed countries by describing vaccination committees' bodies and working processes. The comparison aimed to cover all aspects of NITAGs' policy such as reporting, terms of reference, composition, meeting organization, decision analysis framework, and communication.

2. Methodology

The study was conducted from June 2011 to November 2012 in 13 countries: Australia, Belgium, Canada, France, Germany, Hungary, Italy, the Netherlands, Spain, Sweden, Switzerland, the United Kingdom (UK) and the United States (US). Specific European countries were selected to provide a reasonable representation of developed countries and to reflect a variety of health care organizations and funding mechanisms. Three non-European countries, Australia, Canada, and the US, were selected because of their long history of NITAG practice and the quality and transparency of their decision processes [4,6].

2.1. Data extraction

Twenty-five relevant items, based on Duclos et al. work, were selected to compare NITAGs' processes in the selected countries. Piso et al. article was used to establish a list of relevant criteria used for analytical framework [6,8] (Table 1). Data was extracted from the following three types of sources:

- Source 1: Official sources defined as NITAGs' websites, or when unavailable, those of the relevant parent organizations plus NITAG resource center [9].
- Source 2: Articles identified through a systematic literature review that was performed using the same search strategy and databases (OVID Medline and Global Health) as Bryson et al. [4] (Appendix 1). An additional, *ad-hoc* search was also performed for relevant article on the International Society for

Table 1
List of data searched for each NITAG.

List of 25 relevant items searched for each selected country's NITAG
Name of the NITAG
NITAG's website/official source
Role/missions of NITAG stated on the website/official source
Name of NITAG's parent organization
Identification of the stakeholders (non-core members) involved in NITAG's meetings
Role of the stakeholders involved during the meetings
Number of NITAG's core members
Name of NITAG's core members
Profile composition of NITAG's core members
Are the core members full time employees of the NITAG?
Selection process of chairman/other core members
Duration of appointment for core members
Are the core members remunerated?
Do core members declare conflicts of interest?
Number of NITAG's meetings per year
Length of NITAG's meetings
Do subcommittees exist within the NITAG?
Are NITAG's meetings open to public?
Are the NITAG's meeting agendas published before the meetings?
Are the NITAG's meeting minutes published after the meetings?
Are the NITAG's recommendations published after the meetings?
Are the NITAG's recommendations published through evaluation reports?
What is the timeline to get the NITAG's recommendations publicly available?
Do the NITAG possess analytical frameworks for decision-making?
Criteria used for analytical framework

Pharmacoeconomics and Outcomes Research abstracts database and Google scholar.

- Source 3: Direct contact (primary research) with the NITAGs or their parent organizations via interviews or questionnaires.

Data were searched through hierarchically ordered sources (source 1, then 2 and last 3). The same information found in several sources was reported as retrieved from the first source.

2.2. Data validation and review by the immunization expert panel

Retrieved information was reviewed by an international immunization expert panel composed of 8 members from France, Germany, Hungary, Italy, Spain, the UK and the US. All experts were familiar with vaccine evaluation and NITAGs. There were four experts were current or former members of NITAGs, two public health specialists, two health economists, among which a patients' representative from European Patients Forum. The immunization expert panel was convened for a one-day meeting and provided complementary information and clarifications in order to validate the overall study findings and provided context and details surrounding various NITAG's processes.

2.3. Analysis

Retrieved information analysis was performed using usual descriptive statistics, *i.e.* proportions (Table 2).

3. Results

3.1. Source identification and data collection

Via official sources (Source 1), NITAGs' websites or parent organization websites were identified for all selected countries except Italy [10–21] (Table 2).

A total of 1658 articles were identified through the literature review, and 281 duplicates and 1352 articles were excluded through titles and abstracts review. Thus, 25 studies meeting the

Table 2
Overview of NITAG's official sources and of the proportion of information retrieved by source.

Name of NITAG	Official Sources ^{*,†}	Proportion of data retrieved by source				
		Secondary Research		Primary Research	Not found	
		Source 1 [‡]	Source 2 [‡]	Source 3 [‡]		
European Countries						
Belgium	Standing Working Group on Vaccination (<i>Groupe de travail permanent Vaccination-Permanente werkgroep Vaccinatie</i>)	www.health.belgium.be	40%	4%	40%	16%
France	Technical Vaccination Committee (<i>Comité technique des vaccinations</i> ; CTV)	www.hcsp.fr	46%	–	46%	8%
Germany	The German Standing Vaccination Committee (<i>Ständigen Impfkommision</i> ; STIKO)	www.rki.de	96%	–	–	4%
Hungary	National Center for Epidemiology Committee (<i>Országos Epidemiológiai Központ</i> ; OEK)	www.oek.hu	8%	4%	56%	32%
Italy	National Vaccines Commission (Nazionale Vaccini Commissione; CNV)	Not found [‡]	16%	4%	–	80%
The Netherlands	Committee on the National Vaccination Program (<i>Commissie Rijksvaccinatieprogramma</i> ; RVP)	www.gezondheidsraad.nl	32%	4%	52%	12%
Spain	Working Group on Vaccines (Ponencia del Programa y Registro de Vacunaciones <i>i.e.</i> Ponencia de Vacunas)	www.msps.es	44%	4%	–	52%
Sweden	National Board of Health and Welfare Expert Committees (<i>SocialStyrelsen</i>)	www.socialstyrelsen.se	16%	8%	56%	20%
Switzerland	The Federal Vaccination Commission (<i>Commission fédérale pour les vaccinations – Commissione federale per le vaccinazioni – Eidgenössische Kommission für Impffragen</i> ; CFV)	www.bag.admin.ch	44%	44%	–	12%
UK	The Joint Committee on Vaccination and Immunization (JCVI)	www.gov.uk/government/organisations/department-of-health	100%	–	–	0%
Non-European countries						
Australia	Australian Technical Advisory Group on Immunization (ATAGI)	www.health.gov.au	40%	36%	–	24%
Canada	The National Advisory Committee on Immunization (NACI)	www.phac-aspc.gc.ca/naci-ccni	32%	52%	–	16%
US [‡]	The Advisory Committee on Immunization Practices (ACIP)	www.cdc.gov	96%	–	–	4%

* Websites of NITAGs, or, when not available, those of the relevant parent organization.

† Other Source: NITAG Resource Center [9].

‡ Source 1: Websites of NITAGs or the relevant parent organization; Source 2: systematic literature review; Source 3: direct contact (primary research) with the NITAGs or their parent organizations.

§ No official website, however the National Plan of Vaccination (*Nazionale Prevenzione Vaccinale*) 2012–2014 was available [33].

¶ The National Board of Health and Welfare does not have a standing vaccine committee, as such 'vaccine committees' are founded on an ad-hoc basis, as per primary research.

‡ Smith et al article "The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP)" (Vaccine 2010; [30]) was available on CDC's website, thus considered as source 1.

inclusion criteria were used as a secondary source to supplement the information retrieved through official websites.

Finally, primary research information was obtained for Belgium, Hungary, the Netherlands and Sweden to complete information not available from Sources 1 and 2.

3.2. Overview of retrieved information

Complete information, defined as 100% (i.e. 25 items retrieved on 25), was retrieved only for the UK. The proportion of unfound data ranged from 0% in UK to 80% in Italy, and the level of retrieved information through the official sources was below 50% for 10 countries (Table 2).

3.3. NITAGs' mandate and actual missions

Terms of reference, defining the official mandate of the NITAG, were retrieved for a narrow majority of countries (7 countries out of 13; Table 3). Terms of reference were stated in official websites for Australia, Canada, Germany, Switzerland, and the UK [10,12,14,19,20], in a decree for France [22] and in the charter of Advisory Committee on Immunization Practices (ACIP) for the US [23]. NITAGs' functions were not confined solely to the terms of reference. Additional missions were identified, as specified in Table 3, through official sources such as the German Standing Vaccination Committee's (*Ständigen Impfkommision*; STIKO) Standard Operating Procedure [24], the Joint Committee on Vaccination and Immunization's (JCVI) code of Practice for the UK [25], and through literature review articles for France and Australia [26,27].

In sum, the main mission of all the selected NITAGs is to provide advice for NIP (Table 3). Other functions vary widely from one country to another, from conducting risk-benefit analysis for Germany STIKO's [24] and France's Technical Vaccination Committee (*Comité technique des vaccinations*; CTV) [22] to drawing recommendations for vaccines' research and development for Switzerland's The Federal Vaccination Commission (*Commission fédérale pour les vaccinations*; CFV) [19] and Canada's National Advisory Committee on Immunization (NACI) [28] (Table 3).

3.4. Parent organizations and reporting line

NITAGs' parent organizations are national health agencies, councils or ministries for most countries, such as the High Council for Public Health of France [13], the Superior Health Council of Belgium [11], National Authority for Public Health of Hungary (primary research), the Department of Health and Ageing of Australia [10], the Public Health Agency of Canada [12], the National Board of Health and Welfare of Sweden [18], the Federal Office of Public Health of Switzerland [19], the Health Council of the Netherlands [16], and the National Health System's Inter-territorial Council of Spain [29]. The Robert Koch Institute (RKI) provides all administrative support to the STIKO [14], and the ACIP hold its meetings at the Centers for Disease Control and Prevention (CDC) [21].

Even if parent organizations vary from one country to another, NITAGs' recommendations ultimately reached policy decision makers. Indeed, JCVI advises the Secretary of State for Health, Welsh Ministers but also the Scottish and Northern Irish ministers [20,25], the Australian Technical Advisory Group on Immunization (ATAGI) provides advices to the Minister for Health and Ageing [10], the NACI reports to the Chief Public Health Officer of Canada [12], the CFV advises the Federal Department of Home Affairs and the Federal Office of Public Health [19], the ACIP reports to the Secretary and the assistant Secretary for Health and the CDC Director [23] and STIKO recommendations are forwarded to the Health authorities and the office of the Federal Joint Committee after the RKI's decision [14].

Table 3
Mandates and actual roles and missions of NITAGs.

Roles and Mission	European countries							Non-European countries					
	BE* [11]	CH [19]	DE [14,24]	ES† [29]	FR [22,26]	HU	IT* [33]	NL† [16]	SE† [18]	UK [20,25]	AU [10,27]	CA [12,28]	US [21,23,30]
Recommendation for immunization schedule	✓	x	x	✓	x	*	✓	✓	x	x	x	x	x
Conducts risk-benefit analysis	✓	x	✓	✓	x	*	✓	✓	✓	x	x	x	x
Provide advices on vaccine implementation/scientific assessment	✓	x	✓	✓	x	*	✓	✓	✓	x	x	x	x
Recommendation for prevention of infectious diseases		x	✓	✓				✓	x	✓	x	x	✓
Horizon scanning (identifying vaccines likely to be licensed in the next 3–5 years)									x	✓			
Monitoring of the immunization program (Population coverage and follow-up)		x							✓				
Identify the need for further data	✓	x		✓				✓	✓	✓	✓	✓	✓
Inform the payer	✓	✓							✓	✓	x	x	✓
Prepare handbook		✓							✓	✓	x	x	✓
Recommend on R&D directions		x							✓	✓	✓	✓	✓

European countries: BE: Belgium, CH: Switzerland, FR: France, DE: Germany; HU: Hungary, IT: Italy, NL: the Netherlands, ES: Spain, SE: Sweden, UK: the United Kingdom.

Non-European countries: AU: Australia; CA: Canada, US: the United States.

x Mandates of NITAGs as per terms of reference.

✓ Actual role and missions of NITAGs as per secondary research.

* Mandates of NITAGs as per primary research.

† No term of reference retrieved.

‡ JCVI advice and recommendations inform revisions to the Green Book [25].

Table 4
Composition of NITAGS and members' profile.

	Members		Core members' Profiles	
	Core members [†]	Stakeholders	Composition	Snapshot of 2011 Committee [‡]
European countries				
Belgium	29 [†]	3 [‡]	Members are affiliated to a Belgian University and are selected based on their experience and knowledge in the field of vaccines	n/a
France	17 [22]	9 [22]	Specialists in infectious disease; pediatricians; microbiologists; specialists in epidemiology and public health; general practitioners; immunologist; geriatrician; gynecologist-obstetrician/midwife; internist; workplace physician; health economist; sociologist [22]	8 MD [§] 4 Public health specialists [¶] 3 Biologists [¶] 1 Health economist [¶] 1 sociologist [22]
Germany	12–18 [14]	n/a [¶]	Experts from different scientific disciplines of science and in the field of public health as well as medical professionals, who have extensive, practical experience on vaccination [14]	8 MD [§] 5 Public health specialists [¶] 4 Biologists [14]
Hungary	12 [†]	0 [‡]	Members are OEK employees who are experts in infectiology and virology	n/a
Italy	24 [†]	0 [‡]	n/a	n/a
The Netherlands	13 [†]	3 [‡]	Members have different backgrounds such as: pediatricians, immunologists, epidemiologists, Health-economists, microbiologist, public health physicians, general practitioner, internal medicine, virologists, occupational health physician, ethicist	n/a
Spain	19 [†]	5 [‡]	n/a	n/a
Sweden [¶]	0 [‡]	18 [‡]	Employees from the National Board of Health and Welfare, expert from outside the board as well as relevant people from other public agencies	n/a
Switzerland	16 [31]	4 [‡]	All Members are from the medical field and have expertise in all areas of immunization. Members are chosen for their expertise and taking into account a balanced gender distribution and regions [19]	7 MD [§] 7 Public health specialists [¶] 2 Biologists [31]
UK [#]	18 [20]	n/a	Membership is determined on suitability for the role. Members bring relevant knowledge, skills and experience to the committee [25]	8 MD [§] 4 Public health specialists [¶] 2 Biologists [¶] 1 Health economist [¶] 2 Nurses [¶] 1 Ethicist [20]
Non-European countries				
Australia	11 [10]	n/a	Technical experts, general practitioners and a consumer [10]	6 MD [§] 2 Public health specialists [¶] 1 Biologists [¶] 1 Nurse [¶] 1 Consumer representative [¶] [10]
Canada	13 (in general 12) [12]	17 ^{**} [12]	Recognized experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine, nursing, pharmacy and public health [28]	n/a
US	14 [21]	34 ^{**} [30]	Experts in infectious diseases, pediatrics, internal medicine, family medicine, virology, immunology, public health, preventive medicine, vaccine research and policy, economics and cost-effectiveness, plus a consumer representative [30]	12 MD [§] 1 Public Health Expert [¶] 1 Consumer representative [21]

^{*} Voting members except for Hungary and Spain as the Spanish committee decides by consensus [3], and voting is not applicable for the Hungarian committee as it is a decision-support body (primary research).

[†] Nearest year.

[‡] Data retrieved from Immunization Advisory Committees (2008) [3].

[¶] In Germany representatives of the RKI, the Ministry of Health, the Federal States, the national regulatory authority (Paul-Ehrlich-Institute), the Federal Centre for Health Education, the Joint Federal Committee, the Ministry of Foreign Affairs, and the Federal Armed Forces participate in the meetings without voting right [14].

[¶] The National Board of Health and Welfare in Sweden does not operate with a vaccine committee as such. 'Vaccine committees' are not fixed group/committees, but committees are founded on an ad-hoc basis (according to disease focus, e.g. HPV, hepatitis etc.).

[§] As per primary research.

[#] The Committee consists of such number of members as the Secretary of State for Health and Welsh Ministers determine. Observers from the UK Governments/Administrations (i.e. officials from the Devolved Administrations) attend JCVI meetings and receive committee papers. Scottish and Northern Ireland observers may as well attend.

^{**} 10 liaison members and 7 *ex officio*.

^{**} 26 liaison members and 8 *ex officio*.

3.5. NITAGs' profile of members

Most committees were composed of core members, defined as voting members, except for Spain and Hungary, and stakeholders which can be either *ex officio* or liaison members (Table 4). The total number of NITAGs' members varied greatly from one country to another and ranged from 48 in the US to 12 in Hungary. All

NITAGs, with the exception of Australia and Hungary, had more than 15 members in 2011 and 6 NITAGs out of 13 had more than 20 members (Table 4).

The number and function of members were clearly defined only for the ACIP and the CTV. Indeed, ACIP exact composition was defined in official sources [21], with the committee having to be composed of 15 voting members, 8 *ex officio* members (defined

as representing other federal agencies with responsibility for immunization programs) and 26 liaison members (defined as representatives of liaison organizations). For France, the CTV decree fixed the number and profiles of voting members [22]. However, NITAGs' compositions and members' profiles were not as clearly defined in the other NITAGs. Core members' profiles differed from one NITAG to another and could even differ from one mandate to another for the same NITAG due to a lack of requirements for members' profiles (Table 4). For example, STIKO core members' number could vary between 12 and 18, with members defined roughly as experts from different disciplines such as science, public health, medical science with extensive and practical experience of vaccinations [14]. However, even though NITAGs' composition differed greatly, medical doctors represented the highest proportion of member specialists in 2011, followed by public health specialists, and biologists (Table 4).

Sub-committees, also called working groups, aiming to review available data on specific topics on vaccine and develop backgrounds for development of recommendations, were identified in all selected countries except Hungary, Italy, the Netherlands, Spain and Sweden [11,24–28,30,31]. Sub-committees could be composed by committee members and experts outside the NITAGs' members and may or may not be permanent [25,30].

3.6. NITAGs' appointment process

Committee members are appointed by representatives of Health Ministries or agencies for 6 NITAGs (Australia, Canada, France, Germany, Sweden and the US) [14,22,23,27,28]. In the UK, while the power to appoint JCVI members is held by Welsh Ministers and the Secretary of State for Health, the latter has delegated his appointment functions to the Appointments Commission which makes appointments on merit, usually after advertising each vacancy and specifying the qualities required [25]. Committee members are appointed by the department of home affairs in Switzerland [19] and by the chairman of the Health Council in the Netherlands.

Duration of members' appointment was 4 years in Australia, Canada, France, Switzerland, the Netherlands, the UK and the US [19,22,23,25,27,28] and 3 years in Germany [14]. There is no fixed duration of appointment for committee members in Sweden, and mandated duration was not specified for Hungary (primary research). Data was not available for Belgium, Spain and Italy.

Core members are remunerated in Australia, Belgium, the Netherlands and the US [21,23,32] but not in France, Germany, Sweden, Switzerland, and the UK [14,24–26]. Committee members declare conflict of interest in the majority of the selected countries: Australia, Belgium, Canada, France, Germany, the Netherlands, Sweden, Switzerland, the UK, and the US [13,14,19–21,27,28]. Usually, the declarations are available on NITAGs webpages [13,19–21]. Conflict of interest declarations are not required in Hungary (primary research), and data were not available for Italy and Spain.

3.7. Recommendation-making: Decision analysis framework and meeting process

Germany and the US use a detailed and standardized methodology for reliable, robust and reproducible assessments: the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) [14,21,24,30]. Canada, Italy, Spain and Switzerland's Committees do not use tools as robust and reliable as GRADE but list clearly their decision-making criteria [29,33–35] (Table 5). France, Sweden and the UK state some of the decision-making criteria without defining a clear decision analysis framework [18,25,26]

Table 5
Decision-making criteria in analytical framework of the selected countries NITAGs.

Decision-making criteria	European Countries*						Non-European countries*			
	CH [19,35]	DE [14,24]	ES [29]	FR [26]	IT [33]	NL [16]	SE [18]	UK [20,25]	CA [34]	US [21,23,30]
Disease burden	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Efficacy and effectiveness	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Safety	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Feasibility of program implementation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cost-effectiveness evaluation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clinical trial results	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Equity in access to the vaccine	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Recommendations of other liaison organizations	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

European countries: CH: Switzerland, FR: France, DE: Germany, IT: Italy, NL: the Netherlands, ES: Spain, SE: Sweden, UK: the United Kingdom.

Non-European countries: CA: Canada, US: the United States.

* Belgium and Hungary's NITAG do not possess analytical frameworks for decision-making as per primary research.

+ Australia decision-making criteria were not retrieved as per secondary research.

Table 6

Access to information related to NITAG activities.

	Meetings open to public	Published meeting agenda	Published meeting minutes	Published NITAG advices	Published evaluation reports
Yes	US [21]	UK [20,25]; US [21]	AU [10]; UK [20]; US [21]	AU [27]; BE [11]; CA [28]; CH [31]; DE [24]; ES [17]; FR [26]; HU [*] ; NL [*] ; SE [*] ; UK [25]; US [21,30]	AU [27]; BE [11]; CA [28]; CH [31]; DE [24]; ES [17]; FR [26]; HU [*] ; NL [16]; UK [25]; US [30]
No	BE [*] ; CA [28]; CH [31]; DE [24]; FR [26]; HU [*] ; NL [*] ; SE [*] ; UK [25]	AU [10]; BE [*] ; CA [12]; DE [24]; FR [26]; HU [*] ; NL [*] ; SE [*]	BE [*] ; CA [28]; CH [31]; DE [24]; FR [26]; HU [*] ; NL [*] ; SE [*]		
Not found	IT; ES; AU	CH; IT; ES;	ES; IT	IT	SE; IT

AU: Australia, BE: Belgium, CA: Canada, CH: Switzerland, FR: France, DE: Germany; HU: Hungary, IT: Italy, NL: the Netherlands, ES: Spain, SE: Sweden, UK: the United Kingdom, US: the United States.

* As per primary research.

(Table 5). Decision-making criteria were not found for Australia, Belgium and Hungary, and official NITAGs' time to advice after regulatory approval was not retrieved for all selected countries.

Advices are publicly available in all selected countries except Italy, where only the national plan of immunization was retrieved [11,24–28,30,31] (Table 6). Only Australia, the UK, and the US published meeting minutes [10,20,21], and meetings were open to public only in the US [21] (Table 6).

3.8. Comments and outcomes of the expert panel

Experts validated the findings of the research and acknowledged that vaccines needed a country-specific and distinct decision-making paths compared to other drugs. The panel provided detailed perspectives on Spain and Italy. Specifically, experts pinpointed that, public health decision-making is decentralized in the two countries. Thus, vaccine assessment and recommendation are handled mainly at regional level, making it difficult to retrieve information at the national level.

Experts highlighted the fact that decision-making processes for vaccines were not always as structured and transparent as processes for other medicines, thus leaving room for higher political influence. The panel underlined the importance of vaccines from a public health perspective and regretted the scarcity of public information about NITAGs and their processes. Indeed experts' broad opinion is that NITAG appraisals should be better reported to the general public and the overall information about vaccines should be enhanced. There is a need to provide more information to the public and health councils on reasons for no recommendation (e.g. lack of data, lack of budget, etc.) in order not to jeopardize trust in vaccines.

Finally, experts' opinion was that NITAGs' recommendations should not only be restricted to vaccine of the NIP, fully funded by the public health system, but also concern other vaccines, thereby allowing individuals' access to vaccines with partial or full out-of-pocket payment, as in Switzerland.

4. Discussion

The aim of this project was to compare and analyze NITAG bodies and working processes of 13 developed countries. This comparison aimed to cover all aspects of NITAGs' policies. However, a number of limitations should be considered when interpreting the results of the study due to the lack of data. Indeed, complete information was not always retrieved despite using three sources, and few NITAG specific publications were available. Furthermore, no direct contact could be established for Italy and Spain, for which with amount of available information via official sources and

articles was quite low, leaving a gap in retrieved data. And finally, the study was limited to the formalized process, either published in literature or websites, which, not being systematically updated, might not reflect the actual NITAG's functioning.

Over 80% of the information was retrieved for 9 out of 13 countries, allowing for a robust analysis of the data (Table 2). The level of publicly available information varied highly from one country to another. Data about NITAGs' body and processes was clear and readily available for a few countries, such as Germany, the UK and the US and scarce and incomplete for several other countries such as Hungary, Spain and Italy (Table 2).

None of the selected NITAGs covered the recommended mandate as defined by Duclos et al. [6] (Table 3), and the terms of reference did not cover all actual roles of NITAGs, suggesting that terms of references needed to be updated and new functions of NITAGs fully acknowledged.

Committee members' number and profiles were not clearly stated in most countries, with committees' body varying between countries and years. Only 6 NITAGs had between 10 and 16 core members as recommended by Duclos et al. [6]. The number of core members exceeded 16 in 6 countries, suggesting the need for a very accurate and effective decision analysis framework to ensure a good process with reliable and reproducible recommendations (Table 4). And while Duclos et al. [6] recommended that members be remunerated in order to avoid them giving low priority to their NITAG roles, only 4 NITAGs remunerated their members.

Decision analysis frameworks were only available in 10 out of the 13 selected countries (Table 5). These frameworks using decision criteria are critical for a transparent, structured, reproducible and reliable decision-making [8], as they help increase trustworthiness in introducing new vaccines in the NIP, as well as in promoting public confidence [36]. Lack of standardization in vaccine evaluation was identified as cause of heterogeneity and inequity of immunization programs [34]. Nevertheless, the use of efficient decision-making tools, such as GRADE, has been developing and is expected to expand to more countries in the coming years.

This study also illustrated the very restricted access to important information such as agenda, meeting minutes and full reports. With NITAGs recommendations being ultimately used by policy decision makers for implementation and funding of NIPs, guidances should be well-informed and transparent. Moreover, open data and solid decision-making process are critical for NIP's reliability among the public and health care professionals. Indeed, while lack of access to decision-making processes can have a negative impact on the vaccination's perceived value, understanding of vaccination recommendations, implementation and funding processes, may reduce time-to-access for new vaccines [37].

Finally, although the specific characteristics of vaccines need to be acknowledged in determining the evaluation process, the decision processes would benefit from studying the progress of HTA agencies in general over the last 10 years, especially relating to the analytical decision framework, the time to issuing advice, and the practice of publishing appraisals.

5. Conclusion

This study supports previous findings about the heterogeneity of NITAGs processes, potentially explain the disparity in access to vaccinations and immunization programs across Europe [37,38]. Clearly defined terms of reference that reflect the roles and missions, structured decision analysis framework for the evaluation of the vaccines, together with initiatives such as the VENICE II project [7] that provide access to information and reports, are therefore needed to support the development of best practices among the NITAGs and enhance reliability of NIP.

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Declaration of financial/other relationships

Catherine Weil-Olivier has participated to conferences, meetings and received honoraria from the following companies: Baxter, GSK, Novartis, Pfizer, and SP, SP-MSD. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Dr. Poland is the chair of a Safety Evaluation Committee for novel investigational vaccine trials being conducted by Merck Research Laboratories. Dr. Poland offers consultative advice on vaccine development to Merck & Co. Inc., CSL Biotherapies, Avianax, Sanofi Pasteur, Dynavax, Novartis Vaccines and Therapeutics, PAXVAX Inc, and Emergent Biosolutions. Dr. Poland holds two patents related to vaccinia peptide research. These activities have been reviewed by the Mayo Clinic Conflict of Interest Review Board and are conducted in compliance with Mayo Clinic Conflict of Interest policies. This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and was conducted in compliance with Mayo Clinic Conflict of Interest policies.

Michael Drummond, Professor of Health Economics, Centre for Health Economics, University of York, has undertaken consulting projects for pharmaceutical companies, including companies manufacturing vaccines.

Mondher Toumi, Professor of Decision Sciences at the University of Lyon 1, has undertaken consulting projects for pharmaceutical companies, including companies manufacturing vaccines.

York Zöllner, Professor of Health Economics, Dept. of Health Sciences, Hamburg University of Applied Sciences, has undertaken consulting projects for pharmaceutical companies, including companies manufacturing vaccines.

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Appendix A. Appendix 1 Research strategy

OID Medline

#1 (((immunii* or vacciti* or inoculat*) in ti,ab) or ((explode "Immunization-"/all

SUBHEADINGS in MIME,MJME,PT) or (explode "Vaccines-"/all

SUBHEADINGS in MIME,MJME,PT) or (explode

"Immunization-Programs"/all SUBHEADINGS in MIME,MJME,PT)))

#2 (((mak* or responsib* or autori*) near3 (policy or policies or decision*)) in ti,ab) or ((explode "Decision-Making"/all SUBHEADINGS in MIME,MJME,PT) or ("Policy-Making"/WITHOUT SUBHEADINGS in MIME,MJME,PT)))

#1 and #2

Global Health

1) TI mak* N3 polic* or TI responsib* \3 polic* or AB mak* N3 polic* or AB responsib* N3 polic*

2) TI mak* N3 decision or TI responsib* N3 decision or AB mak* N3 decision or AB responsib* N3 decision

3) TI immuni* or AB iimmun* or TI vaccin* or AB vaccin* or TI inoculat* and AB inoculat*

4) TI autori* N3 polic* or TI autori* N3 decision or AB autori* N3 decision or AB autori* \3 polic*

5) decision making or policy making

6) 1 or 2 or 4 or 5

7) 6 & 3

Conflict of interest statement

The other authors do not have any conflict of interest or financial interest.

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