



# A systematic review of national immunization policy making processes<sup>☆</sup>

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## ABSTRACT

This systematic review aimed to collect and synthesize information available on immunization policy making processes in countries across the globe. Twenty-nine published articles and five websites in either English or French provided varied information on the immunization policy making processes in 33 countries. The information retrieved varied from players involved to types of evidence used when making immunization policies. Fourteen countries reported the presence of a National Immunization Technical Advisory Group (NITAG), an advisory body that provides immunization recommendations to the national government to facilitate their policy making. In conclusion, there is relatively limited information available on immunization policy making processes at the national level.

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## 1. Introduction

Although virtually all countries have a National Immunization Program of some kind, the processes leading to decisions on which vaccines to include are not well described. Yet it is important to understand how vaccine policies are developed given the amount of money spent on vaccines, the increased prices of newer vaccines, the fact that vaccines guard against some of the most deadly diseases, and that they are among the most effective of public health interventions. To facilitate the immunization policy making process, some countries have established national technical advisory bodies, often referred to as National Immunization Technical Advisory Groups (NITAGs). These are ideally independent, expert advisory committees that provide technical advice on vaccines and immunizations and make recommendations to guide policy makers and program managers [1]. As information on the presence, characteristics and functioning of these groups appeared limited, we conducted a systematic review of all information available on immunization policy making processes at the national level, including the presence and characteristics of NITAGs.

**Abbreviations:** NITAG, National Immunization Technical Advisory Groups; UK, United Kingdom; USA, United States of America; WHO, World Health Organization.

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## 2. Methods

### 2.1. Eligibility criteria

Publications, reports and government websites were eligible for inclusion in this review if they contained a description of the process of immunization policy making at a national level. Countries were defined as member states of the World Health Organization (WHO) for the purpose of this article [2]. Because the primary author (MB) has working knowledge of English and French, publications, reports and websites in these languages were eligible for inclusion. Additional eligibility criteria included:

1. Description of immunization policy making processes including players and/or factors involved.
2. The processes described must be that of the national level of a specified country.

### 2.2. Search strategy

The search strategy was developed in the database Medline using the OVID platform and adapted to another database, Global Health. The search strategies combined a search for immunization or vaccination as well as a search for policy making or decision making in Medline (1950–April Week 2, 2008) and Global Health (formerly CAB Health) (1973–April 19, 2008) (Fig. 1). The search strategies were not restricted by language or date.

The secondary references of eligible studies were screened to determine if any of the references could potentially be included in the review.

OVID Medline

#1 (((immuni\* or vaccin\* 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\* N3 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 immuni\* 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\* N3 polic\*

5) decision making or policy making

6) 1 or 2 or 4 or 5

7) 6 & 3

Fig. 1. Search strategies.

The search for grey literature was limited to the search of government websites and contact with experts. Experts who had recently worked in the topic area with the WHO headquarters were asked if they knew of any publications or reports on the topic that were not retrieved through the literature search.

The government websites of the 193 member states of the WHO were searched for information on the immunization policy development processes of the countries. When possible, government websites were accessed using a list of national government websites created by the University of Michigan [3]. When the country was not listed on this website, government websites were searched for using the Google search engine with the key words of "government" and "official" and the name of the country [4]. Once the government official website was accessed, the information on immunization policy development processes was sought by navigating through Ministry of Health or Public Health websites and other relevant pages such as that of immunizations and vaccines. The search of websites was also restricted to those in English or French.

### 2.3. Selection of publications

All titles and abstracts (when available) of the citations identified were screened by two reviewers independently. All records that were identified as potentially relevant were obtained in full text. If there was disagreement between the reviewers as to which citations qualified for inclusion, the citation was included and the full text was obtained. The full text articles were screened by the two reviewers independently in accordance with the inclusion criteria.

### 2.4. Quality assessment

Because this systematic review was descriptive in nature and did not include clinical trials or qualitative research, the quality

assessment of reports did not include the traditional components used to assess the quality of intervention or qualitative studies. The author's affiliation and the sponsorship of the article was used as an indication of potential conflict of interest, as well as the date of publication as an indication of the extent that the information may be dated.

## 3. Results

### 3.1. Selection of published information

The literature search yielded 1530 potential publications for inclusion in this review. Ovid Medline yielded 1213 of the citations and Global Health another 317. Of the citations, 128 papers (94 from Medline and 34 from Global Health) were retrieved as potential candidates for inclusion based on their titles and abstracts. After review of the full papers, only 26 publications contained descriptions of immunization policy making processes at a national level. Eight of the publications were retrieved from both Medline and Global Health [5–12], while another 14 publications were retrieved from Medline only [13–26], and another four from Global Health only [27–30].

Beyond the 26 publications obtained through the literature search, 3 additional publications were included: one from reference sections of the included papers [31], one was provided through contact with an expert in the area [32], and one from the Canadian website on their NITAG. It is unknown why these publications were not obtained through the search strategy.

The websites of five of the countries provided information on national immunization policy development: Australia [33], Canada [34], New Zealand [35], the United Kingdom (UK) [36], and the United States of America (USA) [37]. Therefore, this review is based on the content of 29 publications and 5 websites.

**Table 1**  
 Characteristics of policy processes and National Immunization Technical Advisory Group (NITAG) by country with information available on immunization policy development<sup>a</sup>.

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 <sup>b</sup>
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	

<sup>a</sup> 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.

<sup>b</sup> Unknown if these groups are NITAGs as defined in this paper.

### 3.2. Characteristics of included publications

The 29 publications and 5 websites from which information was abstracted contained information to varying degrees on immunization policy decision making processes in 33 of the 193 WHO member states: Argentina [19], Australia [10,13,23,33], Austria [20,32], Belgium [20], Brazil [5], Bulgaria [20], Cambodia [8], Canada [10,14,31,34,38], China [27], Denmark [15,20], Finland [20], France [17,20,32], Germany [20,32], Greece [20], Iceland [20], Ireland [17,32], Italy [20,32], Luxembourg [20], Mali [9], New Zealand [6,30,35], Norway [12,20], Papua New Guinea [28], Poland [20], Portugal [10,20], Slovakia [20], Slovenia [20], Spain [17,20,32], Sweden [17,20,32], Switzerland [10,17,32], Thailand [7], The Netherlands [10,11,14,20,32], the UK [17,20,24,26,32,36], and the USA [16,18,21,22,25,26,29,37]. The most detailed information was found in publications concerning immunization policy making processes in the UK [24] and the USA [25] as well as on the websites of Australia [33], Canada [34], the UK [36], and the USA [37].

Two publications focused primarily on the process of immunization policy making within a country (the UK and the USA) and discussed a NITAG in detail [24,25]. Fourteen of the publications mentioned NITAGs in the context of discussing a specific issue such as a specific vaccine but did not offer much information on the NITAG [5,6,10,13,14,18,19,21–23,26,29–31]. The five websites provided extensive information on the NITAGs in Australia [33], Canada [34], New Zealand [35], the UK [36], and the USA [37].

### 3.3. Quality assessment

All authors stated affiliations which were consistent with vaccine policy stakeholders. These included members of the Ministry of Health or local universities and often both. Only two of the publications in this review were sponsored by pharmaceutical companies [6,12]. A publication from New Zealand was a collaboration between the national government, Chiron Vaccines, and the University of Auckland but provided only the fact that a NITAG exists [6]. A study from Norway was sponsored by Wyeth Lederle [12], but focused on a cost effectiveness analysis of the 7-valent pneumococcal conjugate vaccine. It is unlikely that the sponsorship of either of these papers affected the quality of the publication with respect to this review.

### 3.4. National policy development processes

Information was retrieved on the immunization decision making processes in 33 countries (Table 1). Belgium [20], Bulgaria [20], Cambodia [8], Denmark [15,20], Greece [20], Luxembourg [20], Norway [20], Papua New Guinea [28], Portugal [10], Slovakia [20], Slovenia [20], and Sweden [17,32] reported groups which make immunization recommendations to the government. However it was unclear from the information collected if these groups were NITAGs that are independent from the national government as defined by the WHO [1]. Cambodia has a national level immunization technical working group that identifies, implements, and monitors National Immunization Programs in Cambodia [8]. However, the members listed are government officials and representatives of international donors. In Papua New Guinea, the National Pediatric Society makes recommendations and publishes guidelines that serve as standards of care by the Health Department [28]. Denmark has a National Board of Health [15,20], Portugal has the National Vaccination Plan committee [10] and Sweden has a governmental advisory agency [15,32] that make national immunization recommendations. The National Board of Health in Denmark conducts a medical technology assessment [15] and mathematical modeling [20] when making immunization policy decisions. This board considers various types of evidence (Table 2).

**Table 2**

Factors considered by countries when making recommendations by presence of National Immunization Technical Advisory Groups reported<sup>a</sup>.

Factors considered when making recommendations	Countries with NITAG	Other countries
Burden of disease	Canada [31,34] Netherlands [14,32] Spain [32] USA [37]	Argentina [19] China [27] Denmark [20] Finland [20] Iceland [20] Mali [9] Portugal [20] Poland [20] Sweden [20,32]
Economic evaluation	Canada [10,34] Netherlands [10,11,32] Switzerland [32] UK [24,36] USA [37]	Argentina [19] China [27] Denmark [20] Finland [20] Iceland [20] Luxembourg [20] Norway [12] Portugal [20] Sweden [20]
Feasibility of local vaccine production		China [27]
Feasibility of recommendation	Canada [31]	Argentina [19]
Recommendations of other countries	Brazil [5]  Canada [34] Switzerland [32] UK [37]	
Public perception		Argentina [19] Denmark [20]
Vaccine safety	Canada [14] Spain [32] USA [37]	Argentina [19]
Vaccine effectiveness	Canada [14] Spain [32] USA [37]	Argentina [19]

<sup>a</sup> Additional factors may be considered in process. This table presents factors specifically reported.

The advisory committee in Norway also uses mathematical modeling when making immunization policy decisions [20]. In the USA, although they have the Advisory Committee on Immunization Practices (which is an independent NITAG), they also have the American Academy of Pediatrics [22,29], the American Academy of Family Physicians [20,22], the American College of Gynecologists and Obstetricians [25], and the American College of Physicians [25] all of whom make immunization recommendations. Efforts are made to harmonize recommendations between these groups [25].

The information retrieved on Thailand concerned the development of the national hepatitis B immunization policy in which many players were involved [7]: the Ministry of Public Health's Department of Communicable Disease Control, the Thai Medical Association, the pharmaceutical industry, and the media. A committee was formed with representations of government, as well as various institutes and associations. It could not be determined from the publication whether this committee and these groups are involved in making all immunization policy decisions, or were only involved for this one vaccine.

The information obtained on the remaining eight countries relates to the types of evidence used when making decisions (Table 2). Burden of disease and economic assessment are the most commonly reported types of evidence used by countries when making immunization policies.

### 3.5. National Immunization Technical Advisory Groups

While many countries may have established NITAGs, their presence was reported in only 14 countries (Australia [10,13,23,33], Austria [17,20,32], Brazil [5], Canada [10,31,34,38], France [17,20,32], Germany [17,20,32], Ireland [17,32], Italy [17,32], New Zealand [6,30,35], Spain [17,20,32], Switzerland [17,32], The Netherlands [10], the UK [17,20,24,26], and the USA [16,18,21,22,25,26,29,37]). There were no reports of NITAGs which had been in existence but were no longer functioning.

Generally, the NITAGs in each country provided advice and guidance to the government on the administration of vaccines to the population. For example, the terms of reference for the Australian NITAG are to provide technical advice on the administration of vaccines available in Australia, advise on and assess the evidence available on existing, new and emerging vaccines, produce the Australian Immunization Handbook, and consult with partners on matters relating to the implementation of the Australian Immunization Program [33].

It is unknown when most of the NITAGs were established, as the dates of the creation of the NITAGs were only provided for 5 of the 14 countries. The NITAG in the UK was established in 1963 [24,36], Canada [34] and the USA [25] in 1964, France in 1997 [32], and Switzerland in 2004 [32]. Although the exact year is not reported, the NITAG in New Zealand has existed since at least 1980 [30].

Of the 14 countries for which information on their NITAGs was retrieved, 12 countries provided information on their membership (all except Brazil and New Zealand) [13,16,17,24,25,32,34,36,37]. The number of members was reported for 8 of the NITAGs and varied from 12 to 17 (Austria, Canada, France, Germany, Ireland, Switzerland, the UK, the USA) [16,17,24,25,32,34,36,37]. Five of the countries reported that a defined term is given for members which lasts three to four years (Austria, Canada, Switzerland, the UK, the USA) [17,25,32,34,36,37] while the reports for Italy and Spain indicated that there is no defined term limit for committee members [32]. The chair of the committee is referred to for three of the NITAGs: Canada, France, and the USA [22,32,37]. There were between 4 and 15 ex-officio members reported by 5 of the committees [16,24,25,32–34,36,37] and between 11 and 27 liaison members reported by two committees [16,25,34,37].

All members on the NITAGs in Canada, the UK, and the USA must declare potential conflicts of interest [25,34,36,37]. In the case of a conflict of interest, the member may be excluded from the final decision making [34,36,37] or if the conflict is significant, they may have to resign [25].

The types of expertise represented on the NITAG was reported for Canada, France, Germany, Italy, New Zealand, Spain, Switzerland, the UK, and the USA [13,16,24,25,32,34–37]. These included clinical medicine, epidemiology, immunology, health economics, health planning, infectious disease, internal medicine, microbiology, nursing, pediatrics, public health, and vaccine research while some also had a community member or an insurance representative. The most commonly reported areas of expertise were infectious disease ( $n=5$ ) followed by immunology, microbiology, pediatrics, and public health, which were all represented on four of the nine committees.

Nine of the 14 NITAGs had a defined number of meetings, of which the majority ( $n=5$ ) met three times per year [24,25,32–34,37]. The highest number of meetings per year was reportedly held by the NITAG in France which met six to eight times per year [32], while the NITAG in Germany met only twice a year [32]. Six of the NITAGs held closed, confidential meetings (Austria, Canada, France, Ireland, Switzerland, the UK) [24,32,34], while only the NITAG in the USA had meetings open to the public [25,27]. Of the eight countries which reported taking meeting minutes, half of the countries published them on the internet (Australia, Canada, the

UK, the USA) [24,25,33,34,36,37] and the other half did not publish them (Austria, France, Ireland, Switzerland) [32].

Information was given on the use of evidence in 8 of the 14 NITAGs (Table 2). Australia mentioned using evidence but did not offer further information [10,13,33]. The NITAGs in Brazil [5], Canada [34,38], and the UK [36] conduct a literature review prior to making recommendations. It was reported that the NITAG in Canada [34,38], the UK [36], and the USA [25] appraise the quality and validity of the evidence to determine if it is strong enough to justify a recommendation in their countries. Canada [34,38] and the USA [25] reported grading the evidence, while the UK's method was not specifically reported [36].

Details about the publication of NITAG recommendations are given for nine countries. While Australia [33], Austria [32], Germany [32], and the UK [24,36] produce an annual report or annual national immunization booklets including the recommendations of the NITAG that were accepted by the government, France and Ireland [32] publish their guidelines every second year in a report. Austria, Canada, New Zealand, the UK, and the USA publish their recommendations online [24,25,32,34–37].

## 4. Discussion

This systematic review is the first known attempt to retrieve and summarize information published about the processes of immunization policy making at a national level. Although every country with an Immunization Program presumably has gone through the process of developing their national immunization policies, the information published and available online about the process of immunization policy development was relatively limited being obtained from only 33 of 193 countries. Further, the amount of information available varied tremendously by country with the most information available on the processes in Australia, Canada, the UK, and the USA for which the information described was fairly comprehensive.

The main limitation of this review is that only publications, reports and websites in English or French were included in the review. There is likely to be additional information available on the processes of immunization policy making at a national level published in languages other than English or French, particularly on national websites, though we were unable to determine to what extent.

The assessment of the quality of information is another limitation of this study. Although the source and date of publication were documented, national policy making processes may have changed over time and it is unknown if the methods employed in the past remain the same today. As well, there are many varying perspectives of players involved in immunization policy development that may not have been reflected in the published literature due to the small number of publications and limited information provided.

Granted the above-mentioned limitations, the lack of detailed information retrieved in print and on the web points to a need for countries to enhance dissemination of information on their immunization policy making processes. This exchange of information could help countries improve their policy making processes by offering concrete examples of feasible policy making methods. Also, governments publishing their decision making processes would increase the credibility and transparency of immunization policy development.

The information retrieved about the immunization policy making processes came mostly from industrialized countries [39], however, there was information about four countries considered to be developing (Brazil, China, Papua New Guinea, and Thailand) and two countries considered to be least developed (Cambodia and

Mali). For the developing and least developed countries, the information retrieved briefly described the players involved and factors considered when making immunization policies. Overall, there was little information available about the processes of immunization policy development particularly in developing countries.

The 14 countries with NITAGs for which information was retrieved in this review are all developed with the exception of Brazil. Brazil is considered a developing country by the United Nations [39], but is known for its strong public health system. Although there are presumably many NITAGs in existence, only 14 were identified in print literature and country websites and limited information about them was published. There is little published or easily accessible website information on the NITAGs outside of those in Australia, Canada, the UK, and the USA, at least in the English and French languages. This reinforces the need for countries to publish information on their immunization policy development processes such as the presence and functioning of NITAGs.

The information collected in this review revealed many differences between countries' NITAGs. Although they have the same purpose, the methods of functioning, membership, decision making processes, and the transparency of the processes vary among groups. The reported modes of functioning of each NITAG are consistent with their purpose but vary according to the context each country.

Of note is that there were no reports of a country that had an NITAG and subsequently dissolved it. Countries wishing to form a NITAG should consider their specific needs and resources and may want to use models developed in other countries to ensure credibility, transparency, accountability, stability, and independence.

No data on process or outcome evaluation of immunization policy making were available in the literature reviewed. This is an important gap in the literature and such an assessment may need to be done in order to convince some governments of the credibility and usefulness of these groups.

This review is a concise presentation of the information retrieved from public sources on immunization policy development processes around the world. Given the effect of vaccines on population health and the vast sums of money needed and spent on vaccines, more attention on the immunization policy development processes is needed in order to document best practices which may benefit all countries. In itself, the scarcity of information raises the question of policy effectiveness and reinforces the need for increased publication to remedy the information gap on immunization policy making processes across the globe.

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## Conflict of interest statement

The authors state that they have no conflict of interest.

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