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**FACULTY OF GRADUATE AND
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Global Immunization Policy Making Processes

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Thesis submitted to the Faculty of Graduate and Postdoctoral Studies in partial fulfillment of the requirements for the MSc degree in Epidemiology

Epidemiology and Community Medicine
Faculty of Medicine
University of Ottawa

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ABSTRACT

Despite national immunization programs existing in each country, the national immunization policy development processes are not well described. One approach used to facilitate the process is that of national immunization technical advisory groups (ITAGs) which make technical recommendations to the national government to guide immunization policies and programs. To better understand the current policy making processes of countries across the globe, a systematic review as well as a global level survey were conducted. This thesis summarizes the characteristics of national immunization policy development processes in all countries as well as the existence of national ITAGs and their characteristics and modes of operation. In conclusion, ITAGs are considered a useful tool by countries for immunization policy development but many countries lack this tool and many of the existing groups need strengthening. Additional evaluation of these groups and further research is needed.

CONTRIBUTION OF THE AUTHORS

This thesis consists of three manuscripts which have been prepared for this thesis and will be shortened prior to submission for publication in peer-reviewed journals. All manuscripts are co-authored by Maggie Bryson, the student, and Dr. Philippe Duclos and Dr. Ann Jolly, the co-supervisors. The student is the first author of all three papers as she was primarily responsible for the data collection, analysis, and writing of the manuscripts. Dr. Duclos coordinated the distribution of the questionnaire with the WHO regions while both co-supervisors provided valuable guidance and feedback throughout the process.

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ABBREVIATIONS

ICC	Interagency coordinating committee
ITAG	Immunization technical advisory group
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

CHAPTER ONE: INTRODUCTION

Rationale

Despite all nations having a national immunization program of some kind, the immunization policy development processes in countries around the world is not well described and documented. Ideally, the processes of immunization policy development are based on scientific evidence and the country's epidemiological situation and public health priorities. The processes should be transparent and should not be unduly influenced by political or industrial motives. This transparency is key to the credibility of the immunization program and facilitates the implementation as it is seen as being a national program with true value. By increasing knowledge on the methods of immunization policy development, support can be targeted to strengthen these processes. Improving immunization policy development processes and thus policies, leads to an increased likelihood of achieving the greatest and most cost-effective impact on vaccine preventable diseases. Policy decisions will still be influenced by the availability of funds and due consideration to opportunity costs.

One method of immunization policy development that facilitates the evaluation of new vaccines and vaccine technologies is the establishment of national Immunization Technical Advisory Groups (ITAGs). These groups are independent advisory committees that make technical recommendations on immunization policies to the national government. They guide policy makers, enabling them to make evidence based policy decisions when introducing new vaccines or updating their national immunization programs. These groups are not implementing, coordinating, or regulatory bodies but instead have merely a technical advisory role.

The premise of national ITAGs is to assist national governments in making evidence-based decisions, which is particularly needed in the context of the complexity of the vaccine armamentarium and increasing cost of vaccines. They bring the necessary expertise and credibility to national immunization policies by having experts who are independent from the government and from industry make technical recommendations to inform policy. These individuals act in their own capacity and when properly selected to be free of conflict of interests and in the context of well-established evidence-review

processes are less likely to be influenced by lobby groups, political motives, or industry; instead, they base their recommendations on the epidemiology within the country and the scientific evidence on vaccines. A national ITAG offers the government support, credibility, and increased technical capacity provided the government is willing to include them in the policy development process by recognizing their recommendations.

Objectives

To better understand the current policy development processes of countries across the globe, a systematic review as well as a global survey were conducted. The objectives of the research were:

- 1) To describe national immunization policy development processes in all countries.
- 2) To describe the characteristics of national immunization technical advisory groups.
- 3) To identify and compare the countries' approaches to using evidence for informing the policy development processes.
- 4) To identify the strategies used to communicate the decisions of national immunization technical advisory groups.
- 5) To identify best practices related to immunization decision making processes.

The systematic review was designed to collect published information on the topic of all objectives. The survey contained questions which addressed the first four objectives. The fifth objective is addressed in chapter four. Although we intended to devise a generic process to be proposed to countries to establish or strengthen national ITAGs, this was not completed due to the great variety in the processes and the lack of evaluation of the groups and their processes.

Without any form of evaluation available and with the difficulty of identifying satisfactory output indicators that measure the success of an ITAG, it was not possible to create a simple generic process to establish or strengthen national ITAGs. From the information we had, we created a 'best practices' list of indicators that we feel are

essential to having a well functioning ITAG. It is also challenging to develop general ITAG modes of operation which would apply in all countries as adjustments are necessary to complement the various cultural environments. To support countries in strengthening or establishing national ITAGs, WHO has prepared a general guidance document on ITAGs which this thesis work has helped to adjust the content.

Outline

This thesis is presented in the form of three papers intended for publication in peer-reviewed journals and will be shortened for publication. The longer version included in the thesis, however, constitutes a more extensive record of information useful for WHO. The thesis consists of five chapters: 1) Introduction, 2) Systematic review, 3) Global immunization policy making processes, 4) A global look at national immunization technical advisory groups, and 5) Conclusions and recommendations.

The systematic review, presented in chapter two contains published information from journals, websites, and reports on the topic of immunization policy development at a national level.

The results of the survey are presented in chapters three and four. Chapter three, the paper entitled 'Global immunization policy making processes', is based on the results of the global survey conducted. It reports on various policy development processes in countries around the world. The survey population included all member states of the World Health Organization (WHO) in the African, American, Eastern Mediterranean, South East Asian, and Western Pacific regions (N=140) as per WHO subdivision. The European region was excluded due to a similar initiative (N=53).

Chapter four, the paper entitled 'A global look at national immunization technical advisory groups', reports on the presence, characteristics, and function of national ITAGs around the world. This paper also outlines a list of best practice process indicators of these groups. It is based on the results of the global survey as well as a similar survey of the European region. The European region received a different questionnaire which was amended to enhance compatibility with the global questionnaire. Where possible, the information from the European questionnaire was combined with that of the global questionnaire to provide global level data. In this

paper, the survey population includes all 193 member states of the WHO with the combination of two questionnaires. Although all member states were invited to participate in the two surveys, this paper focuses only on those who reported the presence of a national ITAG and its characteristics. Both papers report on the presence of national ITAGs for immunization policy development, however the numbers may vary slightly due to the inclusion of the European region in the sample of the second paper.

CHAPTER TWO: SYSTEMATIC REVIEW

Introduction

Immunization is a cost-effective public health intervention that greatly decreases the morbidity and mortality associated with vaccine-preventable infectious diseases. Each year, immunizations prevent over 2.5 million deaths worldwide¹. The currently available vaccines prevent a variety of diseases and more vaccines are under development with several soon to be licensed. Because there are limited resources in every nation, each country must make decisions regarding which vaccines to include in their publicly funded immunization programs and for which populations.

Although virtually all countries have a National Immunization Program of some kind, the processes leading to decisions on which vaccines to offer or include in the national immunization program are not well described. Due to the amount of money spent on vaccines, the fact that they guard against some of the most deadly diseases, and that they are among the cheapest and most effective of public health interventions, it is essential to understand how decisions on vaccines are made.

To facilitate immunization policy development processes, some countries have established national technical advisory bodies, often referred to as national Immunization Technical Advisory Groups (ITAGs). These are independent, expert advisory committees that provide technical advice on vaccines and immunizations and make recommendations to guide policy makers and program managers². However, the information available on the presence of these groups in countries and the characteristics and functioning of these groups is limited.

The objective of this systematic review was to review all information available on vaccine policy decision making processes at a national level across the globe.

Methods

Eligibility criteria

All publications that addressed the processes of immunization policy development at a national level were eligible for inclusion in this review. The unit of

analysis was the country. There were no restrictions within the search strategy with respect to date of publication.

Because the primary author (MB) has working knowledge of English and French, publications in these languages were eligible for inclusion. Additional eligibility criteria included:

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

Search strategy

The search strategy was developed in the database Medline using the OVID platform and adapted to another database, Global Health, through consultation with a professional librarian from Health Canada. The search strategies combined a search for immunization or vaccination as well as a search for policy making or decision making in Medline (1950 to March Week 1, 2008) and Global Health (formerly CAB Health) (1973 to March 4, 2008) (see appendix B for complete search strategies). 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. The government websites of the 193 member states of the World Health Organization (WHO) were searched for information on the immunization policy development processes of the countries. Government websites were accessed using a list of national government websites created by the University of Michigan⁴ when possible. When the country was not listed on this website, government websites were searched for using the Google search engine⁵ with the key words of “government” and “official” and the name of the country. Once the government official website was accessed, the information on their immunization policy development processes was sought by navigating through their Ministry of Health or Ministry of Public Health websites and other appropriate pages such as that of immunizations and vaccines.

Selection of papers

All titles and abstracts (when available) of the citations identified were screened by two reviewers independently. All records that were identified as potentially relevant at this stage were obtained in full text. Because the study was intentionally broad, 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 according to the inclusion criteria.

Data extraction

Once eligible publications were selected for inclusion, the data was abstracted from each publication. The data abstraction form is available in appendix C. Data abstracted included the country name, the source of the information, and any information provided on the immunization decision making process. If the presence of a national ITAG was reported, details on the committee were collected where available such as membership, methods of functioning, funding, committee's authority, consideration of evidence, and communication strategies. Information on the authors and their affiliations was recorded for all publications. The data abstracted varied depending on what was reported.

Quality assessment

Because this systematic review is descriptive in nature and does not include clinical trials or qualitative research, the quality assessment of reports did not include the traditional components by which one would assess the quality of intervention or qualitative studies. The author's affiliation and the sponsorship of the article were considered as an indication of potential conflict of interest and the date of publication was considered as an indication of the extent that the information may be dated.

Results

Selection of published information

The literature search yielded 1343 potential citations for inclusion in this review. Ovid Medline yielded 1030 of the citations and Global Health yielded another 313. Of

the 1343 citations, only 117 (84 from Medline and 33 from Global Health) met the inclusion criteria based on their titles and abstracts. The full records were retrieved and only 20 publications met the inclusion criteria and were ultimately included in the review. The main reason for exclusion was that the publication did not describe the process of immunization policy decision making. Eight of the publications were retrieved from both Medline and Global Health⁶⁻¹³. Another eight publications were retrieved from Medline¹⁴⁻²¹ only while another four from Global Health²²⁻²⁵ only. Appendix D shows a flow diagram describing where the studies were retrieved and reasons for elimination from the review.

The reference sections of the included papers yielded one additional relevant publication²⁶. It is unknown why this publication was not obtained through the search strategy. Contact with an expert in the area also yielded an additional reference²⁷. The websites of five countries provided information on national ITAGs: Australia²⁸, Canada²⁹, New Zealand³⁰, the United Kingdom (UK)³¹, and the United States of America (USA)³². Finally, this review is based on 22 publications and five websites.

Characteristics of included publications

The 22 publications and five websites in this review contained information on policy development processes in 23 of the 193 WHO member states: Australia^{11,14,28}, Austria²⁷, Brazil⁶, Cambodia⁹, Canada^{11,15,26,29}, China²², Denmark¹⁶, France²⁷, Germany²⁷, Ireland²⁷, Italy²⁷, Mali¹⁰, New Zealand^{7,25,30}, Norway¹³, Papua New Guinea²³, Portugal¹¹, Spain²⁷, Sweden²⁷, Switzerland^{11,27}, Thailand¹⁸, The Netherlands^{11,12,15,27}, UK^{20,21,27}, and USA^{17-19,21,24,32} to varying degrees. The processes were described in the most detail in a publication describing that of the UK²⁰ as well as the websites which provided information on Australia²⁸, Canada²⁹, UK³¹, and USA³².

Of the 22 publications, only one had the primary objective of describing the national policy development process²⁰. Nine of the publications discussed a country's experience with a particular vaccine^{6,7,10,12,13,15,16,21,24}. Another nine publications discussed an issue relating to immunization policy development in their country or region mentioned some type of information about their national development process^{8,9,14,19,22,23,25,26,27}. Other publications described clinical services but mentioned a

group involved in making immunization policy recommendations^{17,18}. Two of the reports discussed an issue across multiple countries: Welte¹¹ discussed the role of economic evaluations in vaccine decision making and Freed²⁷ discussed vaccine policy development in Western Europe. None of the publications reported data specific to the topic of this systematic review.

Only one of the publications focused primarily on the process of immunization decision making within a country (UK) and discussed an ITAG in detail²⁰. Twelve of the publications mentioned ITAGs in the context of discussing a specific issue such as a specific vaccine but did not offer much information on the ITAG^{6,7,11,14,15,17-19,21,24-26}. The five websites provided extensive information on the national ITAGs in Australia²⁸, Canada²⁹, New Zealand³⁰, the UK³¹, and the USA³².

The report by Freed provided information on the immunization policy development processes in 10 European countries²⁷ including Austria, England, France, Germany, Ireland, Italy, The Netherlands, Spain, Sweden, and Switzerland.

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^{7,13}. A publication from New Zealand⁷ was a collaboration between the national government, Chiron Vaccines, and the University of Auckland but provided only the fact that an ITAG exists. This is unlikely to have affected the quality of the publication with respect to this review. A publication of study results from Norway¹³ was sponsored by Wyeth Lederle, however because the information collected for this review was secondary to the study itself, i.e. a cost effectiveness analysis of the 7-valent pneumococcal conjugate vaccine, it is unlikely that this sponsorship affected the quality of the publication with respect to this review.

National policy development processes

Information was retrieved on the immunization policy development processes in 23 countries of which 14 had a national ITAG independent from the government

(Australia^{11,14,28}, Austria²⁷, Brazil⁶, Canada^{11,26,29}, France²⁷, Germany²⁷, Ireland²⁷, Italy²⁷, New Zealand^{7,25,30}, Spain²⁷, Switzerland²⁷, The Netherlands¹¹, UK^{20,31}, USA^{17-19,21,24,32}, Table 1). The other nine countries may have had these committees but the information retrieved about their processes of immunization policy development did not make mention of these groups.

Of the nine countries who did not mention a national ITAG, Cambodia⁹, Denmark¹⁶, Papua New Guinea²³, Portugal¹¹, Sweden²⁷, and Thailand⁸ reported other groups which make immunization recommendations to the government. It is unclear from the information collected if these groups were expert advisory committees that are independent from the national government. Cambodia has a national level immunization technical working group that identifies, implements, and monitors national immunization programs in Cambodia⁹. However, the members listed are solely 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 Department²³. They meet to discuss evidence and new developments in child health relevant to the population of Papua New Guinea. Denmark has a National Board of Health¹⁶, Portugal has the National Vaccination Plan committee¹¹ and Sweden has a governmental advisory agency²⁷ that makes national immunization recommendations. The National Board of Health in Denmark conducts a medical technology assessment that analyzes the epidemiology, public preferences, financial implications, and health consequences of vaccines when making recommendations¹⁶. The Swedish advisory committee takes into account the epidemiological data on infectious disease in Sweden and works with external experts to make the best recommendations for their country²⁷. In the USA, although they have the Advisory Committee on Immunization Practices (which is an independent ITAG), they also have the American Academy of Pediatrics^{19,24} and American Academy of Family Physicians¹⁹ both of whom make immunization recommendations.

The information retrieved on Thailand concerned the development of the national hepatitis B immunization policy⁸. There were many players involved in the development of this national policy: 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 is unknown from the literature review if 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 three countries relates to the types of evidence used when making immunization policy decisions. The government of China bases decisions on disease burden, economic impact of disease, and feasibility of local vaccine production²². The government of Mali considers the burden of disease¹⁰ and the government of Norway takes cost-effectiveness data into account¹³.

National immunization technical advisory groups

While many countries may have established national ITAGs, their presence was reported in only 14 countries as previously mentioned. The information provided for each ITAG varied greatly by country. There were no reports of ITAGs which had been in existence but were no longer functioning.

Generally, the ITAGs in each country provided advice and guidance to the government on the administration of vaccines to populations. For example, the terms of reference for the Australian ITAG 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, publish the Australian Immunisation Handbook, and consult with partners on matters relating to the implementation of the Australian immunization program²⁸.

It is unknown when most of the ITAGs were established, as the dates of the creation of the ITAGs were only provided for four of the 14 countries. The ITAG in the UK was established in 1963^{20,31}, Canada in 1964²⁹, France in 1997²⁷, and Switzerland in 2004²⁷. Although the exact year is not reported, the ITAG in New Zealand has existed since at least 1980²⁵.

Table 1 outlines various characteristics of national ITAGs reported. Of the 14 countries for which information on their ITAGs was retrieved, 12 countries provided information on their membership (all except Brazil and New Zealand)^{14,20,27,29,31,32}. There were between four to 15 ex-officio members reported by five of the

committees^{20,27-29,31,32} and between 11 and 27 liaison members reported by two committees^{29,32}. Members of the ITAG in Canada²⁹ and the UK³¹ are not paid; conversely, members of the American ITAG (with the exception of government employees) are paid³².

The types of expertise represented on the committee were reported for Canada, France, Germany, Italy, New Zealand, Spain, Switzerland, UK, and USA^{14,20,27,29-32}. These included clinical medicine, epidemiology, immunology, infectious disease, internal medicine, health economics, health planning, microbiology, nursing, pediatrics, and public health while some also had a community member and insurance representative. The most commonly reported areas of expertise were infectious disease experts (n=5) and immunology, microbiology, pediatrics, and public health, which were all represented on four of the nine committees.

The methods of selecting members were reported for six committees. Members were appointed by the Minister of Health in Austria, France, Germany, and Italy²⁷ and by the Chief Public Health Officer in Canada²⁹. In the USA, members were selected by the Secretary of the US and the Department of Health and Human Services and the chair was selected from amongst members who had been on the committee for over a year³². In Canada, the chair and vice-chair were appointed by the Chief Public Health Officer²⁹. The candidates for these positions were recommended by government officials in the relevant public health departments²⁹.

Information was available on the use of evidence in eight of the 14 national ITAGs (Australia, Brazil, Canada, Spain, Switzerland, The Netherlands, UK, USA). Australia mentioned using evidence but did not offer further information^{11,14,28}. The ITAGs in Brazil⁶, Canada²⁹, and the UK³¹ conducted a literature review prior to making recommendations. The ITAGs in Brazil⁶, Canada²⁹, Switzerland²⁷ and the UK³¹ took the recommendations of other countries into consideration although they are not necessarily a key factor in final decision making. While Canada^{11,29}, Switzerland²⁷, The Netherlands^{11,12,27}, the UK^{20,31}, and the USA³² took economic evaluations into account, Australia²⁸ and Spain²⁷ did not consider economic aspects when making recommendations. In the past, Australia has considered economic aspects when making recommendations^{11,14} but this is no longer part of their mandate as the Pharmaceutical

Benefit Advisory Committee took over this responsibility in 2005²⁸. Burden of disease within the country was considered by ITAGs in Canada^{26,29}, Spain²⁷, The Netherlands^{15,27}, and the USA³² when making recommendations. Canada¹⁵, Spain²⁷, and the USA³² also considered the vaccine efficacy and vaccine safety. It was reported that the ITAG in Canada²⁹ and in the UK³¹ appraise the quality and validity of the evidence to determine if it is strong enough to justify a recommendation in their country. Canada²⁹ reported grading the evidence while in the UK the method was not specifically reported. However, a table was provided on the UK website outlining grades of evidence for intervention studies³¹. The ITAG in Canada also collected evidence on the feasibility of the program in Canada prior to making a recommendation²⁶. ITAGs in Australia, Canada, the UK, and the USA had working groups to collect information on specific topics for the committee^{20,28,29,31,32}.

Details about the publication of ITAG recommendations were given for nine countries. While Australia²⁸, Austria²⁷, Germany²⁷, and the UK^{20,31} released an annual report or annual national immunization booklets, France and Ireland²⁷ published their guidelines every second year in a report. Canada published the Canadian Immunization Guide every four years²⁹. Austria, Canada, New Zealand, the UK, and the USA published their recommendations online^{20,27,29-32}.

Table 1: Characteristics of policy processes and ITAG by country with information available on immunization policy development*

Country	ITAG	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**
Australia	Yes				3	Closed	Yes		
Austria	Yes	16	3		3		No		
Brazil	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				
Ireland	Yes		No		6	Closed	No	Consensus	
Italy	Yes								
The Netherlands	Yes								
New Zealand	Yes								
Papua New Guinea									Yes
Portugal									Yes
Spain	Yes		No					Consensus	
Sweden									Yes
Switzerland	Yes	15	4		5	Closed	No	Vote	
Thailand									Yes
UK	Yes	16	4	Yes	3	Closed	Yes	Vote	
USA	Yes	15	4	Yes	3	Open	Yes	Vote	

*Blank fields indicate that information was not available; limited information was also available on China, Mali and Norway however not related to this table

**Unknown if these groups are national ITAGs as defined in this thesis

Discussion

This systematic review summarizes the limited amount of information published about the processes of vaccine policy decision making at a national level. Although it is assumed that every country must go through this process, the published and online information available about the processes is sparse with this systematic review recovering information on only 23 of 193 countries. The lack of information in print and on the internet demonstrates the need for countries to disseminate 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 while building international relations and increasing their credibility through transparency.

The information retrieved about the immunization policy development processes came mostly from developed countries³³. There was information retrieved about only four countries considered to be developing (Brazil, China, Papua New Guinea, and Thailand) and only two countries considered to be least developed (Cambodia and Mali). Thirteen of the 14 countries with ITAGs for which information was retrieved in this review are developed countries. Brazil was the only exception (it is considered a developing country³³) but is known for its strong public health system. Also, the information available on this country was the most brief.

Cambodia, Denmark, Papua New Guinea, Portugal, Sweden, and Thailand have immunization advisory committees but it was unclear if these committees were independent from the government. Part of the importance of an ITAG is the independence from the government and industry in providing scientific and technical advice on immunization programs in the country. This independence from the government and industry gives the recommendations a higher scientific credibility with less possibility of influence from financial or political motives.

Although there are presumably many ITAGs in existence, only 14 were identified in this review of the literature and country websites and even for these, very limited information was published. There was only one publication in a scientific journal and four websites explaining the role of the group and methods of functioning.

There is essentially no published or easily accessible website information on the ITAGs outside of those established in Australia, Canada, the UK, and the USA.

The information collected in this review demonstrated many differences between countries' ITAGs. Although they have the same purpose, the methods of functioning, the membership, the process of making decisions, and the transparency of the process vary amongst groups. The reported modes of functioning of each ITAG are credible and serve their purpose but vary according to the context of their country.

Of note is that no country in this review had an ITAG and dissolved it. Thus it would appear that countries wishing to form an ITAG 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.

This broad review on immunization policy development processes did not retrieve any information on process or outcome evaluation. There was no literature retrieved which evaluated the processes through which policies were made. Although national ITAGs exist and are well established in some countries, no literature discussing evaluation of the presence or the processes used by these groups was found. 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.

The main limitation of this review is that only publications in English or French were included in the review. There may be additional information available on the processes of immunization policy development at a national level published in languages other than English or French, particularly on national websites. It is unknown to what extent information is missing due to the language restrictions.

The assessment of the quality of information is another limitation of this study. Although the source and date of publication were documented, 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.

This review is a concise presentation of the information retrieved from public sources on immunization policy development processes around the world. In itself, the

scarcity of information raises the question of policy effectiveness and reinforces the need for a survey to remedy the information gap on immunization decision making processes across the globe. It is recommended that countries share their processes not only on the web but also through accessible publications for their own benefit as well as that of others.

References

- (1) World Health Organization. Immunizations, vaccines, and biologicals. [Online] 2007 [cited 2007 Jul 15]; Available from: URL:<http://www.who.int/immunization/en/>
- (2) Duclos P. National immunization technical advisory group (ITAG): guidance for their establishment and functioning. [unpublished]. 2008.
- (3) World Health Organization. Countries. [Online]. 2008 [cited 2008 Nov 14]; Available from: URL:<http://www.who.int/countries/en/index.html>
- (4) The University of Michigan. Foreign government resources on the web. [Online]. 2007 [cited 2008 Nov 15]; Available from: URL:<http://www.lib.umich.edu/govdocs/foreign.html>
- (5) Google. Google Canada. [Online]. 2008 [cited 2008 Nov 14]; Available from: URL:<http://www.google.ca/>
- (6) Cunha SC, Dourado I. MMR mass vaccination campaigns, vaccine-related adverse events, and the limits of the decision making process, in Brazil. *Health Policy* 2004;67(3):323.
- (7) O'Hallahan J, Lennon D, Oster P. The strategy to control New Zealand's epidemic of group B meningococcal disease. *Pediatr.Infect.Dis.J.* 2004;23(12):293.
- (8) Munira SL, Fritzen SA. What influences government adoption of vaccines in developing countries? A policy process analysis. *Soc.Sci.Med.* 2007;65(8):1751.
- (9) Soeung S, Grundy J, Kamara L, McArthur A, Samnang C. Developments in immunization planning in Cambodia--rethinking the culture and organization of national program planning. *Rural & Remote Health* 2007 Apr-Jun;7(2):630.
- (10) Sow SO, Diallo S, Campbell JD, Tapia MD, Keita T, Keita MM, et al. Burden of invasive disease caused by *Haemophilus influenzae* type b in Bamako, Mali: impetus for routine infant immunization with conjugate vaccine. *Pediatr.Infect.Dis.J.* 2005 Jun;24(6):533-537.
- (11) Welte R, Trotter CL, Edmunds WJ, Postma MJ, Beutels P. The role of economic evaluation in vaccine decision making: focus on meningococcal group C conjugate vaccine. *Pharmacoeconomics* 2005;23(9):855-874.

- (12) Welte R, van den Dobbelsteen G, Bos JM, de Melker H, van Alphen L, Spanjaard L, et al. Economic evaluation of meningococcal serogroup C conjugate vaccination programmes in The Netherlands and its impact on decision-making. *Vaccine* 2004 Dec 9;23(4):470-479.
- (13) Wisloff T, Abrahamsen TG, Bergsaker MA, Lovoll O, Moller P, Pedersen MK, et al. Cost effectiveness of adding 7-valent pneumococcal conjugate (PCV-7) vaccine to the Norwegian childhood vaccination program. *Vaccine* 2006 Jul 17;24(29-30):5690-5699.
- (14) The National Centre for Immunisation Research . National centre for immunisation research and surveillance of vaccine preventable diseases. *Commun.Dis.Intell.* 2004;28(1):92-95.
- (15) Blume S, Zanders M. Vaccine independence, local competences and globalisation: lessons from the history of pertussis vaccines. *Soc.Sci.Med.* 2006 Oct;63(7):1825-1835.
- (16) Cowan SA. Denmark decides not to introduce hepatitis B into the childhood vaccination programme. *Euro Surveillance: Bulletin Europeen sur les Maladies Transmissibles = European Communicable Disease Bulletin* 2005;10(11):E051103.3.
- (17) Freed GL, Pathman DE, Konrad TR, Freemand VA, Clark SJ. Adopting immunization recommendations: a new dissemination model. *Matern Child Health J.* 1998 Dec;2(4):231-9.
- (18) Maciosek MV, Coffield AB, Edwards NM, Flottemesch TJ, Goodman MJ, Solberg LI. Priorities among effective clinical preventive services: results of a systematic review and analysis.[see comment]. *Am.J.Prev.Med.* 2006 Jul;31(1):52-61.
- (19) Milstien J, Cash RA, Wecker J, Wikler D. Development of priority vaccines for disease-endemic countries: risk and benefit. *Health Aff.* 2005 May-Jun;24(3):718-728.
- (20) Salisbury DM. Development of immunization policy and its implementation in the United Kingdom. *Health Aff.* 2005 May-Jun;24(3):744-754.
- (21) Terebuh P, Uyeki T, Fukuda K. Impact of influenza on young children and the shaping of United States influenza vaccine policy.[erratum appears in *Pediatr Infect Dis J.* 2004 Apr;23(4):294]. *Pediatr.Infect.Dis.J.* 2003 Oct;22(10 Suppl):S231-5.

- (22) DeRoeck D, Clemens JD, Nyamete A, Mahoney RT. Policymakers' views regarding the introduction of new-generation vaccines against typhoid fever, shigellosis and cholera in Asia. *Vaccine* 2005;23(21):2762.
- (23) Duke T. Slow but steady progress in child health in Papua New Guinea. *J.Paediatr.Child Health* 2004;40(12):659.
- (24) Offit PA, Peter G. The meningococcal vaccine - public policy and individual choices. *N.Engl.J.Med.* 2003;349(24):2353.
- (25) Reid S. Evolution of the New Zealand childhood immunisation schedule from 1980: a personal view. *N.Z.Med.J.* 2006;119(1236):2035.
- (26) Erickson LJ, De Wals P, Farand L. An analytical framework for immunization programs in Canada. *Vaccine* 2005;23 (19):2470-6.
- (27) Freed G. Final report: analyzing vaccine programs/policies in Western Europe. Ann Arbor, MI: Child Health Evaluation and Research Unit, University of Michigan.
- (28) Australian Government. Department of Health and Ageing. Australian technical advisory group on immunisation (ATAGI). [Online]. 2008 [cited 2008 Nov 14]; Available from: URL: <http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/atagi>
- (29) Public Health Agency of Canada. National advisory committee on immunization (NACI). [Online]. 2008 [cited 2008 Nov 14]; Available from: URL: <http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php>
- (30) New Zealand Ministry of Health. Immunisation - New Zealand immunisation schedule. [Online]. 2008 [cited 2008 Nov 14]; Available from: URL: <http://www.moh.govt.nz/moh.nsf/indexmh/immunisation-schedule#review>
- (31) Department of Health. Joint committee on vaccination and immunisation. [Online]. 2002 [cited 2008 Nov 14]; Available from: URL: <http://www.advisorybodies.doh.gov.uk/jcvi/>
- (32) Centers for Disease Control and Prevention. Vaccines & immunizations - recommendations and guidelines: advisory committee on immunization practices (ACIP). [Online]. 2008 [cited 2008 Nov 14]; Available from: URL: <http://www.cdc.gov/vaccines/recs/acip/default.htm>

(33) United Nations. The world economic and social survey: 2007. [Online] 2007 [cited 2008 May 30]; Available from: URL:<http://www.un.org/esa/policy/wess/>

CHAPTER THREE: GLOBAL IMMUNIZATION POLICY DEVELOPMENT PROCESSES

Introduction

With the increasing number of vaccines and vaccine technologies available and the complexity of immunization schedules, each country's national immunization program needs clear processes to make informed decisions. The most current information on the relevant disease in each country as well as the effectiveness of the vaccine needs to be taken into account when making decisions to implement vaccine programs. This requires access to vaccine effectiveness and safety data, local information on disease prevalence and outcome, as well as the expertise to interpret the evidence. A systematic, transparent process for developing immunization policies helps to increase the credibility of each country's national vaccine policies.

Given that vaccines are used in every country, virtually all countries have a National Immunization Program of some kind. However, the processes through which countries make vaccine policy decisions is poorly described and documented. A systematic review of published articles on websites and health journals on this topic revealed only 22 papers¹ and furthermore, found little in depth information on the vaccine policy development process. The systematic review on immunization policy development processes found information on the players involved and the factors and sources of information considered when developing immunization policy decisions in 23 countries¹. Key to these decisions were national bodies known as Immunization Technical Advisory Groups (ITAGs) that provided technical advice to guide governmental immunization policies independent from the national government. The presence of an ITAG facilitates the review of new immunization interventions and assessment of new evidence on existing interventions².

In order to better understand and document the form, function, and components of immunization policy development processes, we conducted a global survey on the development processes guiding national immunization policies in 140 of the 193 member states of the World Health Organization³. This survey was particularly important in light of the limited information retrieved by the systematic review¹. This project was the first known effort to collect global level information on this topic and

was conducted to better understand the scope of immunization policy development processes and the presence, characteristics, and modes of functioning of national ITAGs.

The objective of the survey was to collect information on the development process used in national immunization policies in all countries. This information will be used to synthesize a global depiction of processes used and communicated to countries to hopefully initiate exchange of information and potentially the development of best practices.

Methods

All member states in the African, American, Eastern-Mediterranean, South-East Asian, and Western Pacific regions (140 countries) as per World Health Organization (WHO) subdivision³ were included in the sample for this survey. The European region (53 countries) was excluded due to a similar regional initiative. One questionnaire was to be completed per member state, ideally by the national immunization manager or someone knowledgeable in the immunization decision making processes of the country such as the national ITAG chairperson.

The questionnaire (available in appendix G) was developed by the authors following Dillman's tailored design methods⁴. Although Dillman's techniques were developed for mail surveys, they have been reported to also be effective in email surveys⁵. The questionnaire contained 66 closed and open ended questions of both qualitative and quantitative nature. The questionnaire was divided into two main sections: 1) for all countries, focused on vaccine policy development procedures and consisted of 12 questions and 2) for countries with ITAGs, focused on the characteristics of the ITAG and how it functions and consisted of 54 questions. ITAGs were defined as national independent advisory bodies that make primarily technical recommendations on immunization policies to the national government. They were explicitly differentiated from Interagency Coordinating Committees (ICCs) that are present in some countries. ICCs are aimed at the coordination of various agencies in support of the implementation of immunization policies and programmes, although in some settings technical groups have been established in support of the ICCs. All countries were invited to respond to

the first section of the questionnaire while only those with a national ITAG were to respond to the second section.

The first section of the questionnaire, using mainly closed ended questions, focused on the processes used by the Ministry of Health in developing immunization policies, the various players working with the government, and the sources of information used when developing these policies. To better understand the policy making environment in each country, respondents were asked open ended questions about the challenges, desired changes, and what, if any, support was desired from WHO.

The questionnaire was translated from English into French, Portuguese, and Spanish to facilitate completion by more nations. These languages were chosen because they are the languages used by the relevant WHO regional offices to communicate with their member states.

A draft questionnaire was circulated to WHO staff in the regional offices as well as a few experts in immunization policy development for feedback. This also provided the opportunity for suggestions for inclusion of specific information they would like collected on the topic. The questionnaire was modified to incorporate this feedback.

The questionnaire was pilot tested in February 2008 in six countries in the African region. The responses provided through this pilot test contributed to the modification of responses in closed ended questions as well as the addition of open ended questions. Also, the wording of certain questions was adjusted to enhance clarity. Unfortunately, the six countries involved in the pilot did not have the opportunity to respond to newly included questions in the revised questionnaire. Furthermore, the pilot test version of the questionnaire was circulated to some of the other countries in the African region in error. Thus an additional 15 responding countries did not answer the additional questions which were included on the final version of the questionnaire. From a WHO perspective, it would have been inappropriate to request country officials to complete a new questionnaire. Ethics approval for the study was granted from the Ottawa Hospital Research Ethics Board.

The final revised questionnaire was distributed in March 2008 by WHO headquarters through WHO regional offices to all 140 countries with the exception of the 21 countries that completed the draft questionnaire as noted above. The

questionnaire and follow up letters were distributed by electronic mail between March and July 2008. Up to four reminder letters were sent to non-responders prior to the final submission date of July 1, 2008. The dates of the follow up letters varied by region. The WHO regional offices coordinated the distribution of the questionnaire and follow up letters in order to respect the general operations of WHO where the regional offices deal directly with their designated countries. This was done to potentially increase the response rate as the relationship between the regional offices and countries already existed. Questionnaires could be returned by electronic mail, postal mail, or fax to WHO headquarters in Geneva.

The data were compiled and analyzed using EpiInfo, version 3.4.3. The accuracy of the data entry was confirmed by spot checking ten questions per country. The internal validity of the survey was tested by cross-tabulating certain variables where the responses should be consistent. For example, countries who reported the presence of an active ITAG should also have reported considering the ITAG's recommendations when making decisions. In cases where responses to closed ended questions were unclear and a contact email address had been provided, the respondents were contacted directly by the author (MB) to verify responses.

Responses to open ended questions were grouped by themes defined and categorized by one researcher (MB). The frequency distribution of each variable was calculated. Differences between groups were tested for statistical significance using a two-sided Chi-square test, two-sided Fisher's exact test, or a two-sided Mann-Whitney U test as appropriate. The responses were analyzed by presence of ITAG, region as defined by WHO³, size of country using 2007 United Nations estimates⁶, development status as defined by the United Nations⁷, and length of time since the establishment of national ITAG when applicable. Developed and developing countries were grouped together, hereafter referred to as developing countries, because of the low number of developed countries in the sample. The length of time since establishment of the ITAG was categorized as 1) ITAGs established prior to or including 1998 and 2) ITAGs established after 1998.

Where data was missing, the country was not included in the final rate calculations in order to ensure accurate rates and not falsely deflate the rates by

assuming a non-response indicates a negative response. Therefore, the denominator of each rate reported varied depending on the number of countries that responded to the question.

Results

This paper reports on the responses of all countries relating to their national immunization policy development processes and the existence of national ITAGs; the detailed results relating to characteristics of national ITAGs are reported elsewhere⁸.

The overall survey response rate was 71% (100 of 140 countries surveyed). The response rates varied from a low of 41% (11 of 27 countries) in the Western Pacific region to a high of 91% in the South East Asian (10 of 11 countries) and Eastern Mediterranean regions (19 of 21 countries). Sixty percent of responding countries are classified by the United Nations as developing countries, 37% least developed, and 3% developed. Countries with a population of over one million were significantly more likely to respond to the survey than those with a population under 1 million [83 of 105 countries (79%) with a population over one million responded and 17 of 35 countries (49%) with a population under 1 million responded, $X^2=11.9$, $p<0.001$].

National immunization policy development processes

Respondents were asked about the processes used by the Ministry of Health in determining which immunization policy recommendations to adopt in the form of a multi-response closed ended question. Guidelines from WHO played a key role in the policy development process for the majority of countries with 86% (84 of the 98 countries that responded to this question) indicating that they followed guidelines from WHO regional offices and 73% (n=72) from WHO headquarters. Seventy-nine percent (n=77) of countries reported that final policy decisions were made within the Ministry of Health. Half of the countries reported relying upon recommendations of a national ITAG (51%, n=50) reflecting the number of countries with active ITAGs. About half of the countries (46%, n=45) reported following guidelines from a regional ITAG. A small number of respondents indicated that they followed guidelines from another country (8%, n=8) such as those from the USA, the UK, Australia and Oman. Of those that

follow guidelines from other countries, five of the eight (63%) have national ITAGs and four of eight (50%) are from the Eastern Mediterranean region. Only one least developed country follows guidelines of another country and it does not have a national ITAG. Twenty-two percent (n=22) of countries indicated that they followed recommendations from groups other than those listed such as international or regional organizations (other than WHO), related national working groups, or the country's ICC.

When comparing the countries that reported following guidelines from WHO, nearly all countries (n=84 of 98, 86%) reported following guidelines from WHO regional office; 68 (69%) of these countries also reported following guidelines from WHO headquarters. There were 38 (39%) countries that indicated that they follow guidelines from WHO headquarters, WHO regional office, and a regional ITAG. Ten countries (10%) did not report following guidelines from WHO headquarters or from WHO regional office while nine (9%) of these countries also did not report following guidelines from a regional ITAG. Seven (7%) of these countries reported the presence of a national ITAG upon which they relied for their recommendations. The other two (2%) countries did not report following guidelines from WHO or those of a national or regional ITAG but made decisions within the Ministry of Health. Both of these countries were least developed nations from the African region.

Generally, the processes used by the Ministry of Health in determining which immunization recommendations to adopt were similar amongst countries with an ITAG and those without. Countries without an ITAG reported following guidelines from WHO regional offices significantly more often (93%, 41 of 44 countries) than did those with an ITAG (80%, 43 of 54 countries) ($p=0.05$, Fisher's exact test). However, when stratified by development status, this difference was only present amongst countries that are developing ($p=0.04$, Fisher's exact test) and not amongst those who are considered to be least developed ($p=0.60$, Fisher's exact test). Developing countries without an ITAG also reported following guidelines from WHO headquarters more often (89%, 16 of 18) than did those with an ITAG (64%, 28 of 44) ($p=0.05$, Fisher's exact test). This difference was not significant amongst countries considered to be least developed ($p=0.40$, Fisher's exact test) or when the group was not stratified by development status ($p=0.26$, Fisher's exact test).

When analyzed by development status, there were no differences in processes used to determine which immunization recommendations to adopt.

Players involved in developing national immunization policies

Of the 100 respondents, 55 of the countries reported the presence of a national ITAG. Of the 45 countries that did not report a national ITAG, the majority reported that they would like to establish one (n=38, 84%). The main reason given for not wanting an ITAG was that their present methods of policy development were satisfactory at this point and they did not feel a need for an ITAG.

Although the Western Pacific region reported the highest proportion of countries with a national ITAG (73%, n=8 of 11 respondents), the South East Asian, American, and Eastern Mediterranean regions reported similar proportions of countries with ITAGs (70%, n=7 of 10; 65%, n=17 of 26; 63%, n=12 of 19 respectively). The lowest proportion of ITAGs was reported by the African region at 32% (n=11 of 34).

Larger countries by population were five times more likely to report the presence of a national ITAG when countries with a population of less than one million were compared to those with over one million (OR=5.2; 95% confidence interval: 1.6 to 17.3).

Developing countries were also more likely to report the presence of a national ITAG compared to the least developed countries (OR=5.47, 95% confidence interval: 2.3 to 13.3). A positive linear relationship was reported between presence of a national ITAG and development status of the country. Developed countries reported the highest proportion of countries with national ITAGs (n=3, 100%) followed by developing countries (n=41, 68%), and finally least developed countries (n=11, 30%).

Of the 84 countries that responded to both questions on presence of disease specific ITAGs and presence of a national ITAG, 58% (n=49) reported the presence of a national ITAG and 52% (n=44) reported the presence of disease specific ITAGs. Thirty-seven percent (n=31) reported both a national ITAG and disease specific ITAGs. The majority of these countries reported that the relationship between the national and disease specific ITAGs was that they work together by having disease specific ITAGs present their recommendations to the national ITAG or that the ITAGs had common members. Twenty two countries (26%) indicated that they did not have a national ITAG

or disease specific ITAGs of which 12 are least developed countries and 10 are developing countries.

Respondents identified ministries of government that were involved in the immunization policy development process (N=99). Beyond the ministry of health, the ministry most often involved in the process was the ministry of finance (45%) with the ministries of education (18%), planning (13%), and social affairs (13%) reported less often. The number of ministries involved in the immunization policy development processes other than the ministry of health varied from none to five with a median of one additional ministry involved.

Use of evidence in developing immunization policies

Among the sources of information used when developing immunization policies, 90% (n=89 of 99 countries) of respondents reported that WHO played a key role in providing information. Inter-country meeting reports and recommendations as well as published studies were reported to be common sources of information when making immunization policy decisions used by 72% (n=71) and 67% (n=67) of countries respectively. Over half of the countries used government reports and national committee statements as sources (65%, n=64; 52%, n=51 respectively), while 14% (n=14) of countries indicated that sources of information other than those listed in the questionnaire were used in the policy development processes. These included information from reports from international or regional organizations such as UNICEF, national research conducted within the country, websites, and epidemiological reports from neighbouring countries.

When comparing the sources of information used, the proportion of countries with an ITAG using different types of information was higher than that of countries without an ITAG with few exceptions (Table 2). Countries with an ITAG reported using inter-country meeting reports and recommendations, published studies, national committee statements, information from national institutions, unpublished research, and other additional sources of information more often than countries without an ITAG.

Countries with an ITAG reported using a significantly higher number of sources than those without a national ITAG ($p=0.024$, Mann-Whitney U test). Countries with an

ITAG reported using unpublished research conducted within their country significantly more often than countries without an ITAG (X^2 $p=0.015$). However, development status was a confounder in this relationship. When stratified by development status, the association was no longer significant. Countries considered least developed were significantly less likely to use unpublished research conducted in their country than developing countries ($p=0.02$, Fisher's exact test).

When stratified by development status, developing countries used information from inter-country meeting reports and recommendations (X^2 $p=0.026$), national institutions (X^2 $p=0.05$), national committee statements (X^2 $p=0.02$), other countries (X^2 $p=0.05$), published studies (X^2 $p<0.001$), and unpublished research from within the country (X^2 $p=0.002$) more often than countries considered to be least developed.

Table 2: Sources of information used to inform immunization policies by presence of ITAG

	ITAG n (%)	No ITAG n (%)	X^2 p- value
	n=54	n=45	
WHO vaccine position papers	47 (87)	42 (93)	0.21
Inter-country meeting reports and recommendations	42 (78)	29 (64)	0.19
Published studies	41 (76)	26 (58)	0.07
Government reports	35 (65)	29 (64)	0.93
National committee statements	36 (67)	15 (33)	0.001
Country level interagency coordinating committees	24 (44)	21 (47)	0.76
National institutions (e.g. universities)	25 (46)	14 (30)	0.14
Unpublished research conducted within country	25 (46)	10 (22)	0.02
Other countries' decisions Australia, China, Democratic Republic of the Congo, Kazakhstan, Russian Federation, UK, USA	6 (11)	5 (11)	0.55
Other: Epidemiology of neighbouring countries International/regional organizations (i.e. UNICEF) National research Websites	10 (19)	4 (9)	0.18

Challenges and desired changes in the immunization policy development processes

The challenges and desired changes reported by countries were similar (see Figure 1 & 2). The most common challenge reported was securing sufficient finances with over half of the 96 countries that responded to this question reporting this challenge (53%, n=51). Capturing the epidemiology of the disease in the country (36%, n=35) as well as coordination of government and stakeholders (31%, n=30) were also commonly reported challenges. Thirty countries (31%) reported the implementation of immunization policies as a challenge.

The most common desired improvement was to increase the involvement, communication, or coordination amongst government and stakeholders with 25 of 90 countries (28%) indicating this desired change. The second most common desired improvement was the desire to establish a national ITAG (n=18, 20%) and to strengthen the policy making process (n=18, 20%). Thirteen countries (14%) reported the desire to improve their surveillance or evaluation of disease within their country while thirteen countries (14%) also reported the desire to improve their national ITAG. Twelve countries (13%) desired additional funding.

Although in general the challenges and desired improvements reported were similar across the countries, the percentage of countries listing an issue as a challenge and subsequently as a desired improvement varied from 22% to 100%. For example, all of the countries that listed securing finances and increasing coverage rates as a desired improvement also listed them as challenges. Conversely, only 22% of countries that listed introduction of new vaccines as a desired improvement also listed it as a challenge.

Figure 1: The main challenges countries encountered when developing immunization policies in descending order

- 1) Securing funding
- 2) Capturing the epidemiology of disease in home country
- 3) Coordination of government and stakeholders
- 4) Implementation of immunization policies
- 5) Introduction of new vaccines or scheduling of vaccines
- 6) Coverage rates and reaching target groups
- 7) Lack of human resources
- 7) Lengthy policy making process
- 9) Lack of technical expertise
- 9) No active ITAG
- 11) Need to strengthen ITAG to work more effectively
- 12) Lack of immunization legislation

Figure 2: The desired improvements when developing immunization policies in descending order

- 1) Increase involvement, communication and coordination amongst stakeholders and government
- 2) Establish ITAG
- 2) Strengthen policy making process
- 4) Strengthen ITAG
- 4) Improve surveillance or evaluation
- 6) Increased or securing funding
- 7) Use evidence in decision making
- 8) Introduce new vaccines
- 9) Increase technical capacity
- 10) Strengthen implementation process of policies
- 10) Create or update immunization legislation
- 12) Increase coverage rates
- 13) Increase human resources

The proportion of countries without an ITAG reporting coordination of government and stakeholders as a challenge was higher than those with an ITAG [44%, (n=19 of 43) compared to 21% (n=11 of 53), X^2 p=0.014] as was technical capacity [14% (n=6 of 43) compared to 6% (n=3 of 53), X^2 p=0.17]. When stratified by development status, least developed countries showed no significant difference in the proportion of countries without an ITAG (n=7 of 18) and those with an ITAG (n=4 of 9) that reported coordination of government and stakeholders as a challenge (p=0.58,

Fisher's exact test). Amongst developing countries, significantly more countries without an ITAG (n=7 of 18) listed coordination of government and stakeholders as a challenge than countries with an ITAG (n= 7 of 44; p=0.05, Fisher's exact test). Countries with an ITAG reported finances and introduction of new vaccines as challenges more often than countries without an ITAG although neither of these differences reached statistical significance [57% (n=30 of 53) compared to 49% (n=21 of 43), X^2 p=0.53 for finances; 23% (n=12 of 53) compared to 16% (n=7 of 43), X^2 p=0.60 for introduction of new vaccines].

Least developed countries were more likely to report human resources [24% (n=8 of 34) compared to 7% (n=4 of 62); p=0.03, Fisher's exact test], achieving target coverage rates [27% (n=9 of 34) compared to 8% (5 of 62); p=0.03, Fisher's exact test], and coordination of government and stakeholders [47% (n=16 of 34) compared to 22% (n=14 of 62); p=0.02, Fisher's exact test] as challenges than developing countries.

Significantly more countries with an ITAG reported the desire for increased funding than countries without an ITAG [20% (n=10 of 51) compared to 5% (n=2 of 40), X^2 p=0.04]. This difference is only present amongst developing and developed countries [22% (n=9 of 41) compared to 0% (n=0 of 18) without an ITAG; p=0.03, Fisher's exact test] and not amongst countries considered to be least developed [10% (n=1 of 10) compared to 9% (n=2 of 22); p=0.69, Fisher's exact test]. Respondents from almost half of all countries without an ITAG wished to establish an ITAG (46%, n=18 of 39) to improve the country's immunization policy development processes. There was no difference between countries which are considered least developed (39%, n=10 of 26) and developing countries (42%, n=8 of 19) who would like to establish an ITAG as a desired improvement to their immunization policy development processes.

The challenges and desired changes reported by long established national ITAGs were not statistically different than those with national ITAGs of less than 10 years standing with the exception of finances. Countries with ITAGs established over 10 years ago were more likely to report finances as a challenge in making immunization policy decisions [77% (n=17 of 22) compared to 42% (n=13 of 31); p=0.013, Fisher's exact test].

Desired support from WHO to establish or strengthen immunization policy development processes

The most valued support that countries reported wanting to receive from WHO was technical (68%, n=59 of the 87 countries that responded to this question). This included updated scientific papers as well as relevant workshops and assistance with evaluating various aspects of the immunization programs. Advice on ITAG best practices (40%, n=35) was also desired particularly by countries without an ITAG [55%, (n=22 of 40) compared to 28% (n=13 of 47) of countries with an ITAG]. Twenty-four percent of countries (n=21) wanted financial support and 18% (n=16) suggested WHO play an advocacy role in the establishment of immunization policies in their country. Respondents from 17% (n=8) of countries with an ITAG reported wanting WHO to share experiences of other countries, 11% (n=5) would like to have a WHO representative participate in their ITAG meetings, and 9% (n=4) would like to have an ITAG representative invited to international meetings. Three percent of countries (n=1) without an ITAG identified a need for a WHO representative to participate in their inter-country meetings as well as to be invited to participate in international meetings. Five percent of countries (n=4) requested no support from WHO. There were no differences between those who requested support from WHO when analyzed by development status or length of time since establishment of ITAG.

Discussion

The presence of a national ITAG was recognized as useful tool by the majority of respondents for vaccine policy development. Ninety-four of the 100 countries that responded to the survey either had an active ITAG or wanted to establish a national ITAG. Furthermore, this was the most frequently cited needed improvement by countries without a national ITAG.

With the presence of a national ITAG, disease specific ITAGs should not be necessary. Ideally, the national ITAG has the capacity to analyze and make recommendations regarding immunizations for all vaccine preventable diseases in the country. A disease specific ITAG may inadvertently act as an advocacy group for a specific disease because they do not need to consider the other diseases. Despite this,

37% of respondents indicated that they have both disease specific and a national ITAG, the majority of which indicated that the groups coordinate recommendations in some way. In most cases, the disease specific ITAGs provided advice to national ITAG on specific disease or there were mutual members on each committee. It appears that the majority of disease-specific ITAGs were working groups of the national ITAG. In the case where a national ITAG does not exist, these groups may exist out of necessity and present a model structure by which one national ITAG that addresses all vaccine preventable disease may be developed.

The presence of an ITAG was associated with an increased use of different sources of information. Although all countries reportedly used at least one source of information in their policy development processes, it is likely that the more sources of information used, the better the quality and robustness of the policy. The results of this survey suggest that countries with ITAGs have a) better access to an increased number of sources of information and b) more technical capacity to process additional sources of information as this was a challenge reported by more countries without ITAGs than with them.

The results of this survey also suggest that the presence of an ITAG may facilitate the coordination, communication, and involvement of government and other stakeholders during the immunization policy development process as countries without a national ITAG identified this as a key challenge significantly more often than countries with a national ITAG. Although the presence of an ITAG likely increases both the quality and process of immunization policy development, it may require additional resources in the country in order to be able to coordinate meetings of experts, provide them with the information needed to make informed decisions, and the funding needed for recommended programs. The presence of a functioning ITAG may also identify and rationalize gaps and needs within immunization programs as countries with these groups often reported introduction of new vaccines as a challenge; one that could be addressed by increased funding.

While the overall response rate to this survey was 71%, some regions had a much lower response. Of the 16 countries that did not respond in the Western Pacific region, 12 are small island nations with populations of less than one million that represent over a

quarter of the total non-responders globally. Because larger countries were significantly more likely to respond to the survey and to report the presence of a national ITAG, the reported rate of presence of national ITAGs may be artificially inflated. If all non-responders did not have a national ITAG, the overall rate of national ITAGs would be 39% (55 of 140 countries). On the contrary, if the rate was biased in the other direction and all non-responders had a national ITAG, the overall rate would be 68% (95 of 140 countries).

Although efforts were made to analyze the potential effects of certain additional variables, such as development status and maturity of ITAG, it is difficult to disentangle the many factors that may have influenced the selection of survey answers. The development status, size of country, and even political structure of the country are examples of the many factors that can influence policy development processes. To fully understand the influences on immunization policy development processes in each country, it would need to be examined individually and in more depth.

The importance of analyzing policy processes by level of development of the country was apparent from the results of this survey. Unfortunately, there were only a limited number of developed countries that were in the population sampled and that responded to this survey and therefore analysis could not be performed on developed countries alone because of the small sample size. Consequently, developed countries were grouped with developing countries, which may have skewed the data in some cases. To further confound this problem, countries that were considered least developed were significantly less likely to respond to the survey and therefore, when analyzing least developed nations, differences may not have been detectable due to the smaller sample size.

The main limitation of this study was the exclusion of the European region from this project. It is unfortunate that this region was excluded as this compromised a global depiction of national immunization policy development processes of countries with and without national ITAGs. This region was excluded due to a similar, concurrent initiative in which a survey was being conducted on the topic of national ITAGs. However, that survey did not collect information from countries that did not have national ITAGs and hence the data from that survey could not be included in this paper for discussion.

The exclusion of the European region also has meant that developed countries are underrepresented in this survey. The inclusion of data from the European region would have enhanced the quality of these analyses as it would have been ideal to compare developed, developing, and least developed countries.

Another limitation is that the information collected through this survey is self-reported so the reported policy making process may have differed from actual practice. Respondents may have reported what they felt ought to be done instead of what they were actually doing. Because this survey was conducted by WHO, countries may have emphasized the use of the information provided by WHO, in order to be seen as supportive of what was seen by many as a highly valued service.

Another limitation is the potential that the questions or responses may have been misunderstood or misconstrued in translation. Although the survey was distributed in four languages, respondents may have misunderstood the language of the questions and response choices. There was one known mistranslation of a question into Spanish. Back translation of the questionnaire into English prior to distribution would have decreased the likeliness of mistranslation. Also, responding in a language that is not their primary language may have been a barrier to optimal communication for both closed and open ended questions. It is unlikely that any countries did not respond to the questionnaire because it was only available in English, French, Portuguese, and Spanish. These languages (as well as Russian) are standard for communications between member states and WHO. The Russian language was excluded due to the exclusion of the European region.

There is also the possibility that the countries that chose not to respond differed from those who responded, thus affecting the generalisability of the survey results.

The missing data for some questions was in part due to the circulation of the pilot version of the questionnaire and was not necessarily due to the countries' desire to not answer the question but rather that they were not asked the question. Although efforts were made to correct for this by altering the denominator when calculating the rates to reflect the number of countries with replies, it is unfortunate that the responses to some questions did not include these African countries.

Based on this survey, WHO appears to be a valuable source of information for countries when developing immunization policies particularly for developing and least developed countries. All developing and least developed countries either reported following guidelines from WHO headquarters or regional office or use vaccine position papers as a source of information when making immunization policies. The majority of developing and least developed countries would like technical support from WHO to either strengthen or establish a national ITAG. The reported desired support at a minimum included technical and scientific papers, studies on new vaccines, surveillance information, immunization program evaluation, and regional and global data.

A finding from this survey is the demonstration of the need for clarity in terminology. Although a definition was given for a national ITAG and was differentiated from the country's ICC or ad hoc working groups, there appears to have been confusion given in some of the responses.

This paper provides an important global overview on the immunization policy development process - a topic with little previously published information. There was broad agreement on the value of WHO global and regional vaccine recommendations. Also key was the finding that those countries with ITAGs appeared to derive benefit from the co-ordination between government and immunization stakeholders and from using increased sources of information in decision making. While ITAGs appear to be useful in immunization decision making, the survey indicated an increased need for funding when these groups are present. Presence of these groups may in itself stimulate recognition of funding deficiencies which results in more effective use of vaccine funding.

References

- (1) Bryson M, Duclos P, Jolly A, Bryson J. National immunization policy making processes: a systematic review. [unpublished]. 2008.
- (2) WHO National immunization technical advisory group (ITAG): guidance for their establishment and functioning. [unpublished]. 2008.
- (3) World Health Organization. Countries. [Online]. 2008 [cited 2008 Nov 14]; Available from: URL:<http://www.who.int/countries/en/index.html>
- (4) Dillman D. Mail and internet surveys: The Tailored Design Method. 2nd ed. New York: Wiley; 2000.
- (5) Schaefer DR, Dillman DA. Development of a standard e-mail methodology: results of an experiment. Public Opin Q. 1998; 62 (3):378-97.
- (6) United Nations - Department of Economic and Social Affairs Population Division (2006). World population prospects, the 2006 revision. [Online] 2007 [cited 2008 May 30]; Available from: URL:<http://data.un.org/Browse.aspx?d=CDB>
- (7) United Nations. The world economic and social survey: 2007. [Online] 2007 [cited 2008 May 30]; Available from: URL:<http://www.un.org/esa/policy/wess/>
- (8) Bryson M, Duclos P, Jolly A. A global look at National Immunization Technical Advisory Groups. [unpublished]. 2008.

CHAPTER FOUR: A GLOBAL LOOK AT NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUPS

Introduction

Immunization technical advisory groups (ITAGs) are expert advisory committees that provide recommendations to guide a country's national immunization programs and policies¹. They are independent from the national government and consist of members with the technical capacity to evaluate new immunization interventions and new evidence on existing vaccine interventions. The premise of these groups is to facilitate a systematic, transparent process for making immunization policies by making technical recommendations to the national government¹. Their work is primarily technical and is intended to bring increased scientific rigour and credibility to the process of making immunization policies, free of political or personal interests.

Many countries have national ITAGs, however, published information on the form and function of these groups is limited. A systematic review on the topic of national immunization policy development processes identified the presence of 14 national ITAGs, 13 in developed countries and one in a developing country². The most information publicly available concerned the national ITAGs in Australia, Canada, the UK, and the USA. Limited information was available relating to the size, membership, meeting structure, methods of functioning, and process of final decision making². These factors varied greatly across the ITAGs².

Despite the limited information published, overall there is recognition of the importance of national ITAGs³. Supporting countries in strengthening or establishing national ITAGs is a priority for WHO at headquarters and at the regional level³.

Beyond a systematic review of ITAGs, we conducted a global survey on the development processes guiding the national immunization policies of all countries. The objective of the survey was to collect information on the development processes of national immunization policies in all countries. The survey specifically focused on the presence, characteristics, and processes of national ITAGs. The overall objective of the project was to produce a global depiction of immunization policy making processes particularly detailing the form and function of national ITAGs.

This paper combines the results from two surveys on national ITAGs. In total, the sample comprises every member state (N=193) of the World Health Organization (WHO). This paper summarizes the results of information collected from countries with a national ITAG while the results of all respondents are summarized elsewhere⁴. Characteristics of national ITAGs are described as well as attributes of these groups that appear to be imperative for an effective ITAG.

Methods

The information reported in this paper was collected through two questionnaires. One questionnaire, hereafter referred to as the global questionnaire, surveyed all member states of the African, American, Eastern-Mediterranean, South-East Asian, and Western Pacific regions (140 countries) as per WHO subdivision⁵. The other questionnaire, hereafter referred to as the European questionnaire, surveyed the remaining member states of WHO, those within the European region (53 countries). These countries were sampled separately as this was an already ongoing regional initiative in which these countries received a similar questionnaire that had been adjusted to enhance compatibility.

The methods of the global survey are described in detail in an earlier paper⁴. However, in order to facilitate comparison, a brief summary of the methods used in both surveys is included in Table 3.

Table 3: Details of the Global and European questionnaires

	Global questionnaire	European questionnaire
Sample	African Region (N=46) Region of the Americas (N=35) Eastern Mediterranean Region (N=21) South East Asian Region (N=11) Western Pacific Region (N=23) Total N=140	European Region (N=53)
Authors	Maggie Bryson, University of Ottawa Philippe Duclos, World Health Organization Ann Jolly, Public Health Agency of Canada	Gary Freed, University of Michigan
Recipient	Addressed to all national immunization managers or someone knowledgeable in the national immunization policy development processes (i.e. the Chair of the national ITAG)	Addressed to all national immunization managers or someone knowledgeable in the national immunization policy development processes (i.e. the Chair of the national ITAG)
Distributor	WHO regional offices	WHO regional office
Date of distribution	March 2008	April 2008
Method of distribution	Electronic mail	Electronic mail
Method of return	By electronic mail, fax or mail	By electronic mail
Languages of questionnaire	English French Portuguese Spanish	English Russian
Number of questions	66 (54 on national ITAGs)	39 (27 on national ITAGs)
Follow up letters	Yes – by electronic mail	Yes – by electronic mail

Many of the questions on the two questionnaires were identical. Both inquired about the terms of reference, membership, declaration of interests, modes of operation, and the use of evidence from national ITAGs. The global questionnaire also collected information on the functions, funding, additional players such as the chair, executive secretary, immunization program manager, and working groups, evaluation of evidence, and communication strategies of national ITAGs. Where possible, the results from the European questionnaire were incorporated into the analysis of the data for this paper.

Both questionnaires contained closed and open ended questions. The questions addressing professions or areas of expertise of ITAG members, factors considered when making a recommendation, and sources used to inform recommendations were multi-response closed ended questions in both questionnaires; however, the choices listed were not identical. All questions had some choices listed that were identical but the list of choices was less extensive on the European questionnaire. All closed questions on both questionnaires had an open ended component offering the opportunity to list other possible responses which were not listed.

As part of the global questionnaire, countries were asked to list five factors that are most important when making recommendations and to list the three sources of information that are most important when making recommendations. Neither of these two questions was included in the European questionnaire.

Various terms were defined as follows: *ex-officio members* as representatives from governmental departments who provide expertise to the committee, attend committee meetings, express the views of the department they represent but do not take part in the final decision making process; *liaison members* as representatives from immunization related organizations who provide expertise to the committee but do not take part in the final decision making process; *executive secretary* as an individual who is generally responsible for organizing the logistics of the meetings, for preparing any committee reports and who plays a leadership role and works closely with the chairperson; *systematic review* as a literature review which contains an explicit question, search strategy, inclusion and exclusion criteria, and an examination of the quality of research included in the review.

The data were compiled and analyzed using EpiInfo, version 3.4.3 and SAS. The frequency distribution of each variable was calculated and differences between groups were tested for statistical significance using a two-sided Chi-squared test or two-sided Fisher's exact test as appropriate. The responses were analyzed by region as defined by WHO⁵, development status as defined by the United Nations⁶, size of country using 2007 United Nations estimates⁷, and length of time since the establishment of the national ITAG when applicable. The length of time was divided into two groups: ITAGs established prior to or including 1998 and those established after 1998.

Given that calculated rates could be adversely impacted by assuming a non-response to a question meant a negative, where data was missing the country was not included in the final rate calculations. Thus the denominators for each reported rate varied depending on the number of country responses.

Through informal discussion, the authors developed a list of best practice indicators to identify well functioning national ITAGs. All countries were measured against the seven criteria identified as best practice indicators in a step-wise fashion. In order to be considered for the following criteria, the country had to meet each of the previous criteria. The varying context of countries was taken into consideration when creating the list as the characteristics and methods of functioning of the ITAG depend on the context of the country.

The first criterion was that a national ITAG, independent from the government, had been established. Secondly, it was required that the national ITAG had created a formal terms of reference to ensure that the methods of functioning of the group had been formally agreed upon, consistent, and transparent. The third criterion was that the ITAG had a legislative or administrative mandate recognized by the government. This legislation, whether it is a law, decree, ministerial directive or other, formally recognizes the establishment of the group and generally outlines its role in advising the government.

The fourth criterion was that at least five areas of expertise were represented on the ITAG in order to ensure multi-disciplinary representation. This facilitates a well-rounded discussion of each topic and ensures the perspectives of various disciplines are considered. It ensures adequate technical capacity to make responsible, evidence based decisions.

The fifth criterion was that ITAGs met at least once a year in 2006 and in 2007. This ensures that the ITAG is active and meets frequently to discuss current issues and ensures the vaccine schedule for the country is adequate. If the ITAG was established in 2006, 2007, or 2008, they were not required to meet in years prior to their establishment for this criterion.

Another criterion was that the agenda was distributed prior to the meeting to enable an informed discussion amongst members. The final criterion was that members were required to declare conflicts of interest to increase the likelihood that members are independent and acting in their own capacity. This contributes to a transparent, credible policy development process.

Results

Response rate

The response rate to the global questionnaire was 71% (100 of 140 countries) while that of the European questionnaire was 89% (47 of 53 countries). In total, of the 193 eligible countries for the two questionnaires, 147 (76%) responded. The South East Asian and the Eastern Mediterranean regions had the highest response rates (91%, 10 of 11 countries; 19 of 21 countries respectively). In contrast, the Western Pacific region had the lowest response rate at 41% (11 of 27 countries).

Twenty one percent (n=31) of the 147 responding countries were developed countries, 12% (n=17) were economies in transition, 42% (n=62) were developing countries, and 25% (n=37) were least developed countries.

Of the 193 countries that were eligible for inclusion, countries with a population of over 1 million (125 of 150 countries responded) were significantly more likely to respond to the survey than those with a population under 1 million (22 of 43 countries responded) (X^2 $p < 0.0001$).

Presence of ITAG

The presence of a national ITAG was reported by 61% (n=89 of 147) of countries that responded to the questionnaires. The Western Pacific region and European region reported the highest proportion of countries with a national ITAG

(73%, n=8 of 11; 72%, n=34 of 47) while the African region reported the lowest proportion (32%, n=11 of 34). None of the respondents reported that a national ITAG had been in existence but had since dissolved although this was a selection option.

Larger countries (population of over one million) were three times more likely to report the presence of a national ITAG when compared to countries with a population of less than one million (OR=3.2; 95% confidence interval: 1.3 to 8.3).

Developed countries had the highest reported rate of national ITAGs (94%, n=29) followed by developing countries (69%, n=43) and least developed countries (30%, n=11). Thirty five percent (n=6) of countries with economies in transition reported the presence of a national ITAG.

Characteristics and mode of operation of ITAGs

The oldest reported ITAGs were established in the United Kingdom in 1963 and in Canada in 1964 while the newest ITAG was established in Bhutan in 2008. The median year of establishment reported was 2000 and the mode was also the year 2000 with 12 ITAGs being established in that year. When analyzing countries by year of establishment, the year 1998 was chosen as the cut off because although the year of establishment peaked in 2000, the steep increase began in 1999.

The reported mandates of ITAGs varied slightly but generally were to advise the government on technical issues related to national immunization programs. This typically included which vaccines to offer to specific populations as well as scheduling of these vaccines. Some countries indicated that their ITAGs were responsible for monitoring adverse events as well as providing advice during disease outbreaks.

While the mandates were reported in an open ended question, the global questionnaire also asked countries about the specific functions of their national ITAG in a multi-response closed ended question. Countries reported many functions of their national ITAGs; the most common function was to assist the government in addressing issues of vaccine quality and safety (96%, n=52 of 54)* and in establishing immunization policies and strategies (89%, n=48)*. Many ITAGs also reported evaluating new vaccines (80%, n=43)* or evaluating new immunization technologies (70%, n=38)*.

* Excludes European region

Promoting regional and national vaccine security was a function of 63% (n=34)* of national ITAGs while 50% (n=27)* informed the government of public health needs in vaccine preventable diseases. Other functions were reported by 19% (n=10)* of ITAGs such as: financing immunization activities, training in areas of vaccination, investigation of adverse events related to immunization, advising the government on immunization surveillance, advising the government in the case of an outbreak of vaccine preventable disease, conducting immunization campaigns and health awareness programs, and determining long term immunization research agendas.

Availability of formal terms of reference was reported for 67% (n=57 of 85) of ITAGs. There was no significant difference between the percentage of countries that reported the presence of formal terms of reference for their national ITAG when analyzed by countries' development status, population size, or time since establishment of the ITAG.

Many countries reported that their ITAGs have a legislative or administrative mandate such as a law, decree, or Ministerial directive that recognizes the establishment of the ITAG (73%, n=61 of 83). An administrative mandate such as a ministerial decree or directive from the Ministry of Health was more common than a legislative mandate. When analyzed by region, the African region had the lowest percentage (33%, n=2 of 6) while the Eastern Mediterranean region had the highest percentage (83%, n=10 of 12) of national ITAGs with legislative or administrative mandates. There was no significant difference in the presence of legislative or administrative basis when ITAGs were compared by maturity ($p=0.44$, Fisher's exact test) or by level of development (developed countries versus countries of other development statuses; $p=0.29$, Fisher's exact test).

Respondents of the global questionnaire reported that ITAGs received funding from various sources. Thirty five percent (n=19 of 54)* of countries reported that their national ITAG received funding from their national government, 19% (n=10)* from WHO, and 7% (n=4)* from non-governmental organizations. None of the countries reported that their national ITAG received funding from pharmaceutical companies. Six percent (n=3)* of ITAGs received funding from other sources such as private donations and international aid organizations.

Membership of ITAGs

The number of core members reported varied from five to 43 with a median of 12. However, 95% of ITAGs reported having fewer than 27 members. Unfortunately, 15 ITAGs did not respond to this question, the majority (n=12) of which were due to an inaccurate Spanish translation. A defined duration of time for members to serve was reported by 31% (n=27 of 87) and ranged from one to six years. The number of terms that can be served by members varied specifically from one to eight although some ITAGs reported that there was no limit.

The great majority of countries reported selecting their ITAG members based upon areas of expertise. Experts were often selected from relevant professional associations, universities, or international organizations in the country. This was through nomination by government agencies or by the professional society. In many cases, the member was appointed by the Minister of Health. Only two countries reported that members were selected from government positions and only one country reported that they did not have a specified process in place to select members.

The methods of selection of the ITAG chair also varied by country. The most common response was that the chairperson was selected in view of his/her position within the government (26%, n=14 of 54)* or was nominated by the Minister or Ministry of Health (24%, n=13 of 54)*. The chair was selected by the members of the national ITAG in 20% (n=11 of 54)* of the ITAGs. Two countries reported that there was no specified process in place to select the chair of the ITAG. Another country reported two chairs, one of which was a government representative and one was an independent expert and in another country, the chair of the ITAG rotated amongst members.

The number of professions or areas of expertise reported as represented on the ITAGs varied from two to 10. Globally, the most commonly reported area of expertise was public health (n=83 of 88, 94%) followed by pediatrics (n=80 of 88, 91%) and epidemiology (n=78 of 88, 89%). The great majority of countries also reported the presence of infectious disease experts (n=68 of 88, 77%), clinicians other than pediatricians (n=60 of 88, 68%), and immunologists (n=58 of 88, 66%) on their national ITAGs. Only 24 of 88 (27%) countries reported the presence of a health economist on

* Excludes European region

their national ITAG. Medical microbiologists (n=29 of 54, 54%)* and cold chain expert/logistician (n=25 of 54, 46%)* were also relatively common members of national ITAGs. Representatives of the public (n=8 of 54, 15%)*, statistical modellers (n=7 of 54, 13%)*, and social scientists (n=6 of 54, 11%)* were represented on a much lower proportion of national ITAGs.

Countries in the European region reported that an expert on vaccine manufacturing regulations was present on 44% (n=15 of 34) of national ITAGs while an expert in social services was present on 21% (n=7 of 34) of national ITAGs.

About half (n=42 of 88, 48%) of countries reported the presence of experts in areas other than those listed. The most commonly reported include scientific research, nursing, pharmacy, immunization program managers, and drug regulatory authorities. From the European region, 17 countries indicated that other professions are represented on the ITAG with virology (n=6) and medical microbiology (n=5) commonly listed.

Ex-officio members were reported by 45% (n=39 of 87) of the national ITAGs in all regions.

Combined data from the global and European questionnaires revealed that over half of national ITAGs reported having liaison members (n=46 of 86, 53%) representing various organizations such as academic or professional organizations (n=46 of 86, 53%), international organizations or other countries (n=31 of 86, 36%), non-governmental organizations (n=20 of 86, 23%) or pharmaceutical organizations (n=13 of 86, 15%). The number of liaison members varied from two to 30 with a median of five. The international organizations represented by liaison members included mainly WHO (n=17) and UNICEF (n=13). Five countries had representatives from ITAGs of other countries as liaison members.

The global questionnaire found that 38 of 54 (70%)* national ITAGs reported having an executive secretary of which 27 (77%)* were formal members. The national immunization program manager played a role in all national ITAGs. For the majority, they were the executive secretary (n=28 of 52, 54%)* while in others they were the chair (n=11 of 52, 21%)*. In a quarter of the ITAGs (n=13 of 52, 25%), the national

* Excludes European region

immunization program manager was present at meetings as a resource who provided information on the logistics of the national immunization program when required.

Combined data from the global and European questionnaire revealed that in 39% (n=33 of 84) of ITAGs, members were required to declare potential conflicts of interest. There was a positive linear relationship between development status of country and declaration of conflicts of interest. In developed countries, 59% (n=17 of 29) of ITAGs reported having members declare conflicts of interest while 50% (n=3 of 6) of ITAGs in countries with economies in transition, 30% (n=12 of 40) of ITAGs in developing countries, and 11% (n=1 of 9) of ITAGs in least developed countries had members declare conflicts of interest (X^2 p=0.03). National ITAGs that were established prior to 1999 were significantly more likely to have their members declare conflicts of interest than ITAGs established in the past 10 years (p=0.01, Fisher's exact test).

Meetings of ITAGs

Respondents indicated that for 64% (n=56 of 88) of ITAGs, meetings were held regularly while for 67% (n=58 of 88) of national ITAGs, meetings were held when necessary. A third of national ITAGs reported meeting regularly as well as when necessary (n=30 of 88, 34%).

In 2006 and in 2007, the mean number of ITAG meetings reported was five with a median of three. The great majority of ITAGs met between one and six times in 2006 (n=60 of 80, 75%) and in 2007 (n=64 of 82, 78%). Of the 83 countries that reported their number of meetings in both 2006 and 2007 and were established in both years, 76 (92%) of the ITAGs met at least once a year.

Agendas were distributed prior to meetings for nearly all national ITAGs (98%, n=86 of 88) although it is unknown how far in advance of the meeting the agenda was distributed. The agenda was more often determined by the ITAG chairperson (60%, n=52 of 87) than through the involvement of other ITAG members (40%, n=35 of 87). The Ministry of Health also often contributed to determining the agenda (51%, n=44 of 87) as well as other players (18%, n=16 of 87) such as the secretary, ITAG steering

committee, and government staff. The global survey found that background documents were distributed to members prior to meetings by 87% (n=46 of 53)* of ITAGs.

The majority (84%, n=74 of 88) of countries reported that their national ITAGs hold meetings closed to the public; only members and those invited to attend the meeting were permitted in the meeting room. In 68% (n=60) of ITAGs, those invited to the meeting were permitted to remain for all presentations and discussions. In 16% (n=14) of ITAGs, those invited to the meetings were required to leave when their presentation was completed and were not permitted to stay for discussion and final decision making. Meetings of 13% (n=11) of ITAGs were open to the public for the complete meeting; in 3% (n=3) of ITAGs, visitors were permitted to observe the meeting but had to leave for the final discussion and decision making.

The great majority of ITAGs recorded meeting minutes (94%, n=82 of 87), although most of these were not made available to the public (71%, n=58 of 82). When meeting minutes were published, there were various media of publication such as a journal or newsletter, website, or government bulletin. Many ITAGs distributed the minutes to ITAG members after each meeting while others circulated them amongst relevant government groups.

Decision making process

Many factors were reported as being taken into consideration when national ITAGs made recommendations (Table 4). All ITAGs reported vaccine safety and all except one reported disease burden in home country as a factor considered in making recommendations. All countries in the European region listed severity of disease prevented and over 90% listed adequate vaccine supply as factors considered in making recommendations. The global questionnaire found that almost all countries considered vaccine effectiveness* while over 80% considered financial aspects of the vaccine and economic impact* as a factor.

Factors considered by national ITAGs when making recommendations, other than those listed, included adequate supply of vaccine, feasibility of program, WHO

* Excludes European region

recommendations, sustainability, ability to attain high coverage, and alignment with global health goals.

The majority of factors were reported consistently across development status with a few exceptions. The exceptions included recommendations from ITAGs in other countries ($p < 0.005$, Fisher's exact test), actions in other countries ($p < 0.05$, Fisher's exact test), economic impact ($p < 0.025$, Fisher's exact test), and public health and epidemiology of the disease ($p < 0.025$, Fisher's exact test) which were reported significantly less by least developed countries than by more developed countries.

The factors most commonly reported as most important included disease burden in home country ($n=37$ of 44 , 84%)*, vaccine effectiveness ($n=30$ of 44 , 68%)*, financial aspects ($n=30$ of 44 , 68%)*, and vaccine safety ($n=26$ of 44 , 59%)*.

* Excludes European region

Table 4: Factors considered by national ITAGs to make recommendations

<i>Global & European questionnaires, N=88</i>	n (%)
Vaccine safety	88 (100)
Disease burden in home country	87 (99)
Public health/epidemiology	84 (95)
Financial aspects	80 (91)
Public perception of the disease	52 (59)
Recommendations from ITAGS in other countries	48 (55)
<i>Global questionnaire only, N=54</i>	
Vaccine effectiveness	53 (98)
Economic impact of the disease	46 (85)
Priority of vaccine related to other vaccine-preventable diseases	42 (78)
Priority of vaccine related to all other possible health interventions	37 (69)
Method of administration of vaccine	33 (61)
Ease of distribution of vaccine	31 (57)
Actions in other countries	27 (50)
Disease burden in other countries	24 (44)
<i>European questionnaire only N=34</i>	
Severity of disease prevented	34 (100)
Adequate vaccine supply	32 (94)
Inclusion of vaccine in expanded program on immunizations	26 (76)
<i>Global & European questionnaires, N=88</i>	
Other	20 (23)

When making recommendations, ITAGs used various sources of information (Table 5). The global questionnaire found that the most commonly used sources of information reported were WHO position papers, WHO recommendations or technical documents*, published data or journal articles, and surveillance data* all reported by over 80% of ITAGs. Only four countries of 88 (5%) did not report using WHO vaccine position papers, recommendations, or technical documents as sources of information while 42 countries of 54 countries that responded to the global questionnaire (78%)* reported that their ITAGs used all three as sources of information.

Beyond those sources listed, countries reported using unpublished data, health technology assessments, conference papers, vaccine books, recommendations from

* Excludes European region

ITAGs in other countries, and recommendations from national professional societies as sources of information.

The use of published data and journal articles was reported significantly less in least developed countries than in more developed countries (developing, X^2 $p < 0.025$; economy in transition, X^2 $p < 0.05$; developed, X^2 $p < 0.005$). The use of pharmaceutical documents was also reported significantly less in least developed countries than in developed countries (X^2 $p < 0.005$).

The global questionnaire found that WHO recommendations and technical documents (n=28 of 40, 70%)*, surveillance data (n=22 of 40, 65%)*, and published data and journal articles (n=13 of 40, 33%)* were the most important sources of information used to inform recommendations.

Table 5: Sources of information used by national ITAGs to inform recommendations

<i>Global & European questionnaire, N=88</i>	n (%)
WHO position papers	78 (89)
Published data and journal articles	77 (88)
Pharmaceutical documents	61 (69)
Government reports	60 (68)
<i>Global questionnaire only, N=54</i>	
WHO recommendations or technical documents	50 (93)
Surveillance data	45 (83)
Expert opinion	42 (78)
Consultations with working groups	37 (69)
Regional ITAG documents	36 (67)
<i>Global & European questionnaire, N=88</i>	
Other	15 (17)

To gather the evidence that informed the recommendations, 77% (n=41 of 53)* of ITAGs reported conducting literature reviews while 49% (n=26 of 53)* reported conducting systematic reviews. Committee consultation was reported as being used by 85% (n=45 of 53)* of ITAGs to make recommendations.

* Excludes European region

To collect and prepare a review of the relevant information on a specific topic, 78% (n=42 of 54)* of ITAGs reported having working groups; one third (n=14 of 42)* of which were ad hoc groups, created as needed, while 19% (n=8 of 42)* were permanent groups. Ministry of Health staff were often members of these working groups (74%, n=31 of 42)* as were experts who were members of the ITAG (57%, n=24 of 42)* and some also included specific matter experts from outside the ITAG (36%, n=15 of 42)*.

Process to reach final recommendations

To reach a decision on final recommendations, the majority of ITAGs reported relying on members to come to a consensus (66%, n=56 of 85), while others had members vote on final recommendations (20%, n=17 of 85), and some used both consensus and voting (11%, n=9 of 85).

The global questionnaire found that for many ITAGs, whether the recommendation was confidential or not varied by recommendation (44%, n=23 of 52)* but were always public for 29% (n=15 of 52)* of ITAGs and were always confidential for 27% (n=14 of 52)* of ITAGs.

The methods of communicating recommendations varied. Over half of ITAGs communicated their recommendations to the Ministry of Health through an official document or report (53%, n=28 of 53)*. Other methods of communication to the Ministry of Health included circulation of meeting minutes to the Ministry (19%, n=10 of 53)* or direct feedback from a member to someone within the Ministry (11%, n=6 of 53)*. In 9% (n=5 of 53)* of ITAGs, an employee of the Ministry of Health was a member of the ITAG and in 6% (n=3 of 53)* of ITAGs, the national immunization program manager was responsible for communicating with the Ministry of Health.

The global questionnaire found that the majority of ITAGS reported using a letter or bulletin to communicate their recommendations to practicing health professionals (66%, n=35 of 53)*. Other ITAGs communicated their recommendations through meetings, conferences, or workshops (28%, n=15 of 53)*, while others relied on the Ministry of Health to communicate with health professionals (23%, n=12 of 53)*. Four percent of ITAGs (n=2 of 53)* used journal articles to communicate with this group

* Excludes European region

while 9% (n=5 of 53)* did not communicate their recommendations to practicing health professionals.

The most common method of communicating recommendations to the public was through various forms of mass media such as radio or public health advertisements (62%, n=29 of 47)*. However, 28% (n=13 of 47)* of countries indicated that their national ITAG did not communicate their recommendations to the public.

Elements of ITAG that need strengthening

When both questionnaires asked “what support (if any) could the World Health Organization provide to strengthen your immunization technical advisory group?”, 67 of the 89 countries with ITAGs responded and the majority desired technical support from WHO (57%, n=38). About a quarter of countries requested advice on methods to strengthen areas of the ITAG such as generic terms of reference (24%, n=16). It was also requested that WHO share the experiences of other countries (13%, n=9). Financial support was requested by 19% (n=13) of countries. Fifteen (22%) countries reported that they did not require support from the WHO to strengthen their ITAG.

When asked in the global questionnaire which elements of functioning of ITAG need strengthening, the most common response was increased areas of expertise represented (34%, n=15 of 44)*. Other common responses were increased technical capacity (27%, n=12 of 44)*, increased participation in meetings or frequency of meetings (23%, n=10 of 44)*, improvement in communication of recommendations (14%, n=6 of 44)*, and strengthening or establishment of formal terms of reference (6%, n=14 of 44)*. Other areas that were reported as needing strengthening were securing of funding (11%, n=5 of 44)* and the decision process (9%, n=4 of 44)*. Nine percent (n=4 of 44)* of national ITAGs reported that there were no elements of their ITAG that needed strengthening.

Best practices

Through informal discussion, the authors developed, a list of best practice process indicators that was used to identify well functioning ITAGs (Table 6). There

* Excludes European region

were 23 ITAGs which met all seven criteria; formal terms of reference, legislative or administrative mandates, at least five areas of expertise represented on the group, met at least once in 2006 and in 2007, distributed the agenda to members prior to meetings, and required members to declare conflicts of interest. The countries that met all of these criteria were Belgium, Bulgaria, Canada, Colombia, Cuba, Estonia, Finland, France, Georgia, Germany, Kyrgyzstan, Latvia, Malta, People's Republic of China, Poland, Portugal, Republic of Korea, Slovakia, Switzerland, The Netherlands, Turkey, the UK, and the USA. Of these 23 countries, 15 were developed countries, five were developing countries, and three were countries with economies in transition. Seventeen were from the European region, four from the region of the Americas, and two from the Western Pacific region. Of these countries that provided a date of established, the median year of establishment was 1994. Countries established prior to 1998 were not more likely to meet the criteria of well functioning ITAGs ($p=0.08$, Fisher's exact test).

Table 6: Components of a well functioning national ITAG and the number of countries that met the criteria as well as all previous criteria (N=147)

Criteria	Results
1) Countries must have an active ITAG.	89
2) The ITAG must have established formal terms of reference.	57
3) The ITAG must have a legislative or administrative basis.	43
4) There must be at least 5 areas of expertise represented on the ITAG.	41
5) The ITAG has met at least once in 2006 and once in 2007 (provided they were established in these two years).	39
6) The agenda is distributed to members prior to ITAG meetings.	37
7) The ITAG members must declare conflicts of interest.	23

Discussion

Although the ITAGs in Canada, the UK, and the USA have been in existence for over 40 years, it is only in the past decade that the majority of national ITAGs have been created. There is increasing interest and value seen in the presence of these groups as shown by the 50 national ITAGs created in the past decade. The value of these groups is also demonstrated by the minimum 89 ITAGs that exist worldwide and there are no known national ITAGs that have been created and then subsequently dissolved. This

suggests that ITAGs provide a service that is valued and of use to a country's policy making processes.

Methods of selection of members and the chair for the national ITAGs were reported in open ended questions. Although the answers from these questions gave some indications of how the selection of members and the chair could proceed, very few countries provided enough details to clearly understand the processes. The process of selection should ensure that members and the chair chosen are independent and serve in their own capacity through a transparent and credible process. Many countries reported that their ITAG chair was selected from within the government which does not align with the ITAGs' premise of independence from the government. These are important aspects of ITAGs that deserve further investigation to ensure that the process through which members are selected is transparent, credible, and comprehensive.

About 70% of ITAGs reported either grading of evidence or use of a quality checklist to evaluate evidence when making recommendations. None of the countries provided a reference for this information despite being requested. From discussions with country officials, it is likely that this question was misunderstood and the numbers reported are inflated. It is suspected that very few countries actually use formal grading of evidence in a systematic way to evaluate evidence collected.

A systematic review on the topics of immunization policy making processes² reported that the ITAG in Canada⁸ uses grading of evidence in their decision making process. The ITAG in the UK may also use this process although this was not clear from the information reported on the website⁹. The evaluation of evidence should be a key component when creating informed decisions and policies. This is another important area of ITAGs for further investigation or development.

The only country for which there was detailed published information on their national ITAG and which did not respond to the survey is Australia^{2,10,11}. When analyzing the ITAG from Australia using the criteria from the best practices exercise, it has formal terms of reference¹⁰, a legal basis¹⁰, over five areas of expertise represented¹¹, and regular meetings¹⁰. It was not reported whether agendas were distributed prior to meetings or whether conflict of interests are declared. Although it is unclear if the Australian ITAG meets all seven criteria using the limited information available, from

what is known, this ITAG could potentially meet all criteria outlined indicating a well functioning ITAG.

As noted above, from the responses of the questionnaires, there were 23 countries that met these seven criteria. This does not necessarily imply that these ITAGs function efficiently or that other ITAGs are not effective – each ITAG has strengths and weaknesses including those mentioned. However, these ITAGs possess what we believe to be the minimum required characteristics of an ideal ITAG. Although the majority of these ITAGs are from the European region, this is likely due to the concentration of developed countries in this region.

The combined response rate of the two surveys was high at 76%, however larger countries were significantly more likely to respond to the survey and were also more likely to report the presence of a national ITAG thus potentially causing bias. The reported rate of presence of national ITAGs may have been inflated.

The validity of the responses in this survey is unknown. When compared with a systematic review on the same topic², 12 of the 14 countries who reported having national ITAGs were consistent with their survey responses. One of the countries mistakenly reported the presence of an ITAG in the survey but this group is within the national government¹⁵ and so was not considered an independent national ITAG by the authors. The reason for the other contradictory case, where the systematic review reported a national ITAG but the survey response indicated the opposite, is unknown.

Of the 12 countries that reported having a national ITAG in the systematic review and also reported the presence of a national ITAG on the questionnaire, the great majority of the information that was found in the systematic review was confirmed by the responses on the questionnaire. The one exception noted was in the number of members reported with a variation between what was determined in the systematic review compared to the questionnaire. This may have been due to changes in the number of members between the date of publication of the sources used in the systematic review and the time when the questionnaire was completed. In most cases, this variation was small with only a one or two member discrepancy. However, in one instance, a four member difference was noted between the 16 members found in the systematic review and the 20 members reported on the questionnaire.

The main limitation of this study was the collection of data through two different questionnaires albeit aligned questionnaires, due to the exclusion of the European region from the global survey. Ideally, the same questionnaire would have been used for all member states. The information from the European region is more limited and hence could not be aggregated with the rest of the data for all areas. Finally, global level data is not available for all topics addressed which precludes a global depiction of many of the characteristics of national ITAGs as was originally planned.

Another limitation is the potential that the questions or responses were misconstrued in translation. The global questionnaire was translated into four languages and the European questionnaire into one additional language. However, there is the possibility of inaccurate translation or misunderstanding by the respondent. There was at least one inaccurate translation into Spanish that resulted in missing data for the intended question from 12 countries.

A further limitation was that the information was collected through self-report and hence may not have reflected actual practice. Because of this, the results must be interpreted with caution. However, the purpose of this study was to collect descriptive information on the immunization policy making processes on a national level and the findings are likely valid in terms of general trends. In addition, responses may instead describe ideal rather than existing methods of policy making. This still offers valuable information on methods through which countries can make immunization policies thus motivating these countries to move toward the policy making structure which they envision.

Although national ITAGs appear to be useful and have a strong global presence, the credibility of the group lies in true independence from the national government and some countries may need guidance in this area. There are 89 reported ITAGs in existence. However, government independence is a concept which may need honing in some countries. There appears to be some overlap between government employees and core members of the group. It is important to have a close relationship between the government, who makes the final immunization policies and generally is responsible for implementation of the policy, and the national ITAG, that provides policy recommendations based on technical expertise independent from the national

government. However, to maintain the independence of the ITAG from the national government and the credibility of their recommendations, it is crucial that government representatives are not core members of the group who participate in making final recommendations. This highlights the need for best practice guidelines that include clear definitions.

The results from these surveys highlight the array of ITAG processes and the need for further investigation in many areas relating to these groups, some of which have been highlighted earlier in the discussion. This project offers basic descriptive information that could be used as the basis for many further research projects to explore details of ITAGs in depth. An area that this survey did not address and that needs further investigation is the relationship between ITAGs and industry, particularly vaccine manufacturers. Since they will be involved in some facet with the majority of national ITAGs, it is essential that the relationship is structured and transparent to ensure the ITAG maintains independence and credibility. A best practice model should address this relationship and guidance in managing this example of conflict of interest.

The findings from this survey support the need for the development of and consensus on best practices for national ITAGs. There is a need for clear definitions and general guidelines on national ITAGs outlining the rationale and examples of ideal modes of functioning. WHO has drafted a general framework for the establishment and functioning of national ITAGs. This document will be of great use to countries by offering guidance in developing or strengthening their national ITAGs. The findings from this thesis are being used to adjust the content of this document.

Best practices should ideally be based on scientific evaluations of ITAGs. It is essential to complete evaluations of existing ITAGs including outcomes in order to provide evidence in support of these groups and varying modes of operation. This is particularly important in light of the paucity of published articles in the systematic review².

As an example of best practices for national ITAGs, this paper outlined a list of seven criteria that could assess national ITAGs. However, a criticism of the criteria could be the focus on process indicators and lack of outcome measures. Additional or alternate best practice indicators of national ITAGs may be more important or

appropriate but given the nature of the information collected through this project was all related to process, it is logical to have started with process indicators. Development of outcome indicators matched to immunization policy making processes would be ideal however this may be challenging as a successful policy in one country may not be successful or appropriate in other countries. The suitability and success of policies highly depends on the context of the country and their epidemiological profile as well as financial situation. One method to evaluate national ITAGs would be to survey the public and health professionals in the country regarding their perception of the national ITAG and its recommendations and their credibility.

Indicators should be discussed on an international level amongst experts in the area to create a consensus on best practice indicators for national ITAGs. This information could then be disseminated by WHO and would offer guidance to countries establishing national ITAGs as well as help strengthen ITAG where they already exist. In the longer term, having WHO facilitate the sharing of solutions in different settings on how to achieve the indicator function for an ITAG would help strengthen ITAGs globally.

This survey also highlights important areas of investment to ensure effective and relevant policies. Surveillance data was reported to be the most important source of information used by ITAGs and disease burden in the home country was reported to be a common factor upon which ITAGs base recommendations. Both factors emphasize the importance of national surveillance systems. Since this is the type of information reportedly most valued, national and regional research agendas should reflect this to ensure that these findings are of quality and can be used to maximize benefit for public policy.

This survey offers useful information on the types and sources of evidence used by ITAGs to make recommendations to the national government about immunization policy. Ideally, ITAGs ensure that policies are evidence based and are an important link between research, local surveillance data, and policy. It is important for researchers to be aware of how research information can inform policy makers and use this to guide research agendas. The relationship between researchers and policy maker has the potential to be mutually beneficial if both parties communicate their needs. By

producing research that policy makers can use, this will enhance the development of evidence based immunization policies.

This survey could be repeated in a few years to collect longitudinal data on this topic and compare responses to determine if progress in the policy making arena has been made in many of these countries. If possible, it may even be helpful to include a limited number of questions on this topic on the WHO/UNICEF joint reporting form¹² to collect longitudinal data from the countries. This information would be relevant to the joint reporting form in that it relates to immunization practices, is of use to WHO, and would maintain an up-to-date global perspective on the presence of ITAGs. This option would allow WHO to continue this project with minimal additional work as the joint reporting form is a well established process which occurs annually. This information could be used as an evaluation tool for progress on policy development. Ideally, with this information, the presence and functioning of ITAGs could be linked to outcome indicators by country.

The topic of strengthening ITAGs is being pursued by various WHO regional initiatives. One initiative in the European region aims at disseminating knowledge and best practices on immunization and offering a platform to share information¹³. There are currently 29 countries, mostly members of the European Union, participating in this initiative¹³. Regional WHO offices are also becoming involved, many drafting guidelines on the establishment, functioning, and terms of references of national ITAGs within the context of their specific region¹⁴. It is hoped that this project will provide useful background information as well as enhance enthusiasm for ITAGs regionally.

In summary, this paper provides a global overview of national immunization technical advisory groups - a topic with little previously published literature. This is the first known collection of global information on national ITAGs. It provides basic information on the functioning of these groups and also highlights the gaps in knowledge and need for research in this area. It is hoped that this study will stimulate a global level dialogue through which countries share their ITAG processes and experiences for the benefit of all nations striving to achieve the best possible policy making processes in each country.

References

- (1) WHO. National immunization technical advisory group (ITAG): guidance for their establishment and functioning. [unpublished]. 2008.
- (2) Bryson M et al.. Global level immunization policy decision making: a systematic review. [unpublished]. 2008.
- (3) Duclos P. Papers - National ITAGs [online]. Email to Maggie Bryson (mbrys045@uottawa.ca) 2008 Dec 15 [cited 2008 Dec 15].
- (4) Bryson M et al. Global level immunization policy making processes. [unpublished]. 2008.
- (5) World Health Organization. Countries. [Online]. 2008 [cited 2008 Nov 14]; Available from: URL:<http://www.who.int/countries/en/index.html>
- (6) United Nations. The world economic and social survey: 2007. [Online] 2007 [cited 2008 May 30]; Available from: URL:<http://www.un.org/esa/policy/wess/>
- (7) United Nations - Department of Economic and Social Affairs Population Division (2006). World population prospects, the 2006 revision. [Online] 2007 [cited 2008 May 30]; Available from: URL:<http://data.un.org/Browse.aspx?d=CDB>
- (8) Public Health Agency of Canada. National advisory committee on immunization (NACI). [Online]. 2008 [cited 2008 Nov 14]; Available from: URL:<http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php>
- (9) Department of Health. Joint committee on vaccination and immunisation. [Online]. 2002 [cited 2008 Nov 14]; Available from: URL:<http://www.advisorybodies.doh.gov.uk/jcvi/>
- (10) Australian Government. Department of Health and Ageing. Australian technical advisory group on immunisation (ATAGI). [Online]. 2008 [cited 2008 Nov 14]; Available from: URL:<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/atagi>
- (11) Nolan T. New arrangements for vaccines: ATAGI and PBAC. [Online]. 2008 [cited 2008 Nov 14]; Available from: URL:<http://www.medicinesaustralia.com.au/pages/images/Terry%20Nolan.pdf>
- (12) World Health Organization. WHO/UNICEF joint reporting process. [Online] 2008 [Cited 2008 Aug 3]; Available from: URL:http://www.who.int/immunization_monitoring/routine/joint_reporting/en/index.html

(13) VENICE: vaccine European new integrated collaboration effort. [Online]. 2008 [cited 2008 Nov 14]; Available from: URL:<http://venice.test.cineca.it/index.html>

(14) Cakmak N. National Advisory Committees on Immunization – European Region [online]. Email to Maggie Bryson (mbrys045@uottawa.ca) 2008 Dec 8 [cited 2008 Dec 10].

(15) Freed G. Final report: analyzing vaccine programs/policies in Western Europe. Ann Arbor, MI: Child Health Evaluation and Research Unit, University of Michigan.

CHAPTER FIVE: CONCLUSIONS AND RECOMMENDATIONS

This thesis summarizes a systematic review and survey on the topic of immunization policy development, particularly the presence of national ITAGs and their characteristics.

The systematic review highlighted the scarcity of information relating to national immunization policy development processes. It retrieved information on the policy development processes of four developed countries, Australia, Canada, the UK, and the USA, which included descriptions of various characteristics of their national ITAGs. A key conclusion from this project is that there is little published information available on immunization policy development at a national level despite this presumably occurring in each country. The gap was especially noticeable amongst developing and least developed countries where only one publication addressed the process in a country that was not developed. Over half of the countries that responded to the questionnaire reported the presence of national ITAGs yet there is little published information available on this topic. I would encourage countries to publish their immunization policy development methods and strategies either in scientific journals or on their websites to share with other countries and with their citizens. Making this information publicly available will increase the countries' credibility amongst their citizens and other countries. This lack of information confirmed the need for a survey of countries on their immunization policy development processes.

The global questionnaire collected information from all countries on their immunization policy development processes and reported on the value of national ITAGs seen by countries. Another key conclusion from this project is that the presence of a national ITAG was recognized as useful tool in the national immunization policy development process. This group was already in place in 89 countries and in the global level survey, 94% of respondents either had a national ITAG or wanted to establish one (respondents of the European questionnaire were not asked this question). In addition, amongst respondents, there was never an ITAG established and later dissolved. This would imply that once created, these groups provide useful contribution to the policy development process. Furthermore, amongst countries without a national ITAG,

establishment of this group was the most frequently cited desired improvement by countries.

The global and European questionnaires were combined to provide a description of the processes of national ITAGs around the world. This is the first known effort to collect this type of information and will be of use to those on the national, regional, and international levels who recognize the value of these groups. Despite the prevalence of ITAGs, many processes of ITAGs need improvement to achieve optimal benefit. This project highlighted the need to develop clear guidelines outlining best practices of national ITAGs including clear definition of terms. This was the second most commonly requested type of support from WHO, with over half of countries without an ITAG requesting this guidance. Countries with established ITAGs could also benefit from these guidelines as some of the processes reported contradict the premise of the group. Also, many ITAGs lack components that contribute to the credibility and transparency of these groups such as formal terms of reference. It is recommended that guidelines outlining best practices of national ITAGs are developed by consensus amongst experts.

In addition to the limited published information on the topic of immunization policy development and ITAGs, there was no published information retrieved on the evaluation of these processes. Evaluation is an important component of any process including immunization policy development, especially considering the vast amount of money spent on vaccines and the potential impact vaccines can have on the health of a population. Because of the prevalence of ITAGs and growing interest in these groups, it is important that they also be evaluated scientifically. The survey reported that countries with an ITAG requested increased funding and reported the challenge of introducing new vaccines significantly more often than countries without an ITAG. It may be that countries with ITAGs not only require small amounts of funding to function but also are more aware of the need for additional vaccines in their country which also increase funding required. A favourable evaluation could justify the additional resources spent on the presence of this group and may be needed to convince additional governments of the usefulness of this group.

The results from this project indicate that countries derive great value from information provided by WHO. Nearly all countries report using WHO technical documents, position papers, or recommendations to inform their immunization policy decision making. Furthermore, the most commonly reported type of support desired from WHO is technical with almost 70% of countries requesting this support in some form. WHO has an important role in providing current technical information relating to vaccines. This is a strong point of contact with countries that could eventually be used to coordinate the exchange of information amongst countries and communicate information about immunization policy making processes such as evaluations or best practice guidelines on national ITAGs.

There were limitations to this thesis. Firstly, it is unfortunate that the systematic review was limited to information available in English and French. There may be important information available in other languages. Another limitation is the possibility of mistranslation of the questionnaires or the responses that would lead to inaccurate data.

Another limitation is the collection of information through two surveys. This prevents the reporting of global level data on many variables and increases the potential for bias. Using two different tools to collect the data and then combining the data is not ideal. There are also limitations associated with the collection of data from self-administered questionnaires. The data is presented as it was reported from the countries and the accuracy is highly dependent on the knowledge and efforts of the individual responding to the questionnaire.

This project was intended to describe the current immunization policy decision making processes in nations across the globe. It is the first known global portrayal of these processes. It is hoped that these papers will be published to add to the scarce literature base on this topic and that this will inspire others to publish their work in the area of national immunization policy development. Through increased understanding of these processes, it is hoped that policies will be improved, ultimately achieving the greatest impact on vaccine preventable diseases.

**APPENDIX A: LETTER OF APPROVAL FROM THE OTTAWA HOSPITAL
RESEARCH ETHICS BOARD**



The Ottawa Hospital | L'Hôpital
d'Ottawa

Research Ethics Board
Conseil d'éthique en recherches
798-5555 ext 14146, 14902 or 15072
Fax No. ~ 761-4311
<http://www.ohri.ca/ohreb/>

Monday, March 03, 2008

Ms. Maggie Bryson
5 Kinalea Crescent
Ottawa, ON
K2S 1L1

Dear Ms. Bryson:

Re: Protocol # 2008065-01H Global Level Immunization Policy Decision Making Processes
Protocol approval valid until - Monday, March 02, 2009

I am pleased to inform you that this protocol underwent expedited review by the Ottawa Hospital Research Ethics Board (OHREB) and is approved. Approval is for the Thesis Proposal dated November 26, 2007, the English cover letter, the reminder letter, and the Questionnaire received January 29, 2008. No changes, amendments or addenda may be made to the protocol or the consent form without the OHREB's review and approval.

Further to Mary Ann Laviolette's email of February 28, 2008, Catherine Paquet, Interim Assistant-Director (Ethics) at the University of Ottawa, has confirmed that the contract between you and The Bill & Melinda Gates Foundation must be reviewed by the Technology Transfer Business Enterprise (TTBE) before you begin your research. TTBE can be reached at 613-562-5399. This approval is conditional upon receipt of their acceptance of the contract.

If the study is to continue beyond the expiry date noted above, a Renewal Form should be submitted to the OHREB approximately six weeks prior to the current expiry date. If the study has been completed by this date, a Termination Report should be submitted.

The Ottawa Hospital Research Ethics Board is constituted in accordance with, and operates in compliance with the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; Health Canada Good Clinical Practice: Consolidated Guideline; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Health Information Protection Act 2004 and its applicable Regulations.

Yours sincerely,

Raphael Saginur, M.D.
Chairman
Ottawa Hospital Research Ethics Board

/mal

APPENDIX B: SEARCH STRATEGIES

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 authori*) 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 authori* N3 polic* or TI authori* N3 decision or AB authori* N3 decision or AB authori* N3 polic*

5) decision making or policy making

6) 1 or 2 or 4 or 5

7) 6 & 3

APPENDIX C: DATA ABSTRACTION FORM

COUNTRY:

Review title: _____

Data Extraction Form

Reviewer: _____

Identification:

Article #: _____

Title: _____

Authors, Qualifications & Affiliations _____

Journal: _____

Year ____; Vol. ____; Starting Page _____

Contact address: _____

Source of sponsorship: _____

Comments: _____

Source of Information:

Published article Government Website Published report

Other/Comments _____

Presence of a National Advisory Committee:

Yes No Unknown

If Yes:

Membership:

Methods of Functioning:

Structure of meeting

Meeting frequency

Conduct of Meetings

Existence of other immunization committees in country/region (i.e. professional organizations):

Funding of Committee:

Committee's Authority:

Consideration of Evidence:

Communication Strategies:

Other Information:

All:

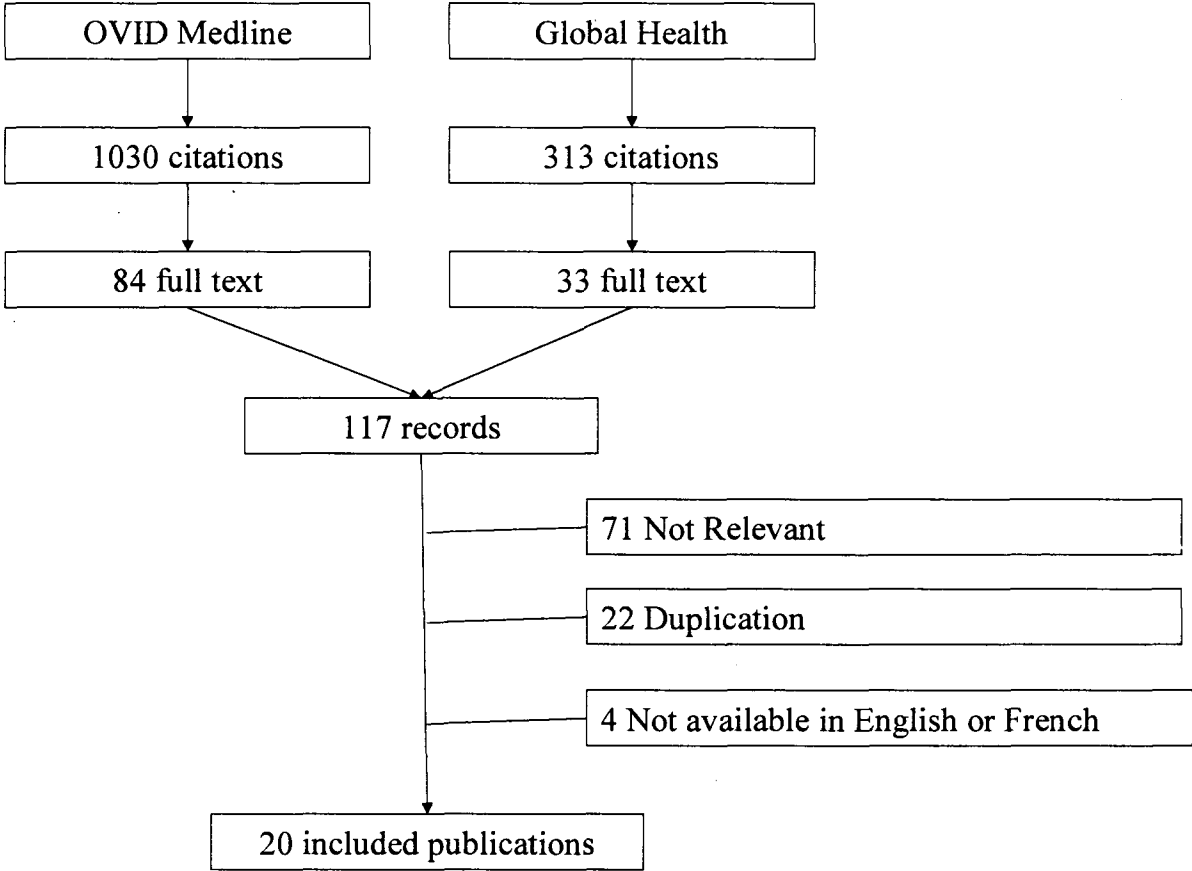
What is the process of decision making?

What is the role of manufacturers in the decision process?

What communication strategies are used once decisions are made?

Other:

APPENDIX D: FLOW DIAGRAM OF SEARCH STRATEGY AND REASONS FOR EXCLUSION OF ARTICLES



APPENDIX E: ANNOTATED BIBLIOGRAPHY

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
Australia	Unknown author, National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, 2004 (14)		YES	<ul style="list-style-type: none"> - liaison members - NCIRS has a core of experts related to immunization research and surveillance such as public health, preventative medicine, paediatrics, infectious disease, epidemiology, health economics, behavioural research and laboratory science which supports ATAGI 	<ul style="list-style-type: none"> - working groups support ATAGI 	<ul style="list-style-type: none"> - ATAGI receives evidence-based summaries of recent literature from health policy group of NCIRS
Australia	Welle, R., Trotter, C., Edmunds, J., Postma, M., & Beutels, P., The Role of Economic Evaluation in Vaccine Decision Making, 2005 (11)		YES			<ul style="list-style-type: none"> -uses economic evaluations & unpublished research in its decision making process (2005)
Australia	ATAGI website http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/atagi 2008 (28)		YES	<ul style="list-style-type: none"> - ex-officio members 	<ul style="list-style-type: none"> - Terms of reference outlined - appointed by the Minister to advise the Minister, PBAC, NHMRC on medical administration of vaccines - authors of the Australia Immunization Handbook - sets up working parties to consider specific issues in detail -meets 3 times per year - meeting minutes published on the website 	<ul style="list-style-type: none"> - as of 2005 ATAGI is no longer responsible for advising on funding of vaccines

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
Austria	Freed report (27)		YES	<ul style="list-style-type: none"> - approximately 16 members - members appointed by the minister - serves a 3 year term 	<ul style="list-style-type: none"> - vaccination advisory committee that is part of the Supreme Health Board named Impfausschus - responsible for advising on immunization programs in Austria - publishes an annual Vaccination Plan Booklet - meets 3 times per year - meetings closed to the public - meeting minutes are not published - final recommendations published in the Ministry of Health weekly newsletter, in the Journal of the Austrian Medical Association and on the websites of related professional associations 	
Brazil	Cuhna, S. & Dourado, I., MMR mass vaccination campaigns, vaccine-related adverse events, and the limits of the decision making process, in Brazil, 2004 (6)		YES			<ul style="list-style-type: none"> - decisions based on literature review and recommendations in other countries
Cambodia	Soeung, S., Grundy, J., Kamara, L., & McArthur, A., Developments in immunization planning in Cambodia -- rethinking the culture and organization of national program planning, 2007 (9)		YES		<ul style="list-style-type: none"> - identifies, implements, and monitors key national priorities in immunization management - supported financially by the Ministry of Finance and Health and international donors 	

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
Canada	Blume, S., Vaccine independence, local competences and globalisation: lessons from the history of pertussis vaccines, 2006 (15)		YES		- NACI makes immunization recommendations	- considers adverse events as well as efficacy when making recommendations
Canada	Erickson, L.J., De Wals, P., Farand, L., An analytical framework for immunization programs in Canada, 2005 (26)		YES		- NACI evaluated new vaccines	- important factors in making decisions: burden of disease, vaccine characteristics, immunization strategy, cost-effectiveness, acceptability, feasibility, ability to evaluate, research questions, equity, ethical considerations, legal considerations, conformity of programs, political considerations
Canada	Welte, R., Trotter, C., Edmunds, J., Postma, M., & Beutels, P., The Role of Economic Evaluation in Vaccine Decision Making, 2005 (11)		YES			- NACI uses economic evaluations in their decision making process
Canada	NACI website http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php 2008 (29)		YES	- NACI includes experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health - chair person, vice chair and 11 members (September 2008) - Members, the chair and vice chair appointed by the Chief Public Health Officer of Canada - The chair is a non-voting member	- NACI makes recommendations on the use of vaccines approved in Canada, including target groups and national vaccination strategies and vaccine development research - statements published in the online and every four years in the Canadian Immunization Guide - minutes and statements available online - meet 3 times a year and as needed by teleconference	- to develop recommendations, NACI does a review of the literature including economic analyses, reviews recommendations of other advisory groups such as the American ACIP, reviews the Canadian context of the disease and feasibility of the program, and finally, a grading of available evidence to determine if the level of evidence is sufficient to make a recommendation

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
Canada (cont'd from page 79)	NACI website http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php 2008 (29) (cont'd from page 79)			-Executive Secretary - 11 liaison representatives, 6 ex-officio members - term of 4 years	- meetings closed - NACI was established in 1964 - Only core members vote - Experts invited to make presentations - agenda items suggested to secretary and accepted by executive secretary and chair - Agenda is distributed 6 weeks prior to meetings - meetings are confidential -members declare potential conflicts of interest - working groups created as topics addressed	
China	DeRoock, D., Clemens, J.D., Nyamete, A. & Mahoney, R.T., Policymakers' views regarding the introduction of new-generation vaccines against typhoid fever, shigellosis and cholera in Asia, 2005 (22)	- disease burden, potential economic impact of disease and feasibility of local vaccine production are main factors in setting priorities	Not known			
Denmark	Cowan, S., Denmark decides not to introduce hepatitis B into the childhood vaccination programme, 2005 (16)	- National Board of Health conducted a medical technology assessment covering epidemiology, vaccine types, public knowledge and preferences, financial implications and health consequences of introducing hepatitis B into the vaccination program in making immunization recommendation	Not known			

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
France	Freed report (27)		YES	<ul style="list-style-type: none"> - Members of CTV consist of experts in infectious disease, public health, and clinicians - 16 voting members appointed by the Minister of Health - 15 ex-officio members 	<ul style="list-style-type: none"> - France has a Technical Committee on Vaccines (CTV) which makes recommendations on immunizations to the High Committee on Hygiene - CTV was established in 1997 - responsible for publishing The National Vaccination Guide every two years - CTV meets 6-8 times a year. - meetings closed to the public - meeting minutes are not published 	
Germany	Freed report (27)		YES	<ul style="list-style-type: none"> - 17 members appointed by the Minister of Health - experts in immunology, microbiology or clinical care - There is also a member representing insurance companies 	<ul style="list-style-type: none"> - STIKO is the committee in Germany which makes immunization recommendations to the federal government - publish an annual immunization guide & their recommendations are published by the Robert Koch Institute -STIKO meets twice a year 	

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
Ireland	Freed report (27)		YES	<ul style="list-style-type: none"> - The number of members on the IAC varies - there is no defined term for members 	<ul style="list-style-type: none"> - The National Immunization Advisory Committee (IAC) of the Royal College of Physicians of Ireland determines the national immunization program - make recommendations on immunization schedules to the Department of Health and Children - publishes Immunization Guidelines for Ireland every 2 years - approximately 6 IAC meetings per year - meetings are closed to the public - meeting minutes not published - recommendations made by consensus at a meeting and are rarely voted upon 	
Italy	Freed report (27)		YES	<ul style="list-style-type: none"> - Members are recommended by the Director General of Prevention of the Ministry of Health and selected by the Minister of Health - experts in pediatrics, public health, infectious disease, and health planning 	<ul style="list-style-type: none"> - Italy has a national vaccine committee, Commissione Nazionale Vaccini, which makes national recommendations to the Minister of Health 	<ul style="list-style-type: none"> - This committee analyzes the feasibility of implementing and funding this recommendation - If the recommendation is adopted, it is the responsibility of this committee to communicate the recommendation to health professionals

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
Mali	Sow, S. O., Diallo, S., Campbell, J. D., Tapia, M. D., Keita, T., Keita, M. M., et al., Burden of invasive disease caused by haemophilus influenzae type b in Bamako, Mali: Impetus for routine infant immunization with conjugate vaccine, 2005 (10)	- government considers burden of disease when making immunization policy	Not known			
The Netherlands	Blume, S., Vaccine independence, local competences and globalisation: lessons from the history of pertussis vaccines, 2006 (15)		YES		- Health Council (which advises the Minister of Health and Parliament on medical science) makes immunization recommendations - National immunization recommendations in the Netherlands are made by the National Immunization Committee	-uses surveillance data on burden of disease in the population
The Netherlands	Freed report (27)		YES			- recommendations based on the health of the population and although taken into consideration with economic evaluations, economic issues are considered secondary
The Netherlands	Welte, R., Trotter, C., Edmunds, J., Postma, M., & Beutels, P., The Role of Economic Evaluation in Vaccine Decision Making, 2005 (11)	- the Dutch government makes decisions based on economic evaluations				
The Netherlands	Welte R. van den Dobbelaer G. Bos JM. de Melker H. van Alphen L. Spanjaard L. Rumke HC. Postma MJ., Economic evaluation of meningococcal serogroup C conjugate vaccination programmes in The Netherlands and its impact on decision-making, 2004 (12)	- the Dutch government makes decisions based on economic evaluations				

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
New Zealand	O'Hallahan, J., Lennon, D., & Oster, P., The Strategy to Control New Zealand's Epidemic of Group B Meningococcal Disease, 2004 (7)		YES	- national advisory group exists in New Zealand with minority representation on the committee	- committee advises the government of New Zealand on immunization policy since at least 1980	- scientific evidence is used in making recommendations
New Zealand	Reid, S. Evolution of the New Zealand Childhood Immunization Schedule from 1980: a personal view, 2006 (25)		YES	- there is a chair	- Although they have a public health advisory committee, it is unclear their role in immunization policy making - The Immunisation Technical Working Group (ITWG) reviews the National Immunisation Schedule and provides recommendations to the Ministry of Health - the final recommendations are published on their website	
New Zealand	Website http://www.moh.govt.nz/moh.nsf/indexmh/immunisation-schedule#review (30)		YES	- The ITWG are an expert advisory committee, made up of paediatricians, microbiologists, infectious disease physicians, a general practitioner, and a registered nurse/immunisation coordinator		
Norway	Wisloff, T., Abrahamsen, T., G., Bergsaker, M. A., Lovoll, O., Moller, P., Pedersen, M. K., et al., Cost effectiveness of adding 7-valent pneumococcal conjugate (PCV-7) vaccine to the Norwegian childhood vaccination program, 2006 (13)	- Norwegian government, Ministry of Health and Ministry of Finance use cost-effectiveness data during the decision process of which vaccines to implement	Not known			

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
Papua New Guinea	Duke, T., Slow but steady progress in child health in Papua New Guinea, 2004 (23)	<ul style="list-style-type: none"> - Papua New Guinea Paediatric Society proposes policy & have been influential in shaping public child health policy - meet annually to discuss child health - include evidence in their recommendations - publish guidelines 	Not known			
Portugal	Welte, R., Trotter, C., Edmunds, J., Postma, M., & Beutels, P., The Role of Economic Evaluation in Vaccine Decision Making, 2005 (11)	<ul style="list-style-type: none"> - the National Vaccination Plan Committee decided to introduce the MCC vaccine based on economic evaluations 	Not known			
Spain	Freed report (27)		YES	<ul style="list-style-type: none"> - members are usually physician trained health administrators - there is no term limit 	<ul style="list-style-type: none"> - Government officials and invited experts attend meetings - recommendations made by consensus of working group members 	<ul style="list-style-type: none"> - decisions are made by considering disease burden and vaccine efficacy and safety and not financial aspects
Sweden	Freed report (27)	<ul style="list-style-type: none"> - Sweden does not have an advisory committee external to its government. The National Board of Health and Welfare (NB) is a government advisory agency which develops immunization recommendations - advisory group works with the Swedish Institute for Infectious Diseases (SMI) which provides epidemiological data on infectious disease - Uses all available data in making recommendations 	NO			

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
Switzerland	Freed report (27)		YES	<ul style="list-style-type: none"> - majority of members are external to the government officials from the immunization program - 15 members - serve a 4 year term - chosen based on areas of expertise that should be represented on the committee 	<ul style="list-style-type: none"> - formed in 2004 - meets 5 times per year - meetings are not open to the public - meeting minutes are not published - all discussions of the committee are confidential - Recommendations are made by a majority vote by members 	<ul style="list-style-type: none"> - evaluates each vaccine systematically and takes into account economic factors - takes into consideration the recommendations of other countries
Switzerland	Welte, R., Trotter, C., Edmunds, J., Postma, M., & Beutels, P., The Role of Economic Evaluation in Vaccine Decision Making, 2005 (11)	<ul style="list-style-type: none"> - Swiss government uses epidemiological, immunological, and biological evidence when making policy 				
Thailand	Munira, S.L., Fritzen, S.A., What influences government adoption of vaccines in developing countries? A policy process analysis, 2007 (8)	<ul style="list-style-type: none"> - introduction of hepatitis B vaccine involved the Ministry of Public Health's Department of Communicable Disease Control, the Thai Medical Association, the pharmaceutical industry and the media - have formed disease specific ITAG but final decision making had to be screened and approved by the Minister of Public Health -committee used evidence including disease burden, prevalence of carriers, cost-effectiveness of vaccine 	Not known			

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
UK	Freed report (27)		YES		<ul style="list-style-type: none"> - established in 1963 - closed meetings - minutes public - members declare conflict of interest - manufacturers not allowed at meetings - members are selected by an independent appointment commission and appointed by the Minister of Health 	
UK	Salisbury, D., Development of Immunization Policy and its Implementation in the United Kingdom, 2005 (20)		YES	<ul style="list-style-type: none"> - 18 members - experts in public health, child health, primary care, nursing, microbiology, immunology, infectious disease and one lay representative. - ex-officio members 	<ul style="list-style-type: none"> - JCVI established in 1963 under the NHS Act 1977 - 3 meetings per year - closed meetings - observers permitted - subcommittees meet as needed - meetings confidential to ensure research confidentiality, commercial confidentiality, advice to government on issues of bioterrorism - publishes minutes, agenda, annual report, recommendations, interests of members and code of practice online - no executive function -- solely provides advice and recommendations 	<ul style="list-style-type: none"> - considers cost-benefit results - JCVI recommendations are communicated to the chief medical health officer and health ministers by the Department of Health

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
UK	JCVI website http://www.advisorybodies.doh.gov.uk/jcvi/2008 (31)		YES	- a chairman and 14 members - 4 ex-officio members -serve for four years duration normally - members declare conflicts of interest	- JCVI established in 1963 - Terms of Reference are: "To advise the Secretaries of State for Health, Scotland, Wales and Northern Ireland on matters relating to communicable diseases, preventable and potentially preventable through immunisation." - agenda, meeting minutes and annual reports are published on the website - meetings are confidential - meet three times a year - recommendations published in "Immunisation against infectious diseases" and through other routes, for example Chief Medical Officer (CMO) Letters - members not paid	- JCVI takes into account the need for and impact of vaccines, the quality of vaccines - A systematic literature review ensures all current evidence is examined - also use unpublished research - an appraisal process assesses and interprets the evidence by considering its quality, validity, results and relevance - As part of this review process, recommendations or advice from international and national bodies (e.g. WHO, ACIP, IoM or NICE) is also considered - reference on website to grading of evidence tool
USA	Freed, G., Pathman, D., Konrad, T., Freeman, V., & Clark, S., Adopting Immunization Recommendations: A New Dissemination Model, 1998 (17)	- ACIP releases an immunization schedule jointly with CDC, American Academy of Pediatrics, and the American Academy of Family Physicians however recommendations are not always coordinated	YES			
USA	Mactosek, M., Coffield, A., Edwards, N., Flottemesch, T., Goodman, M., & Solberg, L., Priorities Among Effective Clinical Preventive Services, 2006 (18)		YES			- ACIP uses evidence in making their recommendations

Country	Source	Information given (other than re: ITAG)	ITAG	Membership	Methods of Functioning	Consideration of Evidence
USA	Milstein, J., Cash, R., Wecker, J., & Wikler, D., Development of Priority Vaccines for Disease-Endemic Countries: Risk and Benefit, 2005 (19)	- The American Academy of Pediatrics and the American Academy of Family Physicians provide input into policy & program decisions.	YES	- programmatic decisions are made by the ACIP in the USA		
USA	Offit, P. & Peter, G., The Meningococcal Vaccine – Public Policy and Individual Choices, 2003 (24)	- The ACIP, the American Academy of Pediatrics, and the CDC make immunization recommendations	YES			
USA	Terebuh, P., Uyeke, T., & Fukuda, K., Impact of influenza on young children and the shaping of United States influenza vaccine policy, 2003 (21)		YES			- recommendations based on published studies on burden of disease
USA	ACIP website http://www.cdc.gov/vaccines/re/cs/acip/default.htm 2008 (32)		YES	- 15 members including the chair - liaison members - 8 ex-officio members - can serve for terms of up to four years - Chair appointed for a 3-year term - Chair chosen from members who have been voting member for at least one year and have ability to lead the advisory committee and to work effectively with federal agencies and partner organizations. - Members who are not full-time federal employees are paid - Members and Chair selected by the Secretary and the CDC	- immunization recommendations for children and adults include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications - agendas and minutes are published online - meetings are open to the public - visitors must register in advance to observe the meetings - governed by Public Law - decisions made by vote - Meet about three times per year - recommendations available online	

APPENDIX F: QUESTIONNAIRE COVER LETTER

March 6, 2008

Dear National Immunization Manager,

The World Health Organization (WHO) is conducting a global level survey regarding national immunization policy decision making processes. The survey will document the existence and characteristics of national immunization advisory committees within each country and identify specific challenges and support needed from WHO. This will allow the organization to better serve its member states by increasing awareness and understanding the processes by which countries make immunization policy decisions. From this project, WHO will learn from successful experiences of countries and will be able to better target its support to countries and adjust its recommendations for setting-up national immunization technical advisory groups. The survey is being conducted with the support of the Public Health Agency of Canada and the University of Ottawa.

Each country which participates in this study will contribute to a complete global perspective that this project hopes to achieve. This project will disseminate information relating to immunization decision making for all nations to benefit from the experiences of others. Countries will benefit through learning the methods, various challenges, and strategies of other nations around the world. They will also benefit through the tailored support that WHO will provide in response to the survey. This survey provides an opportunity for each country to document their policy making needs and to express their needs to WHO.

While this survey is voluntary, we count on your participation and kindly ask that you complete and return the attached questionnaire by email to WHOITAGsurvey@who.int at your earliest convenience before 4 April 2008.

It is important that all countries respond to the questionnaire, those with an established immunization committee and those without. This will ensure an accurate description of the global situation. Responses will be kept confidential and data will only be reported in an aggregated manner. In the case that we believe your experiences could help others and we would like to share individual elements of your responses, we will contact you to obtain permission.

Your time and consideration is appreciated. We thank you in advance for your participation. It is only with your help that this project can be successful.

Sincerely,

Dr. Philippe Duclos
Senior Health Advisor, Department of Immunization, Vaccines and Biologicals
World Health Organization, Geneva, Switzerland

**APPENDIX G: QUESTIONNAIRE - NATIONAL LEVEL IMMUNIZATION
POLICY DECISION MAKING PROCESSES**

QUESTIONNAIRE

National level immunization policy decision making processes

The purpose of this questionnaire is to document the processes by which countries make recommendations regarding vaccines used in routine immunization schedules. WHO is seeking your input on your country's processes. This survey addresses the establishment of national technical advisory bodies. These groups can have varying titles but are referred to as Immunization Technical Advisory Groups in this survey. The work of immunization technical advisory groups is primarily technical and focuses on the topic of immunization. These groups are not synonymous with Interagency Coordinating Committees (ICCs). ICCs may offer policy recommendations on immunization; however, their work is primarily operational.

We thank you for taking the time to complete this questionnaire.

=====
Country:

Name:

Title:

Contact Information:

Section 1: Vaccination Policy Making

1) Please name all organizations (e.g. national institutions, national units within a health ministry, special state agency) which make recommendations on national immunization programs in your country.

For each organization listed, please specify if their recommendations focus on a specific population group and/or vaccine preventable disease.

Organization	Specific population group or vaccine preventable disease

2) What is current the process used by the Ministry of Health in determining which recommendations to adopt? Please check all that apply.

- Rely upon recommendations of a national immunization technical advisory group
- Follow guidelines from the World Health Organization headquarters
- Follow guidelines from the World Health Organization regional office
- Follow guidelines from a regional technical advisory group
- Follow guidelines from another country or group of countries. Please specify country(ies) in the text box below
- Decision made within Ministry of Health
- Other - Please list in the text box below

3) What are the sources of information used in making immunization policy decisions?
Please check all that apply.

- Country level interagency coordinating committees
- Government reports
- Intercountry meeting reports and recommendations
- National institutions (e.g. universities)
- National committee statements
- Neighboring countries' decisions: Please list countries in text box below
- Other countries' decisions: Please list countries in text box below
- Published studies
- Unpublished research conducted in your country
- WHO vaccine position papers
- Other: please list in text box below

4) Please name the ministry(ies) of government which are involved in the decision making process for immunizations.

5) Does your country have disease specific technical advisory group(s)? These groups would address specific vaccine preventable disease(s) but not all vaccine preventable diseases. These may be in addition to national immunization technical advisory groups or a country may solely have disease specific technical advisory groups.

- Yes
- No

6) Does your country have a national immunization technical advisory group which addresses immunization for all vaccine preventable diseases? This group is not the same as having an Interagency Coordinating Committee (ICC). It is a more specific, policy-oriented, technical group. Although the name of the committee may vary, these immunization technical advisory groups are permanent committees which deal exclusively with vaccine preventable diseases. They are not ad hoc committees with a narrow focus. If there is technical advisory group within a larger group which addresses all vaccine preventable diseases, please consider this group as your country's immunization technical advisory group.

- Yes
- No (**Please skip forward to question 8**)
- No current group but one existed in the past (**Please skip forward to question 8**)

7) How do these disease specific national technical advisory groups relate to the immunization technical advisory group? **(Please skip forward to question 9)**

8) If you do not have a national immunization national technical advisory group, would you like to establish an immunization technical advisory committee?

- Yes
- No

9) What are the main challenges encountered when making immunization policy decisions in your country?

10) What are the main successes experienced with respect to making immunization policy decisions in your country?

11) Is there anything you would like to change or improve with your country's immunization decision making?

12) What support (if any) could the World Health Organization provide to establish or strengthen your immunization technical advisory group?

**If your country has an immunization technical advisory group,
please continue on to section 2.**

If your country does not have an immunization technical advisory group, you have completed the questionnaire.

**Thank you for participating.
Your time and cooperation are appreciated.**

Please return the questionnaire by email to WHOITAGsurvey@who.int

Thank you again.

Section 2: Information on the Immunization Technical Advisory Group

13) What is the official name of the immunization technical advisory group?

14) In which year was this immunization technical advisory group established?

15) What is the mandate of your immunization technical advisory group?

16) Does the immunization technical advisory group have formal/written terms of reference (i.e. mode of functioning, etc.)?

- Yes (**Please attach at the end of the questionnaire**)
 No

17) Is there a legislative or administrative basis (e.g. law, decree, Ministerial directives) for the committee?

- Yes - Please describe in text box below
 No

18) What are the specific functions of your immunization technical advisory group?
Please check all that apply.

- Assist government to address issues of vaccine quality and safety
- Assist government in establishing immunization policies and strategies
- Evaluate new vaccines
- Evaluate new immunization technologies
- Promoting regional and national vaccine security
- Inform government on the public health needs for vaccine-preventable diseases
- Other - Please list in text box below

19) Does your immunization technical advisory group receive specific funding?

- Yes
- No (**Please skip forward to question 21**)

20) What are the immunization technical advisory group's sources of funding? Please check all that apply.

- Government funds
- WHO
- Non-Governmental Organization (NGO) funds
- Pharmaceutical company
- Other – Please list in text box below

Section 3: Membership of the Immunization Technical Advisory Group

Section 3a: Core Members

21) How many members are normally serving on the immunization technical advisory group? Please include only the core members who would be involved in the final decision making.

22) Through what process are members selected for the immunization technical advisory group?

23) How is the chair of the immunization technical advisory group selected?

24) Is there a defined duration of time which each member of the committee serves?

- Yes
- No (**Please skip forward to question 27**)

25) What is the duration of a term served by members on the immunization technical advisory group?

26) What is the maximum number of terms members can serve?

27) What professions or areas of expertise are represented on the immunization technical advisory group? Please check all that apply.

- Cold Chain expert/logistician
- Clinician (other than a pediatrician)
- Epidemiologist
- Health economist
- Immunologist
- Infectious disease expert
- Medical microbiologist
- Pediatrician
- Public health expert
- Representative of the public
- Statistical modeller
- Social scientist
- Other - Please list in the text box below

28) Do members receive any payment (other than travel costs) for serving on the immunization technical advisory group?

- Yes
- No

29) Do members make a declaration of potential conflicts of interest?

- Yes
 No

Section 3b: Ex-officio & Liaison Members

30) Does your immunization technical advisory group have ex-officio members? Ex-officio members are representatives from governmental departments which provide expertise to the committee but do not take part in the final decision making process. Ex-officio members are present at meetings to bring knowledge to technical advisory group discussions and express the views of the department they represent.

- Yes
 No

31) Does your immunization technical advisory group have liaison members? Liaison members are representatives from related organizations which provide expertise to the committee but do not take part in the final decision making process. Liaison members are present at meetings to bring knowledge to technical advisory group discussions and express the views of the organization they represent.

- Yes
 No **(please skip forward to question 38)**

32) Does your immunization technical advisory group have liaison members from academic or professional organizations?

- Yes
 No

33) Does your immunization technical advisory group have liaison members from pharmaceutical organizations?

- Yes
 No

34) Does your immunization technical advisory group have liaison members from non-governmental organizations (NGOs)?

- Yes
 No

35) Does your immunization technical advisory group have liaison members from international organizations or from other countries?

- Yes - Please list the international organization or countries in the text box below
 No

36) How many liaison members does your immunization technical advisory group have?

37) Please list the organizations which are represented by the liaison members.

Section 3c: Additional Players

38) What is the role of national Immunization Programme Manager within the immunization technical advisory group?

39) Is there an executive secretary appointed to the immunization technical advisory group? An executive secretary is generally responsible for organizing the logistics of the meetings as well as preparing any reports. They generally play a leadership role and work closely with the chairperson. They could be part of the Ministry of Health or may be one of the committee members.

- Yes
- No (please skip forward to question 41)

40) Is the executive secretary a formal member of the immunization technical advisory group?

- Yes
- No

Section 4: Meetings of the Immunization Technical Advisory Group

41) Do meetings occur at regular intervals or only when necessary? Please check all that apply.

- At regular intervals
- When necessary
- Other - Please list in the text box below

42) In 2007, how many times did your immunization technical advisory group meet?

43) In 2006, how many times did your immunization technical advisory group meet?

44) Who determines the agenda? Please check all that apply

- Ministry of Health
- Immunization technical advisory group chairperson
- Immunization technical advisory group members
- Other - Please describe in the text box below

45) Is the agenda circulated to the members ahead of the meetings?

- Yes
- No

46) Are background documents circulated to the members ahead of the meetings?

- Yes
- No

47) Which of the following statements describes the meetings best? Please select one answer.

- Meetings are open. Visitors are permitted to observe and remain for the entire meeting.
- Meetings are partially open. Visitors are permitted to observe but must leave for at least a part of the meeting for private discussion amongst members.
- Meetings are closed with exceptions by invitation only. Only members and those invited to attend the meeting are permitted in the meeting room for the entire meeting.
- Meetings are closed. Only members and those invited to attend the meeting are permitted in the meeting room. The people invited must leave when their presentation is completed.
- Other - Please describe in the text box below.

48) Is the information presented at meetings confidential?

- Yes
- No

49) Are meeting minutes recorded?

- Yes **(please attach latest minutes at the end of questionnaire)**
- No **(please skip forward to question 51)**

50) How are meeting minutes published? Please check all that apply.

- Government bulletin - Please indicate name in the text box below
- Journal or newsletter - Please indicate name in the text box below
- Website - Please indicate address in the text box below
- Other - Please describe in the text box below
- They are not published

51) Are there working groups which prepare information for the immunization technical advisory group meetings?

- Yes
- No **(please skip forward to question 53)**

- 52) Which of the following describes the working groups? Please check all that apply.
- Consist of immunization technical advisory group members
 - Consist of experts which are not members of immunization technical advisory group
 - Consist of Ministry of Health staff
 - Working groups are permanent groups
 - Working groups are ad hoc when needed

- 53) Are experts outside committee members invited to meetings to present information on specific topics?
- Yes
 - No

- 54) Are pharmaceutical industry representatives invited to meetings to present information on specific topics?
- Yes
 - No

Section 5: Decision Making Process of the Immunization Technical Advisory Group

- 55) Which of the following factors are considered when the immunization technical advisory group is making a recommendation? Please check all that apply.
- Actions in other countries
 - Disease burden in other countries
 - Disease burden in home country
 - Economic impact of the disease
 - Financial aspects (eg. cost-effectiveness, cost-benefit)
 - Ease of distribution of vaccine
 - Method of administration of vaccine (eg. lack of invasiveness)
 - Priority of vaccine related to other vaccine-preventable diseases
 - Priority of vaccine related to all other possible health interventions
 - Public health/epidemiology
 - Public perception of the disease
 - Recommendations from immunization technical advisory groups in other countries
 - Vaccine effectiveness
 - Vaccine safety
 - Other - Please describe in the text box below

56) From question 55, please list the five factors which are most important in making a recommendation.

57) Which of the following sources of information are used to inform recommendations? Please check all that apply.

- Consultations with working groups
- Expert opinion
- Government reports
- Pharmaceutical documents
- Published data and journal articles
- Regional technical advisory group documents
- Surveillance data
- WHO recommendations
- WHO position papers
- WHO technical documents
- Other - Please list in the text box below

58) From question 57, please list the three factors which are most important in making a recommendation.

59) To decide on recommendations, does the committee undertake in the following exercises? Please check all that apply.

- Committee consultation
- Literature review
- Systematic review. *A systematic review is a literature review which contains an explicit question, search strategy, inclusion and exclusion criteria, and an examination of the quality of research included in the review.*
- None of the above **(please skip forward to question 61)**
- Other - Please list in the text box below

60) How do you examine the quality of evidence collected by the method from question 59? **Please attach reference to questionnaire and/or provide reference below if possible.**

- Grading of evidence
- Quality checklist for each study included
- None
- Other – Please list in the text box below

61) How does the group reach its final conclusions/recommendations? Please select one answer.

- Consensus
- Vote
- Other - Please describe in the text box below

Section 6: Communication Strategies of the Immunization Technical Advisory Group

62) Are recommendations made by the immunization technical advisory group to the ministry of health confidential or public?

- Confidential
- Public
- Varies with recommendation

63) How are these recommendations communicated to the ministry of health?

64) How are these recommendations communicated to the public? If a website is used, please provide the website address.

65) How are these recommendations communicated to practicing health professionals?

Section 7: Future directions

66) What are the elements of functioning of your immunization technical advisory group which need strengthening?

Reminder

Please attach

- 1) the immunization technical advisory group's formal terms of reference
- 2) the latest meeting minutes from ITAG meeting
- 3) the tool used in the recommendation process (e.g. grading of evidence by an expert or quality checklist)

**Thank you for completing this questionnaire.
Your time and cooperation are appreciated.**

Please return the questionnaire by email to WHOITAGsurvey@who.int

Thank you again.

APPENDIX H: QUESTIONNAIRE FOLLOW UP LETTER

March 25, 2008

Dear National Immunization Manager,

Please accept this letter as a reminder of the survey mailed to you on March 6, 2008. The World Health Organization is conducting a global level survey regarding national immunization policy decision making processes. As previously stated, the survey is part of a wider project to support the establishment and strengthening of national policy decision making processes. The survey will document the existence and characteristics of national immunization advisory committees within each country and identify specific challenges and support needed from WHO. This will allow the organization to better serve its member states by increasing awareness and understanding the processes by which countries make immunization decisions.

Each country which participates in this study will contribute to a complete global perspective that this project hopes to achieve. This project will disseminate information relating to immunization decision making for all nations to benefit from the experiences of others. Countries will benefit through learning the methods, various challenges, and strategies of other nations around the world. This survey provides an opportunity for each country to document their policy making needs and to express their needs to WHO. Every survey completed and returned is of great importance and will impact the success of the study.

We are requesting that you please take a few moments now to complete and return the questionnaire to WHOITAGsurvey@who.int. If you have already emailed the questionnaire, would you kindly resend the email, as it has not yet been received.

Thank you for your time, consideration, and participation.

Sincerely,

Dr. Philippe Duclos
Senior Health Advisor, Department of Immunization, Vaccines and Biologicals
World Health Organization, Geneva, Switzerland