



## A global look at national Immunization Technical Advisory Groups

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### ABSTRACT

This paper presents the results of a global survey that aimed to collect information on country's immunization policy development processes, particularly on the presence and function of national Immunization Technical Advisory Groups (ITAGs). Characteristics of national ITAGs are described as well as attributes of these groups that appear to be imperative for an effective ITAG. ITAGs provide a valued service to over 89 countries that reported their establishment, some of which have been in existence for over 40 years. This paper provides basic information on the functioning of these groups and encourages future efforts to address gaps in knowledge and research in this area.

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### 1. Introduction

Immunization Technical Advisory Groups (ITAGs) are expert advisory committees that provide recommendations to guide a country's national immunization programs and policies [1]. They consist of independent experts with the technical capacity to evaluate new and existing immunization interventions. The premise of these groups is to facilitate a systematic, transparent process for developing immunization policies by making evidence-based technical recommendations to the national government [1]. Their role is primarily technical and advisory and is intended to bring increased scientific rigour and credibility to the complex 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-making processes identified the presence of 14 national ITAGs [2] with the most information being available for those in Australia, Canada, the United Kingdom, and the United States of America [3–6]. The limited information relating to the size, membership, meeting structure, methods of functioning, and processes of final decision-making that was available indicated that these attributes varied greatly across ITAGs [2].

Despite the limited information published, overall there is recognition of the importance of national ITAGs. Supporting coun-

tries in strengthening or establishing national ITAGs is a priority for WHO at headquarters and at the regional level [7–10].

We conducted a global survey to collect information on the development processes guiding 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 development processes, particularly detailing the form and function of national ITAGs.

This paper reports the results collected from countries with a national ITAG while the results of all respondents are summarized elsewhere [11]. Characteristics of national ITAGs are described as well as attributes of these groups that would seem important for an effective ITAG.

### 2. Methods

The information reported in this paper was collected through two questionnaires. One questionnaire, hereinafter referred to as the global questionnaire, included all member states of the African, American, Eastern-Mediterranean, South-East Asian, and Western Pacific regions (140 countries) as per WHO subdivision [12]. The other questionnaire, hereinafter referred to as the European questionnaire, surveyed the Member States of WHO within the European region (53 countries) [13]. These countries were sampled separately as this was an already ongoing regional initiative. The questionnaires were similar as the European had been adjusted to enhance compatibility.

The methods of the global survey are described in detail in another paper [11]. However, in order to facilitate comparison, a

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brief summary of the methods used in both surveys is included here.

Many of the questions on the global and European questionnaires were identical and common topics included the terms of reference, membership and 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.

The 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 closed questions in both questionnaires; however, the list of choices was more extensive on the global questionnaire. All closed questions had an open-ended component offering the opportunity to list other possible responses which were not listed. Where appropriate, the results from the two questionnaires were combined for this paper. Although the data from the European questionnaire has been published [13], some of the specific data used in this paper to calculate global statistics were not published.

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.

The global and the European questionnaires were distributed through the WHO regional offices to each country for completion by the immunization manager or someone knowledgeable in the immunization development processes of the country such as the national ITAG chairperson. Both questionnaires prepared in English were translated into appropriate languages for the WHO regions (including French, Portuguese, Spanish and Russian).

The global questionnaire was distributed in March 2008 and the European questionnaire in April 2008 [13]. The questionnaires and follow up letters encouraging participation were distributed by electronic mail. The majority were returned by electronic mail however, there were also hand-written questionnaires returned by mail and fax.

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 depending on the number of expected responses. Responses were analyzed by geographic region as defined by WHO [12] and by development status as defined by the United Nations [14].

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 based on their experience working in the topic area. As the characteristics and methods of functioning of the ITAG depend on the context of a country, this was taken into consideration when creating the list.

The first indicator was 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. Another indicator 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 third best practice indicator was that at least five areas of expertise were represented on the ITAG 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.

Another indicator used was that the ITAG met at least once a year. This ensures that the ITAG is active and meets frequently to discuss current issues and ensures the vaccine schedule for the country is adequate. Another criterion was that an agenda was distributed prior to the meeting to enable an informed discussion amongst members.

The final best practice indicator 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.

### 3. Results

#### 3.1. Response rate

In total, of the 193 eligible countries for the two questionnaires, 147 (76%) responded. The response rate to the global questionnaire was 71% (100 of 140 countries surveyed) while that of the European questionnaire was 89% (47 of 53 countries) [13]. The South-East Asian and the Eastern-Mediterranean regions had the highest response rates (91%, 10 of 11 and 19 of 21 member states, respectively). In contrast, the Western Pacific region had the lowest at 41% (11 of 27 member states).

Twenty one percent ( $n = 31$  of 147) of 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.

#### 3.2. Presence of ITAG

The presence of a national ITAG was reported by 61% ( $n = 89$  of 147) of countries that responded. 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 [13]) 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.

Developed countries had the highest reported rate of national ITAGs (94%,  $n = 29$ ) followed by developing countries (69%,  $n = 43$ ), countries with economies in transition (35%,  $n = 6$ ) and least developed countries (30%,  $n = 11$ ).

#### 3.3. Characteristics of ITAGs

The oldest ITAGs were established in the United Kingdom in 1963 and in Canada and the United States of America in 1964. The median and mode of the reported year of establishment was 2000 with 12 ITAGs being established in that year.

The reported mandate of ITAGs varied slightly but generally was to advise the government on technical issues related to national immunization programs such as recommendations on vaccine use. Some countries indicated that their ITAGs were responsible for monitoring adverse events as well as providing advice during disease outbreaks.

In reviewing the common functions of ITAGs, excluding the European region, were to provide guidance on issues of vaccine quality and safety (95%,  $n = 52$  of 55) and in establishing immunization policies and strategies (87%,  $n = 48$  of 55). Many ITAGs also reported evaluating new vaccines (78%,  $n = 43$  of 55) or evaluating new immunization technologies (69%,  $n = 38$  of 55). Promoting regional and national vaccine security was a function of 62% ( $n = 34$  of 55) of national ITAGs while 49% ( $n = 27$  of 55) informed the government of public health needs in vaccine-preventable diseases. Other functions were reported by 18% ( $n = 10$  of 55) of ITAGs including: financing immunization activities, training in areas of vaccination, investigation of adverse events, 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.

Many national ITAGs reported having formal terms of reference (68%,  $n = 57$  of 84) and slightly more reported having legislative or administrative mandates such as laws, decrees, or Ministerial directives that recognize the establishment of the ITAG (73%,  $n = 61$  of 82). An administrative mandate such as a ministerial decree or directive from the Ministry of Health was more commonly reported than a legislative mandate.

### 3.4. Membership of ITAGs

The median number of ITAG core members was 12 with 2–10 (median of 7) professions or areas of expertise represented. 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 majority of countries also reported the presence of infectious disease experts ( $n = 68$  of 88), clinicians (other than pediatricians) ( $n = 60$  of 88), immunologists ( $n = 58$  of 88) and medical microbiologists\* ( $n = 29$  of 54) on their national ITAGs. Cold chain experts/logisticians ( $n = 25$  of 54, 46%)\* were also relatively common members of national ITAGs. Only 24 of 88 (27%) countries reported the presence of a health economist on their national ITAG. Fewer than 20% of ITAGs had representatives of the public\*, statistical modellers\*, or social scientists\* as members.

About half ( $n = 42$  of 88, 48%) of countries reported the presence of experts in areas other than those listed. The most common included scientific research, nursing, pharmacy, immunization program managers, and drug regulatory authorities.

The methods of selection of the ITAG chair 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.

Ex-officio members were reported by 45% ( $n = 39$  of 87) of the national ITAGs and liaison members were reported by 53% ( $n = 46$  of 86). The two questionnaires revealed that 39% ( $n = 33$  of 84) of ITAGs required members to declare potential conflicts of interest.

### 3.5. Decision-making processes for issuance of recommendations

Countries reported that ITAGs take many factors into consideration when making recommendations (Table 1). It was reported that all ITAGs consider vaccine safety and all except one consider national disease burden when making recommendations. The global questionnaire found that almost all countries considered

**Table 1**

Factors considered when the national ITAG makes recommendations.

	Factor considered, $n$ (%)
Both questionnaires, $N = 88$	
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)
Global questionnaire only, $N = 54$	
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)
European questionnaire only, $N = 34$	
Severity of disease prevented	34 (100)
Adequate vaccine supply	32 (94)
Inclusion of vaccine in expanded program on immunizations	26 (76)
Global and European questionnaires, $N = 88$	
Other	20 (23)

vaccine effectiveness (98%,  $n = 53$  of 54)\* while over 80% considered financial aspects of the vaccine (such as cost-effectiveness or cost-benefit) and economic impact\* as a factor.

Factors considered by national ITAGs when making recommendations, in addition to the above, included an adequate supply of vaccine, feasibility of the program, WHO recommendations, sustainability, ability to attain high coverage, and alignment with global health goals.

Countries reported that ITAGs use many sources of information when making recommendations (Table 2) such as WHO vaccine 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 (5%) did not report using WHO vaccine position papers, recommendations, or technical documents as sources of information while 42 of 54 countries (78%)\* reported that their ITAGs use all three.

Countries also reported using unpublished data, health technology assessments, conference papers, vaccine books, recommendations from ITAGs in other countries, and recommendations from national professional societies as sources of information.

**Table 2**

Sources of information used by national ITAGs to inform recommendations.

	Source used, $n$ (%)
Both questionnaires, $N = 88$	
WHO position papers	78 (89)
Published data and journal articles	77 (88)
Pharmaceutical documents	61 (69)
Government reports	60 (68)
Global questionnaire only, $N = 54$	
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)
Global and European questionnaire, $N = 88$	
Other	15 (17)

\* Excludes European region.

**Table 3**  
Components of a well functioning national ITAG and number of countries that met the criteria (out of 89 countries reporting the existence of an active ITAG).

Criteria	Number of countries, n (%)
ITAG with formal terms of reference.	57 (64%)
Legislative or administrative basis for the ITAG.	61 (69%)
At least five areas of expertise represented on the ITAG.	78 (88%)
ITAG has met at least once in 2006 and once in 2007 (provided they were established in these 2 years).	76 (85%)
Agenda distributed to members prior to ITAG meetings.	86 (97%)
ITAG members must declare conflicts of interest.	33 (37%)
All of the above six indicators met.	23 (26%)

### 3.6. Best practices

Between 33 and 86 countries met each process indicator, with only 23 of the 89 countries with national ITAGs meeting all six process indicators of well functioning ITAGs (Table 3): had formal terms of reference, had legislative or administrative mandates, had 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. Most of these countries were developed countries based in the European region.

## 4. 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 ( $n = 50$ ) of national ITAGs have been created reflecting the increasing interest and value seen in the presence of these groups. The value of these groups is also demonstrated by the reported 89 ITAGs that exist worldwide and that there are no known national ITAGs that have been created and then subsequently dissolved suggesting that ITAGs provide an important service.

Twenty-three of 147 respondent countries met all of the six process indicators identified by the authors for adequate functioning of an established national ITAG, thereby demonstrating that the indicators are achievable. Meeting all of the criteria does not necessarily imply that these ITAGs function efficiently or that other ITAGs are not effective – each ITAG has strengths and weaknesses. However, these ITAGs possess what we believe to be the minimum required criteria of an ideal ITAG.

The validity of the responses in this survey is unknown. When compared with a systematic review on the same topic [2], 12 of the 14 countries who reported having national ITAGs were consistent in their survey responses. One of the countries mistakenly reported the presence of an ITAG in the survey but this group is within the national government [15] 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. One exception was the number of members reported which may have been due to membership changes between the date of publication of the sources and the time when the survey was completed.

The main limitation of this study is the collection of data through two different questionnaires, due to the exclusion of the European region from the global survey. The information from the European region is more limited and hence could not be aggregated with the rest of the data for all criteria. As a result, there is not global level data 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. There was at least one inaccurate translation into Spanish that resulted in missing data for the intended question from 12 countries. Lastly, the information was collected through self-report and hence may not have reflected actual practice.

Although national ITAGs appear to be valued and have a strong global presence, the credibility of the group lies in true independence from the government. There appears to be overlap between government employees and core members on some ITAGs. While it is important to have a close relationship between the government, who is generally responsible for the final immunization policy and its implementation, and the national ITAG, it is crucial that government representatives are not core members of the group who participate in making final recommendations to maintain the independence and credibility of the ITAG.

There is a need for clear definitions and general guidelines on national ITAGs outlining their mandates and examples of ideal modes of functioning. The findings from this survey support the need for the development of best practices for national ITAGs that should ideally be based on scientific evaluation of existing ITAGs to guide the establishment and improvement of national ITAGs. Evaluation of existing ITAGs and their outcomes should be conducted in order to provide evidence in support of these groups and varying modes of operation.

As an example of best practices for national ITAGs, this paper outlined a list of six criteria to assess national ITAGs. A criticism of the criteria could be the focus on process indicators and lack of outcome measures. 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 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 their financial situation.

This paper provides baseline information that could be used to guide international discussion aiming to reach a global 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 those that exist. Various WHO initiatives are in progress to strengthen national ITAGs. 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 region [1]. There is an initiative within the European region that aims at disseminating knowledge and best practices on immunization and offers a platform to share information [16]. There are currently 29 countries, mostly members of the European Union, participating in this initiative [16].

In summary, this paper provides a global overview of Immunization Technical Advisory Groups – a topic with little previously published literature. This is the first known collection of global information on ITAGs. It provides a starting point with basic infor-

mation on the functioning of these groups and encourages future efforts to address gaps in knowledge and research in this area.

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### Conflict of interest statement

The authors state that they have no conflict of interest.

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