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Informing decision makers: Experience and process of 15 National Immunization Technical Advisory Groups☆

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ABSTRACT

This supplement of *Vaccine* contains detailed descriptions of the experiences and processes of 15 well-established National Immunization Technical Advisory Committees from all regions of the world. All of these committees provide information to national governments that is used to make evidence-based decisions regarding vaccine and immunization policy. Nevertheless, many differences between committees exist including their legal basis, size and scope of committee membership, scope of work, role of the Ministry of Health on the committee, existence of conflict of interest policies, and ultimate role in the decision-making process. Individual country authors identified numerous areas for improvement and these are summarized here.

1. Introduction and background

Compared to the wealth of information on immunizations and vaccines, there is a paucity of published information on National Immunization Technical Advisory Groups (NITAGs) [1]. The current *Vaccine* supplement was developed to provide examples and insight on the functioning of well-established committees. The purpose of the supplement is to inform other countries wishing to establish or revise their own NITAG on the composition and functioning of 15 NITAGs from all regions of the world.

The process was conceived and implemented by the Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative (which is described in a separate article) [2]. The process for selecting countries for inclusion was based on an informal solicitation of opinion from World Health Organization (WHO) staff – with a view toward identifying well-established committees from all regions of the world – supplemented by expert advice from government officials and public health experts. Twenty countries were approached and 15 were eventually included (Australia, Canada, China, France, Honduras, India, the Islamic Republic of Iran, the Sultanate of Oman, South Africa, Republic of Korea, Sri Lanka, Switzerland, Thailand, the United Kingdom, and the United States) [3–17]. Countries included here are not exhaustive of strong committees either globally or regionally.

We did not use a systematic process to obtain results for specific NITAG features. Country authors were sent a framework developed by the SIVAC team in order to guide them in considering what to develop in their manuscript. Categories of topics the authors were asked to address included: (1) description and background, including committee membership and historical perspective; (2) terms of reference and meeting process, including declaration of interests by members; (3) development of recommendations and the basis for decision making, including the role of working groups; (4) the role played by economic evaluations and other financial issues in decision making; (5) the role of the committee in the ultimate decision-making process, including case studies of recent key committee decisions; (6) the role of manufacturers, insurers, and other private and professional interests; (7) communication activities and training practices; (8) problems encountered, limitations, and future developments; and (9) summary and conclusions. The authors themselves made the final decision of what to include and highlight and in view of the space constraints it is likely that authors did not list all potentially relevant aspects of their committees. Consequently, absence of information should not be interpreted as absence of process unless otherwise specified.

Abbreviations: MOH, Ministry of Health; NITAG, National Immunization Technical Advisory Group; SIVAC, Supporting Independent Immunization and Vaccine Advisory Committees; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

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The resulting publications highlight the variety of approaches taken by NITAGs and provide examples, successes and challenges faced by these groups. The articles also provide information from an evolving group of committees that were formed as early as the 1960s (in the case of Canada, Sri Lanka, the United Kingdom, and the United States) to within the past 10 years (in the case of India, Oman, South Africa, and Switzerland); when reading committee descriptions and processes, the reader should keep differences in the duration of committee existence in mind. The reader also should keep in mind this synthesis includes data from in-depth reporting provided by a few countries while the article by Bryson et al. [1] provides a broader but less detailed overview. Consequently, the data in the two articles are not necessarily directly comparable.

All of the NITAGs reviewed here have an established record of providing support and guidance on vaccine and immunization-related issues to national decision makers. This has been achieved despite considerable differences in committee structure, function, and responsibilities. The article included here by Duclos [18] on WHO guidance for NITAGs, through its flexible recommendations, recognizes that local contexts may require a variety of approaches by countries to maximize the influence of NITAGs on the decision-making process.

For the purposes of this document we will use the term Ministry of Health (MOH) to refer to government decision-making bodies existing within the central government or executive branch. Additionally, not every country has a committee with responsibilities limited to immunizations and vaccines. Nevertheless, we will use the term NITAG to refer to all committees.

2. Synthesis of results

2.1. Legal structure

All of the NITAGs included in this supplement report a federal government-sanctioned basis for their creation. Two basic models exist, namely ministerial or executive branch decree or a legislative act. The former is by far more common with only the United States, United Kingdom, South Korea, and Sri Lanka indicating the existence of a law authorizing committee creation.

2.2. Scope of work

The vast majority of NITAGs report operating under specific mandates or terms of reference. The relative merits of broad versus narrow mandates are subject to debate, and both models have advantages and disadvantages. Ten of the committees report that their mandate is limited to vaccines and immunizations (often including immunoglobulins) while five have broader mandates to work in other areas of communicable disease control. The broadest mandate reported is that for China, which included recommendations on vaccines and immunizations, recommendations on other communicable diseases, design and implementation of education and research studies, vaccine preventable disease surveillance policy, outbreak response, and programmatic issues such as vaccine supply.

Within the realm of vaccines and immunizations, all NITAGs specifically report that their role includes developing recommendations on new vaccine introduction and schedules. Other common activities reported include recommendations related to high-risk groups, vaccine formulation, research priorities, and implications of adverse events. Other less commonly reported topics for which committees issue recommendations include those for vaccine coverage, logistics, supply, and regulation; supplementary immunization activities (for example, activities associated with polio eradication); vaccine and immunization program financing; and communicable or vaccine preventable disease surveillance, control, or outbreak response. Additional activities include responding to questions from key groups or the public and educational efforts related to vaccines and immunization.

2.3. Committee membership

The process of committee member nomination is diverse. The broadest recruitment process is used by countries like the United States and United Kingdom, which advertise nationally and accept nominations from any source. In France, nominations come through the general medical community. In four countries, members are selected based on positions allocated to the central government or professional organizations. In the case of the former, members serve as long as they remain in their position and in the case of the latter they are nominated by the organization. For the remaining five countries for whom this information is known, the MOH, the NITAG itself, or both put forward nominations.

Regardless of the nomination process, MOH representatives play a central role on almost all the committees, either by virtue of holding the position of chairperson or secretary, holding various fixed positions, or acting as the committee secretariat. In some instances, numerous MOH agencies (including regulatory) have committee representation.

Expertise represented on the committees is primarily medical or public health and includes paediatricians, family practitioners, infectious disease experts, experts on vaccinology or immunization, public health experts, and in rare cases economists. Community representation was included on four committees: a consumer representative in South Korea and the United States, a consumer expert in Australia, and a “lay person” in the United Kingdom.

Appointment to committees varies from 2 years to unlimited, for example, positions assigned to specific government positions. The most common duration is 4 years, and usually reappointment is allowed (either a limited or indefinite number of times). Korea, with the shortest period of appointment at 2 years, does not allow reappointment nor does the United States.

The total number of official committee members that vote or participate in consensus decisions (depending on the decision-making process) varies from 5 in Honduras (all paediatricians) and 10 in Oman to 33 in India and 38 in Sri Lanka. The median number is 19. In some cases, the size of the committees is augmented to a large degree by numerous liaison and *ex officio* members.

Most committees include *ex officio* or liaison members, implying that these persons or organizations may participate but not vote. These members usually include government representatives from Expanded Program on Immunization programs or programs related to disease control, regulatory affairs, and in one case a government vaccine producer. Other *ex officio* or liaison members include representatives of professional organizations, UNICEF, and WHO. Differences between committees may reflect in part differences in the definitions and roles of liaison and *ex officio* members.

Except in the one case of a government vaccine producer, pharmaceutical companies do not have formal representation or voting rights on the committees. In 6 of 10 NITAGs that report this information, however, industry representatives are allowed to attend meetings and present information when necessary.

2.4. Meeting procedures

Most countries report regularly scheduled NITAG meetings, ranging from 1 to 8 per year, and in all cases but two of these countries also report *ad hoc* meetings to address urgent issues (most recently the influenza H1N1 pandemic). China and Thailand report that meetings are scheduled only *ad hoc*. The number of meetings

per year, however, may not measure the work or efficiency of particular NITAGs since meeting duration is variable, in some cases as short as a half day.

Among 12 NITAGs reporting this information, meetings are open to the public in only two countries (South Korea and the United States). However, four other countries indicated that specified members of the public could attend with a formal invitation.

The meeting agenda determines which topics the NITAG will discuss and thus is an important instrument in determining eventual policy. Eleven countries identify who determines the agenda and in most cases this includes the MOH either solely or in part. NITAG members themselves are also a common source of agenda items. Less frequently, NITAGs solicit or allow agenda items from private health care providers, WHO, professional organizations, and the public.

2.5. Data sources

The majority of NITAGs make use of working groups to assemble data for presentation to the full committee. These may be permanent, temporary but for a prescribed duration, or *ad hoc*. Size may vary from one to an unlimited number of persons. Working group membership consists in most cases of a NITAG member, usually in the role of working group chairperson. Other working group members may include government officials (which is obligatory in some countries), liaison or *ex officio* members, and invited experts (either national or international).

Most countries do not report a codified and systematic process for collecting and evaluating data for the decision-making process. An example from one end of this spectrum is Canada, and the reader is encouraged to examine Table 4 of the Canadian manuscript [4]. Some countries identify specific epidemiological criteria that are considered (often in order of prioritization) when considering new vaccine recommendations, the most common of which is mortality attributable to the disease prevented by the vaccine. Other criteria identified include disability or quality adjusted life years lost, hospitalizations, morbidity, and epidemic potential for the disease in question plus issues of equity and the possibility of disease eradication.

Many countries report that they rely more and more frequently on local data and where reported universally indicate a preference for local data. Local data may be particularly relevant for diseases with highly variable epidemiology or for vaccines that behave differently in different populations. Committees not only use, or in some cases require local data but in most cases also make recommendations on additional local research and data that are needed before a decision can be made.

Economic evaluation data are considered by all committees with the exceptions of Australia and Canada (where a separate advisory committee evaluates economic issues). However, only the United Kingdom's committee uses specific cost-effectiveness cut-offs for making recommendations on including vaccines in the public vaccination schedule.

Five countries report that their committee considers financial sustainability when reviewing evidence (Iran, Korea, Oman, Sri Lanka, and Switzerland). The Sri Lankan committee reports that it does not recommend a vaccine unless it is certain that the country can sustain financing regardless of the availability of donor support such as through the GAVI mechanism. The other four committees do not report how financial sustainability issues affect committee recommendations. In contrast to these five countries, the remaining countries included in the supplement indicate that financing aspects are taken into consideration by the government after issuance of committee recommendations.

In general countries use all sources of data available to them. This may include peer-reviewed articles, findings of other NITAGs, WHO documents, regional data (for example, Oman shares data with other gulf countries), and local data (published or unpublished).

Beyond the use of data and publications from WHO, six countries report on the influence of WHO recommendations for final committee decisions. In three instances (Honduras, Oman, and Switzerland) the committee to date has supported all WHO recommendations. Three committees (South Africa, Thailand, and the United States) state that they modified WHO global recommendations to the local national circumstances.

Twelve NITAGs indicate the process by which final recommendations are made and in seven cases this is by consensus and in five by voting. Among groups that vote, this usually occurs by majority vote.

2.6. Conflict of interest policies

NITAG recommendations may have considerable implications for vaccine sales and thus most of the included manuscripts emphasize that committee members must be independent of pharmaceutical industry influence. Eleven of 13 countries reporting this information have some formal conflict of interest policy, but three of these indicate no written declaration is required. The remaining two countries (India and Sri Lanka) have no formal policy.

The consequences to committee members when they report a conflict of interest vary by country. For example, depending on the level of conflict, members of the Australian NITAG might participate and vote, participate but not vote, attend the meeting but remain silent, or be barred from the meeting altogether. The United Kingdom as well report a relatively nuanced policy, based on whether a conflict of interest is personal (e.g., stock ownership) or non-personal (such as involvement in a study through an academic institution) and whether the conflict is specific or not to the vaccine in question.

2.7. Ultimate role of the committee in the decision-making process

In most cases, authors report that committee recommendations are advisory and not legally binding. However, in five countries the committee has some form of legal responsibility for determining some or all policy related to the topics under their mandate. In Iran, for example, the government is obliged to implement committee recommendations, although no law requires this. In Oman and Sri Lanka, the government is legally obligated to implement recommendations. Recommendations from the United Kingdom also carry legal weight but a recommendation may be made only if economic data are convincing (as described above); otherwise, findings are considered advisory and are not legally binding. Lastly, the United States NITAG recommendations are advisory in most instances. The exception is the Vaccine for Children's Act, which regulates financing of vaccines for low income children; in this case, committee decisions determine which vaccines will be funded under this program.

Some countries specifically state that not all recommendations are followed, such as South Africa, South Korea, and Thailand, where budget limitations are the most common reason for lack of implementation of recommendations. Other countries, such as Honduras and Switzerland, report that decisions do not carry legal force but to date all recommendations have been implemented.

2.8. Areas identified for improvement

Almost all committees identified areas for improvement. Of great interest is that this is the area with the greatest variation in results, with very little overlap between committees. The most

Table 1
Areas for improvement identified by 15 National Immunization Technical Advisory groups.

Topic area
Better availability and use of economic data
Insufficient expertise on committee
Insufficient data available to committee
Insufficient independence from pharmaceutical industry influence
Increasing level of work
Broaden agenda to include programmatic issues
Improved coordination between government and committee
Lack of committee representation from all relevant stakeholders
Lack of specific scientific criteria for new vaccine approval
Lack of a specific conflict of interest policy
Improved availability of committee results
Insufficient committee funding
More transparency in committee processes
Lack of modelling expertise
Lack of legal force of committee decisions
Better decision-making process (in this case, voting instead of consensus)
Lack of presentation of recommendations in specific evidence-based format
Increasing demands from stakeholders
Presence of duplicate national committees with overlapping agendas for vaccines and immunizations
Lack of committee member pay
Improved interaction with other national committees
Insufficient public recognition of committee role
Need for more frequent meetings
Fulltime secretariat support
Insufficient implementation of committee recommendations
Need for formal working groups
Lack of formal committee terms of reference

commonly identified area for improvement (mentioned in eight reports) is in the realm of economic data including lack of policies regarding how to weigh economic data, lack of economic expertise on the committee, and insufficient weight given to economic data. The second most commonly identified area for improvement (mentioned in five reports) is lack of overall necessary expertise to reach optimal evidence-based decisions, followed by insufficient data availability, an increasing level of work, and insufficient committee independence from the pharmaceutical industry (three reports each) (Table 1).

3. Summary and conclusions

This supplement represents the first effort to pull together in one place the detailed processes and experiences of a set of well-established NITAGs. These committees are becoming more commonplace globally and the information presented by individual committees should provide valuable examples for other committees as well as for countries seeking to develop committees. These reports are particularly helpful in this respect as individual manuscript authors have provided a candid insider's view of committee functioning, with clear descriptions of NITAG structures, successes, and difficulties. Overall, examples of strong committees that provide evidence-based information to national decision makers exist from all regions of the world, from countries at various levels of socio-economic development, and from countries with both large and small populations.

Some commonalities seem important to emphasize. A government-sanctioned structure is essential, although it is probably not important whether this occurs through a government decree or legislative action. Most of the committees described here focus on the limited area of vaccines and immunizations although a broader scope is not necessarily problematic. The role of government in committees may raise concerns about committee independence from political influence. However, in the sample of committees presented here government influence – whether formally through committee membership, appointing committee members, serving as the secretariat or setting the meeting agenda – was large. It is not clear how this heavy involvement of government affects the influence of science in the decision-making process.

One of the most vexing issues for NITAGs is the proper role of vaccine manufacturers. Decisions about the purchase of vaccines have significant implications to both manufacturers and the taxpayer. It is therefore not surprising that all committees recognized the importance of minimizing the influence of manufacturers on the scientific process. Influence can occur through conflicts of interest for otherwise independent committee members and through direct participation of pharmaceutical representatives. With respect to the former, most committees have specific conflict of interest policies in place. It seems clear that this should be a fundamental component of the committee and should include written conflict of interest guidelines with specific policies in place for actions to deal with different levels of conflict of interest. With respect to direct pharmaceutical representative participation, all committees (with the exception of one committee that includes a local vaccine producer) indicated that industry did not participate in voting. However, some committees indicated that industry representation or participation was allowed at meetings. In this sense, financial or material influence must be differentiated from scientific information and industry may be the best source in some cases, such as safety data or the full portfolio of data on vaccine performance. This type of information may be provided through documents, telephone, or a specific invited meeting presentation without otherwise involving pharmaceutical representatives in the NITAG process, for example, the example of the United Kingdom. Other less obvious conflicts, such as competing priorities within different parts of the MOH and impact on private practitioners if governments recommend a vaccine free-of-charge through the public sector, were not explicitly addressed.

Official committee terms were relatively limited, but the option of reappointment made *de facto* committee terms lengthy in many countries. Many countries also cited a lack of local expertise and it is possible that this has influenced the decision by some countries to forego time-limited or short-term committee appointments.

The final impact of a committee is in its influence on policy. In most countries, committee decisions were advisory and thus their influence on policy derived from the respect in which national decision makers held the NITAG. In four countries, influence was assured through some measure of legal obligation conferred by committee decisions. Regardless, the most common reason provided for lack of implementation was financial limitations and in two countries in which recommendations carried a legal obligation this was true only if economic criteria were met. Thus it was not surprising that the most common area noted for improvement was more emphasis on economic issues.

Some may wonder why countries need NITAGs given the issuance of global or regional recommendations by WHO and its advisory bodies. Although many countries indicated that their recommendations were always in line with those of WHO, others reported that adjustment was necessary at the national level. This helps emphasize that while global or regional WHO guidance is important for countries to consider, NITAGs play a critical role in placing these recommendations into a context that considers local differences in national budgets, disease epidemiology, and health priorities. Moreover, WHO recommendations do not cover the full scope of vaccine and immunization issues of national concern.

NITAGs are likely to continue to increase in number and influence over vaccine policies. Many countries that do not have NITAGs

have taken decisions to initiate them, as evidenced by the recent inauguration of a NITAG in Cote d'Ivoire (with support from the SIVAC Initiative). NITAGs, including many of those reported in this supplement, have seen their workloads and responsibility increase, for example in response to the influenza pandemic. Because of this, it is essential that these committees function well and reach scientifically sound, evidence-based decisions. The information presented in this supplement from individual countries, WHO, and the global NITAG review should further this goal through sharing of both information as well as extensive examples of various models in committee structure and function.

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References

[1] Bryson M, Duclos P, Jolly A, Cakmak N. A global look at National Immunization Technical Advisory Groups. Vaccine 2010;28(Suppl. 1):A13–7.
[2] Senouci K, Blau J, Batmunkh N, Faye P, Gautier L, Da Silva A, et al. Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) initiative: a country-driven and multi-partner program. Vaccine 2010;28(Suppl. 1):A26–30.
[3] Nolan T. The Australian model of immunization advice and vaccine funding. Vaccine 2010;28(Suppl. 1):A76–85.
[4] Ismail S, Langley J, Harris T, Warshawsky B, Desai S, Farhang Mehr M. Canada's National Advisory Committee on Immunization (NACI): evidence-based decision making on vaccines and immunization. Vaccine 2010;28(Suppl. 1):A58–63.
[5] Zheng J, Zhou Y, Wang H, Liang X. The role of the China Advisory Committee on Immunization Practices (ACIP). Vaccine 2010;28(Suppl. 1):A86–9.
[6] Floret D, Deutsch P. The French Technical Vaccination Committee (CTV). Vaccine 2010;28(Suppl. 1):A42–7.
[7] Molina-Aguilera I, Mendoza-Rodriguez L, Palma-Rios M. Valenzuela-Castillo R An overview of the National Consultative Council of Immunization in Honduras Vaccine 2010;28(Suppl. 1):A64–7.
[8] Jacob JT. India's National Technical Advisory Group on Immunization. Vaccine 2010;28(Suppl. 1):A90–2.
[9] Zahraei SM, Marandi A, Sadrizade B, Gouya MM, Rezaei P, Vazirian P, et al. Role of National Immunization Technical Advisory Group on improvement of immunization programmes in the Islamic Republic of Iran. Vaccine 2010;28(Suppl. 1):A35–8.
[10] Al Awaidy S. The National Committee for Vaccines Regulation and Surveillance of Vaccine-Preventable Diseases in the Sultanate of Oman: evidence-based approach and consensus decision-making. Vaccine 2010;28(Suppl. 1):A39–41.
[11] Schoub BD, Madhi S, Ngcobo NJ. The National Advisory Group on Immunization (NAGI) of the Republic of South Africa. Vaccine 2010;28(Suppl. 1): A31–4.
[12] Cho H, Kim CH, Go UY. Immunization decision-making in the Republic of Korea: the structure and functioning of the Korea Advisory Committee on Immunization Practices. Vaccine 2010;28(Suppl. 1):A93–7.
[13] Wijesinghe PR, Palihawadana P, Pieris TSR. Participatory decision making through broadening immunization stakeholders in the Advisory Committee of the Communicable Diseases: the Sri Lankan experience. Vaccine 2010;28(Suppl. 1):A98–105.
[14] Masserey V. The Federal Vaccination Commission in Switzerland: an officially appointed independent commission insuring evidence-based recommendations and transparent procedures. Vaccine 2010;28(Suppl. 1):A48–53.
[15] Muangchana C. Immunization policy development in Thailand: the role of the Advisory Committee on Immunization Practices. Vaccine 2010;28(Suppl. 1):A106–11.
[16] Hall AJ. The United Kingdom Joint Committee on Vaccination and Immunisation. Vaccine 2010;28(Suppl. 1):A54–7.
[17] Smith JC. The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). Vaccine 2010;28(Suppl. 1):A68–75.
[18] Duclos P. National Immunization Technical Advisory Group (NITAGs): guidance for their establishment and strengthening. Vaccine 2010;28(Suppl. 1): A35–8.