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National Immunization Technical Advisory Groups (NITAGs): Guidance for their establishment and strengthening☆

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ABSTRACT

The majority of industrialized and some developing countries have formally established national technical advisory bodies to guide immunization policies; other countries are working towards or contemplating the establishment of such bodies. These advisory bodies are often referred to as National Immunization Technical Advisory Groups (NITAGs). A NITAG is a technical resource supplying guidance to national policy makers and programme managers to enable them to make evidence-based immunization related policy and program decisions. The focus of this paper is to: (1) review the value and functions of a NITAG; (2) provide directions and identify issues for countries to consider when establishing or improving the functioning of a NITAG; and (3) outline potential WHO and partners' roles and activities in support of the establishment and strengthening of NITAGs.

1. Background

While for many years, at both the global and the country levels, the focus of immunization programmes has been on infants and a limited number of traditional vaccines, the vaccine world has evolved with new demands and expectations of global and national policy makers, donors, other interested parties, and the public. The development and availability of several new vaccines targeting a variety of age groups, the emergence of new technologies, the increased public focus on vaccine safety issues, the enhanced procedures for regulation and approval of vaccines, the need to expand the immunization schedule with consideration of all age groups and specific at-risk populations are all demanding increased attention [1].

Key to improving routine immunization programmes and sustainably introducing new vaccines and immunization technologies is for countries to ensure that they have the necessary evidence and clear processes to enable informed decision making in the establishment of immunization programme priorities and the introduction of new programme strategies, vaccines and technologies. Similarly, such evidence and processes are needed to justify the continuation of, or any necessary adjustments to, existing immunization programmes and policies.

Whereas developing countries have long struggled with vaccine funding problems and limited ability to optimize coverage with standard immunization programs, even industrialized nations today face problems involving the financing and delivery of expanded vaccine programs. While there is increased funding flowing through new financing mechanisms to support the introduction of new vaccines by developing countries [2–4], from a public health perspective, the overall limited financial resources require that distribution of funds must be undertaken in as fair and as effective a manner as possible in order to achieve the best possible outcomes. Therefore decisions on introducing new vaccines into national immunization programs should be unbiased, comprehensive and systematic and based on deliberate, rational, comprehensible and evidence-based criteria [5]. Certainly all governments have to consider opportunity costs in their investments.

At present, the majority of industrialized and some developing countries have formally constituted national technical advisory bodies to guide immunization policies. Other countries are only starting to work towards or are just contemplating the establishment of such bodies. Still others have not even embarked on thinking about such a body. These advisory bodies are often referred to as National Immunization Technical Advisory Groups (NITAGs) and will be referred to as such in the remainder of this document. They can also be referred to using different names such as National Advisory Committee on Immunization or National Committee on Immunization Practice to name a few of the most commonly used titles. Many countries still lack credible decision-making processes

Abbreviations: ICC, Coordinating Committees; 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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that can facilitate the review and assessment of immunization interventions and strategies [6].

The focus of this document is to: (1) review the value, roles and functions of a NITAG; (2) provide directions and identify issues for countries to consider when establishing or improving the functioning of a NITAG; and (3) outline potential WHO and partners' roles and activities in support of the establishment and strengthening of NITAGs.

2. Value, roles and functions of a National Immunization Technical Advisory Group

A NITAG is both a technical resource and a deliberative body to empower the national authorities and policy makers to make evidence-based decisions. Such a resource is particularly important in view of the complex and vast bodies of evidence and the global interdependence and integration of health systems.

A well balanced and institutionalized group can aid a national programme to resist pressure from any interest or lobby group with narrow scopes or interests, including, but not only, that of industry and anti-immunization groups. This protective function is important, because without it, pressure from special interest groups could result in programme changes that are not well justified in the local context and may even cause harm.

A major advantage of a NITAG is the credibility of the process by which major policy decisions are made, which in turn adds credibility to the national immunization programme and to the government at large [7,8]. This credibility is of course linked to the rigor, transparency, and informed/evidence-based processes by which the NITAG arrives at its decisions. Highly credible decisions can positively impact perceptions within the government, within the country or even beyond the country, thereby lending additional weight to proposed adjustments to the immunization programme and enhancing the ability to secure government or donor funding, support from professional organizations, and acceptance from the public.

In addition, a standing NITAG will facilitate a more comprehensive and cohesive country immunization program perspective that cannot easily be achieved by a series of disease or vaccine specific task forces or *ad hoc* committees composed of specific disease experts and advocates. These latter groups often provide recommendations in isolation without consideration of the complete immunization program picture within the full context of other intervention strategies. Ideally, disease-specific technical working groups should be supported by and report to a NITAG.

A NITAG or even a group which may have a broader mandate, such as an infectious disease control committee, will help consolidate programmes and have a more comprehensive and integrated approach in terms of interventions and target populations (*e.g.* they ideally would, consider the health of the entire population *versus* that of infants only). In theory, advisory groups could have a broader health mandate that extends beyond vaccines and immunization. However, an immunization focus is recommended to ensure that the required expertise is included on the committee and due attention given to vaccines, which could not be given by a more generic or all-purpose advisory committee serving the Ministry of Heath.

NITAGs mandates usually include to recommend national immunization policies and strategies that take into account the local epidemiologic and social contexts; and possibly to advise on implementation of national immunization programmes and to monitor programme impact.

With the above in mind, the overall objective of establishing a functioning technical advisory body at the country level is to provide guidance to policy makers and programme managers for making evidence-based immunization related policy decisions, including choices of new vaccines and technologies and needed adjustments to existing programmes and schedules. The proposed broad general terms of reference for such a group are as follows:

- Conduct policy analyses and determine optimal national immunization policies.
- Guide the national government and the national immunization programme on the formulation of strategies for the control of vaccine preventable diseases through immunization.
- Advise the national authorities on the monitoring of the immunization programme so that impact can be measured and quantified.
- Advise the government on the collection of important disease and vaccine uptake data and information.
- Identify the need for further data for policy making.
- Guide, where appropriate, organizations, institutions or government agencies in the formulation of policies, plans and strategies for research and development of new vaccines and vaccine delivery technologies for the future.

Each country will have to adjust its NITAG's terms of reference based on its own needs and resources. Therefore, the terms of reference proposed above are general and not necessarily exhaustive or inclusive.

Although the role of NITAGs is essentially consultative and the ultimate decisions about programs remains in the hand of government officials, this process requires the acceptance of the government to yield some level of control over the decision-making process. One of the indirect benefits of a NITAG is to help keep the national authorities and those working for the national immunization programme updated on the latest scientific developments in the area of vaccines and vaccine-preventable disease epidemiology and control. Such a group also helps to foster inter-departmental linkages and promote partnership among government, civil society, industry and donors to promote immunization in a sustainable, scientifically sound and credible manner.

There are cautions to be considered in the formation of a NITAG. A NITAG should have only a technical advisory role for in the development of vaccine recommendations and should not serve as an implementing, coordinating or regulatory body. Therefore, an NITAG should be distinguished from the Inter-agency Coordinating Committees (ICC) that are already established in countries eligible for funding by the GAVI Alliance [9]. The main purpose of these ICCs is to coordinate and support funding, planning, implementation, and advocacy. The ICCs' work is primarily operational, not technical in nature, and these groups are not intended to replace NITAGs or to substitute partners' inputs for the deliberative opinions of proper national decision making bodies. In some settings, however, due to a lack of NITAGs, ICCs have been asked for advice on certain immunization policy related issues. In some places ICCs have even gone as far as establishing their own technical advisory groups, recognizing the importance of such advice in vaccine decision making. NITAGs should also clearly be distinguished from National Regulatory Authorities, which have licensing, testing, inspecting, quality control and post marking surveillance functions. Finally, NITAGs should be distinguished from disease-specific technical advisory working groups, such as those on polio, measles, and hepatitis, which are formulated to focus on one disease for a specified time period and deliverable(s) and whose recommendations and work would be better harnessed under the umbrella of a NITAG as noted above.

If a NITAG is to succeed, there are modest but required costs for its establishment and functioning both in terms of managerial support and financial investments that are required if it is to succeed. NITAGs will also potentially add some delays in the immunization and program decision making process given that without a NITAG a decision could be made instantaneously—though such a decision is

unlikely to be evidence based, robust, thoughtful and useful. Attention does need to be paid to avoiding undue delays that might be caused by inertia on the part of a NITAG or its secretariat.

As an alternative to a NITAG, some very small countries and countries with limited technical resources may prefer collaboratively to explore a sub-regional or inter-country mechanism to provide independent and expert advice rather than rely on an individual country approach. This, however, requires a genuine willingness to accept extra-national recommendations as well as the necessity for this inter-country group to understand and appreciate the specific situations and needs of individual countries.

In some countries such as the United States of America, Canada and India, professional organizations such as the National Academy of Pediatrics or other similar groups may have established a national advisory process to issue recommendations on vaccine use that are intended for their members [10,11]. In such situations it is important to ensure close liaison between these groups and the NITAG so that one will not end up with conflicting recommendations that would be counterproductive and undermine the credibility of either group. As an example, such a situation with issuance of different recommendations by the US Advisory Committee on Immunization Practices and the Committee on Infectious Diseases of the American Academy of Pediatrics (the so-called Red Book Committee) existed in the past in the United States. Over the years, however, these two committees have worked increasingly closely and now publish harmonized immunization recommendations [7,12].

3. Guidance for the membership and mode of operation of a NITAG

The following discussion identifies elements that need to be well defined in the membership and mode of operations of a NITAG. The proposed structure for NITAGs outlined below may in part be seen as an example towards which to aim, but it is well accepted that establishing a fully functional NITAG may take a number of years. Furthermore, the guidance provided below is general guidance and the optimal process for reaching the best evidence-based decisions may vary from country to country. Each NITAG's composition and *modus operandi* must be adjusted to take into account the local situation, resources and the social and legal environment.

The following set of recommendations was initially developed by WHO with input from and review by a group of external experts and building on the experience from existing NITAGs (such as but not limited to those in Canada, the United Kingdom and the United States) that enjoy credibility and recognition at country level and across borders. Admittedly these recommendations are based on limited robust scientific evidence. Indeed there is variability in the mode of operating of what seem to be successful committees [6,12–16]. Furthermore, little has been published when it comes to the process of establishing immunization policy recommendations [17], making it more difficult to assess the key important elements of successful committees. More has been published on the elements to take into consideration than on the optimal structure of a committee. The initial guidance referred to above has been further adjusted in this document to take into account the observations, challenges and successes of recent efforts at establishing and strengthening NITAGs reported during regional meetings of immunization managers and regional technical advisory groups on immunization. These meetings have included participation of NITAG Chairs and members.

3.1. Establishment of the committee

The committee should be formally established through a ministerial decree or any other appropriate administrative mechanism, including legislative action if necessary. Such a formal establishment process may also help with securing the necessary funding for the operation of the committee operation and secretariat support.

To ensure that the government gives proper attention to committee recommendations, it is important that the committee reports to a high level official of the Ministry of Health who is not a member of the group. A formal relationship should be established between the committee and the Ministry of Health, delineating roles and responsibilities. This would include clarifying reporting requirements, financial arrangements and secretariat support. This may include appointing an Executive Secretary who may or may not be a staff member from the Ministry of Health. It is recommended that the immunization program provides secretariat service to the NITAG, and that the immunization program manager be closely in touch with this process. Terms of reference must be clearly stated.

It is recommended that the Ministry of Health budgets this activity in its annual and multi-year plans. This should be reviewed on a regular basis to determine if budgets remain adequate for the demands placed on committees.

3.2. Membership and composition of NITAGs

3.2.1. Size

There are no fixed rules about the size of a NITAG but this can and should be influenced by local considerations such as the need for geographic representation, the size of the country, the availability of resources and so on. Experience has shown that successful committees function with about 10–15 core members who serve in their personal capacity and represent a broad range of disciplines encompassing many aspects of immunization and vaccines [6,12–16]. This allows for some useful redundancy of expertise that ensures more fruitful and balanced debate. As well, some redundancy is helpful as not all members will likely be able to attend all meetings. For committees with a small number of members the effect of absentees would be particularly noticeable. Too large a committee is more costly and more difficult to manage. Beyond a limited number of members, as long as the necessary expertise is already captured on the committee, there is little to be gained by enrolling additional members. Groups with an odd number of members may be more effective for resolving disagreements and reaching more speedy decisions [18–21].

3.2.2. Composition

The composition of the group should include two categories of members: core and non-core members. All core members should be independent and credible experts who serve in their own capacity and who do not represent the interests of a particular group or stakeholder. Members should refrain from promoting the policies and views and products of the organization for which they work.

Independence from government is defined by the absence of a direct or indirect supervisory relationships within the immunization program, or ideally, within the larger Ministry of Health. Members should feel free and encouraged to express their views even if at odds with those of the immunization programme managers or Ministry of Health policies. Core members only should participate in advising and deciding on the final set of recommendations.

Non-core members can be further subdivided into two groups, namely *ex officio* [22] and liaison members [23]. *Ex officio* members hold key positions with important government entities they represent (*e.g.* National Regulatory Authorities or drug/vaccine licensing bodies and from the National Control Laboratory performing the controls of vaccines, and administrative groups with responsibility for immunization programmes, planning, education, finance, and other activities) and their presence is solicited because of the position held. Liaison members generally represent various impor-

tant professional societies or associations, other national advisory committees, and key technical partners (*e.g.* WHO and UNICEF) [12–14,17]. The determination of who should serve as a representative of the organization should be left to the organization itself, who will identify the most appropriate individual from its membership. A rotation process can also be decided by the organization although it is better to have some stability rather than have a too frequent change of liaison representatives. The role of non-core members is to contribute to the discussion and to help provide background information or needed evidence. They should not be directly involved in deciding on the final set of recommendations. An individual can serve in only one capacity. The participation of liaison members can also facilitate the quick dissemination of the recommendations back to the membership of the professional organization when settled. This helps to ensure support for and quick and smooth implementation of the new recommendations.

It is recommended that the committee be multidisciplinary and represent a broad range of skills and expertise through the selection of technically sound and experienced individuals as members. At a minimum and when feasible (*i.e.* depending on the size and capacity of country), it is recommended for countries to consider including experts as core members from the following disciplines/areas: clinical medicine (paediatrics and adolescent medicine, adult medicine, geriatrics), epidemiologists, infectious diseases specialists, microbiologists, public health, immunology, vaccinology, immunization programme, and health systems and delivery. Consideration should also be given to appointing members with expertise in clinical research (clinical trials design) and health economics. Such expertise, however, may be limited in some settings and individual countries could consider providing ability to interpret cost-effectiveness studies *via* the secretariat and/or expertise beyond that of the core group. The collective expertise should obviously be adjusted to the specific terms of reference for the group.

Other considerations in terms of membership include: gender distribution, geographic diversity, representation of special population groups, and the need or not to ensure representation of the public. This latter member might be a consumer representative who could bring the consumer's perspective or social and community aspects of immunization programmes. If public representation is desired, decisions need to be made on how this could be done (*i.e.* through a seat on the core membership or rather through *ex officio* or liaison members) and how to identify a suitable representative.

Given the substantial financial implications that recommendations may have for the public and private sectors, as well as for vaccine manufacturers, members should be free of conflicts of interest and enjoy satisfactory credibility. Members with declared interests compatible with serving on the committee will be asked to recuse themselves from participating in the discussion and decision making of the issues relating to that interest. A member who is in any doubt as to whether they have a conflict of interest that should be declared, or whether they should take part in the proceedings, should ask the Secretariat and Chairperson for guidance. Appearance of conflicts of interests should be avoided through both pre- and post-appointment considerations and regular open disclosure of competing interests (see below).

It is important to differentiate members involved in the decision-making process from observers or invited experts. Observers or invited experts may contribute to the discussion and can help to provide background material or needed evidence, but they should not be involved in the final decision making, regardless of whether they represent particular interests.

The Chair and members of the Committee will play a critical role in ensuring the Committee's continued standing as an internationally recognized leading body in the field of immunization and that it continues to observe the highest standards of impartiality, integrity and objectivity in its deliberations and that its recommendations are driven by available scientific evidence. Thus the Chair and members of the Committee should be chosen carefully and thoughtfully.

3.2.3. Nomination process

Members, including the Chair, should be nominated and appointed formally by senior level government officials through a well-defined process. Public calls for nominations and the establishment of an independent selection process may be envisioned for the purposes of transparency and credibility. Moreover, the Chair should be identified as a senior, widely respected and independent core member.

Prior to being appointed it is important that members be asked to complete a declaration of interests with enough detail and specificity to identify what would constitute a potential conflict of interest. A conflict of interest involves a conflict between the public duty and private interests of a public official, in which the public official's private capacity interests could improperly influence the performance of their official duties and responsibilities [24]. Conflicts of interest can be of a personal (*e.g.* owning shares in a vaccine manufacturing company, direct employment of the candidate or an immediate family member by a vaccine manufacturer, serving on a vaccine company board, or acceptance of honoraria or travel reimbursement by a vaccine manufacturer or its parent company) *versus* non-personal nature (*e.g.* research grant to an institution) and can be specifically or not related to the object of discussions and decisions to be taken by the group.

It should then be determined by the Secretariat and the chairperson if the declared interests, which indicate actual or potential conflicts, would completely preclude the expert from serving on the committee or if they should just be reported and the member be excluded from decision making or even discussing specific issues at a given meeting. (*e.g.* members with a personal specific interest will be asked to leave the room for the discussion and decision making; members with a personal non-specific interest could participate in discussions but not take part in the decision making; members with non-personal specific interests could answer direct questions from the chairperson but not take part in the decision making; members with non-personal non-specific interests could participate in the discussion and the decision making). Other categorization of conflicts of interest include major or minor conflicts, and actual, apparent or potential conflicts of interest [25–28].

The declaration of interest should be kept up to date. The most convenient approach may be to ask members to update their declaration of interest as need be before each meeting. Reported interests may be disclosed during the meeting and possibly posted in a summarized manner on the Internet and/or made available at public request. Screening for conflicts of interest should be rigorous and balance the possibility of bias caused by a conflict with the need for vaccine and immunization expertise. Some data important to the committee can be obtained only through working relationships with vaccine manufacturers. Additionally, many of the top national experts in the field of immunization and vaccines will have some relationship with various interest groups, including industry, professional associations, and governments. Consequently, the goal is not to include only persons with absolutely no relevant interests but to manage potential conflicts of interest in a transparent and ethical fashion.

An increasing number of allegations of collusion between national government and industry, particularly in the context of the introduction of expensive new vaccines, have recently been reported in the media. It is therefore essential that due attention be paid to the declaration of interests and their disclosure.

Members may also be required to sign a confidentiality agreement if, in the process of the meeting or work of the group, they

are provided in trust with confidential information. Confidentiality agreements should also be signed by special invitees.

The format for the declarations of interests and confidentiality agreements should be adjusted to fit the specific requirements and practice of the country. Clearly the assessment of what would constitute a conflict of interest is context dependent. For example, a consultation fee of US$ 1000 will have a variable weight and impact depending on the country's average wages.

Examples of such documents and summaries of reported interests can be found at http://www.who.int/immunization/sage/national_advisory_committees/en/index2.html.

3.2.4. Rotation of membership for core members

A process of rotation for core members with limited duration of terms of service is essential for the credibility of the group and standard operating procedures which specify the nomination, rotation and termination processes should be developed [12]. Subject to the above, members would normally be appointed for a term of a fixed number of years, which possibly could be renewed (though the number of renewals allowed should be specified and limited). Care should be taken to ensure there is continuity in the committee so that not all members' terms would expire at the same time. Terms of three to four years with or without provisions for renewal of a term are common practices. Renewal of appointments at the end of the first period of office if provisions for such renewals have been made should be subject to satisfactory appraisal. There should be no expectation of automatic reappointment and this should be made clear to all members when they are appointed.

Possible reasons for termination of membership should be made clear and include the following: a failure to attend a specified number of consecutive meetings; a change in affiliation resulting in a conflict of interests; and a lack of professionalism involving, for example, a breach of confidentiality.

3.3. Modes of functioning of the NITAG/process of meetings

3.3.1. Conduct of meetings: process and basis for decision making

It is highly recommended that the immunization program and/or Ministry of Health provide new committee members with briefing sessions and/or information packages and orient the members to the terms of reference and group operating procedures. When a new NITAG is created it may be helpful at least for the first meeting or, in advance of the first meeting or during a pre-meeting session, to allow time and venues for members to become acquainted and discuss processes so that they feel at ease during the committee's discussions and deliberations. In this regards, provision of information on context, clarification of roles and responsibilities and mutual expectations may be important.

Standard operating procedures are required that specify the preparation and circulation of agendas, background documents and information, as well as the conduct of meetings and the process for recording and communicating of the committee's conclusions and recommendations.

The following elements should be decided upon and made clear in the standard operating procedures of the group:

- *Open versus closed meetings*. Combinations of this may occur. For example, formal NITAG deliberations may be open while working group sessions are closed (see thereafter). Open meetings increase transparency and may improve public acceptance but at the same time may make the process less efficient and may inhibit NITAG members from speaking as openly as they otherwise would.
- *Participation of industry and participation of observers*. Manufacturers should usually not be allowed in meetings but occasionally invited in highly structured participation settings to inform the committee about their products. If and when manufacturers are invited to observe meetings, the setting and handling must prevent undue influence by these manufacturers.
- *Process to review and share evidence with the group*. In preparation for the meeting specific questions put to the committee should be clearly articulated. The agenda should be circulated at least a week before the meeting with necessary relevant background documents to allow for committee members to prepare themselves for the discussions ahead.
- *Process for decision making, i.e. decision by vote or consensus*. Each of the different approaches has its own advantages and inconveniences and one approach cannot be prescribed over the other.
- *Establishment of working groups and their mode of operation*. Committee's working groups may be a helpful resource for gathering, analyzing and preparing information for presentation and for decision making by the full NITAG. It is advisable that such working groups comprise a minimal number of core members with additional subject-matter experts. These may include relevant *ex officio* or liaison members and invited national or international experts. Vaccine manufacturer's representatives should not serve on the working groups although they could be asked to provide specific information to the working groups. Alternatively other mechanisms to bring information and facilitate the decision-making process could be used, such as through reliance on the secretariat, or through preparation by paid consultants. In the latter instance, the consultant should not have any conflicts of interest that might cause concern about the validity and independence of the prepared document.
- *Basis for decision making*. Various similar approaches have been published [12,29–33].

  Elements of information that should be considered when making recommendations include the following:

  Disease epidemiology [34] (disease burden including age specific burden for mortality, morbidity, and societal impact; age distribution of disease; projections for future disease burden; specific risk groups; epidemic potential; disease occurrence over time; serogroup or serotype distribution for serogroup or serotype specific vaccines; and changes in epidemiology over time).

  Clinical characteristics (clinical management of disease, disease severity, primary/secondary/tertiary care implications, and long term complications of disease and health requirements).

  Economic considerations (projections for future disease burden to the health care system, cost of disease including the impact of epidemics on social and political structures, cost and cost effectiveness [35,36], and affordability of immunization).

  Vaccine and immunization characteristics (efficacy, effectiveness and population impact of vaccine; indirect effects; vaccine safety; cold chain and logistics concerns; vaccine availability; vaccine schedules; acceptability of vaccine and vaccine schedules to the public and health professionals).

  Political and public health considerations (actions in other countries; regional and global recommendations if available; potential of disease for international spread and pandemic potential).

When national data are not available, information generated from countries with similar characteristics can be used. Where sufficient data is not available, the committee should solicit additional data/work to secure the relevant data. In the absence of data or when data is inadequate, expert options can be used to make recommendations. When data permit, specific rules of evidence can be used to judge the quality of data and make decisions regarding the strength of recommendations [37–44]. A theoretical framework/explicit process for decision making could be developed and

go as far as using grading of evidence but very few committees currently have such a structured approach [31,45].

- *Process for deciding on agenda items and input requested from the committee*. Although most of the questions put before the committee should come from the Ministry of Health, it is appropriate that the members of the committee themselves be asked to contribute to the development of the agenda and based on their expertise identify important issues to be discussed. Industry and professional societies could also put forth suggestions.

It is essential that sufficient administrative (*e.g.* secretarial) support be provided to prepare for meetings. Given that members have to invest the necessary time in getting ready for the meeting and reviewing information ahead of meetings, the secretariat should ensure that all background information is well prepared. This is especially important as generally members are not or are only minimally financially compensated for serving on an advisory group. Travel expenses should be compensated.

3.3.2. Meeting frequency

Although there should be flexibility in calling a meeting at any point to discuss important decisions or urgent matters in rare occasions that may require the organization of additional meetings, there should be regular or fixed meetings scheduled in advance. It is recommended that the NITAGs meet regularly and at least twice a year, with a meeting on a yearly basis being a very strict minimum. Several groups such as those in Canada, the Unites States or the United Kingdom operate successfully with three or four meetings a year. A higher number of meetings may be more difficult to manage both for committee members and for the secretariat but allow for more issues to be discussed in a satisfactory manner and also allows for reducing the time lag for issuance of the needed recommendations.

3.3.3. Communication/reports

Summary minutes of each meeting with the focus on the main conclusions and recommendations must be available and endorsed by the group within a reasonable time period after the meeting (within no more than two months after a meeting). A clear process must be in place for the recommendations to be communicated to the decision makers.

It must be decided if the minutes are public or private and if public how they will be published, *i.e.* through government bulletins, journals, website, or other mechanisms. Generally speaking public dissemination of the minutes, if/when appropriate, is encouraged as it lends more credibility and transparency of the decision-making process. Although one may fear that this could potentially expose the government to criticism if recommendations from the NITAG were not implemented, this would not necessarily occur as long as reasons for not implementing the NITAG recommendations are well justified and transparent (*e.g.* inability to secure sufficient funds and higher opportunity costs). Some committees periodically publish books or compendiums that include all committee recommendations on vaccine use. In other circumstances, recommendations and information about the committees and their work is posted on a website (*e.g.* http://www.advisorybodies.doh.gov.uk/jcvi/; http://www.phac-aspc.gc.ca/naci-ccni/; http://www.cdc.gov/vaccines/recs/acip/). Consideration should also be given to a communication strategy/plan.

3.4. Evaluation

It is extremely difficult to come up with a specific outcome indicator that objectively assesses the performance of a NITAG as a recommendation taken in a particular country may be the proper decision at that time but may not be the right one in another setting or another time. Nevertheless, consideration should be given to developing process and output and intermediate outcome measures to demonstrate the contributions of NITAG to the overall improvement of the immunization decision-making process.

Indicators for a "well-functioning" NITAG have been proposed that can help countries assess where they stand and allow for monitoring of progress at regional or global levels, particularly when combined as a composite indicator. Focusing on the needed formal, independent, and technical nature of NITAGs, the following indicators have been proposed: formal legislative or administrative basis (*e.g.* a Ministerial decree) establishing the committee in a sustainable manner; availability of formal written Terms of Reference; core members required to systematically declare any interest; technical competence (core membership with a least 5 main expertise areas represented among members (paediatrics, public health, infectious disease, epidemiology, immunology), committee meets at least once a year on a regular basis, agenda (and background documents) distributed to members at least 1 week ahead of meetings. These proposed process indicators have the advantage of simplicity and are applicable in all regions and all cultures making it easy for the immunization managers to determine if the NITAG complies with each of these criteria [46]. They, however, represent a minimum that can be particularly useful to monitor progress at the global level.

It is important that the NITAG be consulted for all key policy decisions and that all NITAG recommendations be given due consideration by the Ministry of Health. Intermediate outcomes measure could therefore include the number or proportion of recommendations given due consideration or implemented, as well as the proportion of key decision taken by the Ministry of Health that have been made through soliciting the advice of the NITAG.

Recommendations should be regularly revisited and revised if need be based on the availability of new evidence and particularly with the benefit of accrued surveillance data and this could also be taken into account in the evaluation of NITAGs.

4. WHO's and partners' roles and support for the establishment, strengthening and functioning of NITAGs

WHO has placed a high priority on the development of national decision making process and capabilities. The directions for countries to consider when establishing or improving the functioning of a NITAG take time and are not always easy to follow as many countries do not always have the culture of elements such as the independence of expertise, a clearly defined approach in the case of conflict of interest and a well established evidence based process for decision making. In most of the countries where the NITAGs are functioning quite well, these elements have been introduced progressively and sometimes it took several decades to reach such levels of excellence. Therefore, to assist in the rapid establishment or strengthening of functional, sustainable independent NITAGs, and to benefit from the experience of the most advanced committees, the WHO is working through its regional and country offices and with partners to support countries with the following activities:

- Providing more specific regional guidance documents and facilitation of access to framework documents such as standard declarations of interest.
- Fostering linkages among and between committees.
- Providing technical guidance for the establishment/strengthening of the NITAG.

- Providing technical guidance to the NITAGs in the formulation of immunization policies and strategies for vaccine preventable disease control.
- Providing global and regional policy recommendations and giving access to references and other background material that constitute the evidence for such recommendations [47].
- Providing regular updates and latest developments on the vaccine pipeline, guidance about recommended immunization schedules, vaccine delivery technology, vaccine preventable disease surveillance, safety and quality data/information, *etc*. WHO will send, on a regular basis, information on the latest developments in vaccines and immunization to the chairman of the NITAG who, in turn, will circulate it to the other members.
- Providing assistance or guidance in identifying potential sources of financial support to help with the establishment of a NITAG.
- Developing training materials.
- Facilitating exchange between NITAGs and participation of NITAGs chairperson at regional immunization meetings.

Among key WHO partners taking part in the direct support to countries are the US Centers for Disease Control and Prevention, the ProVac Initiative, launched in 2006 to provide technical cooperation and strengthen national capacity to make evidence-based, informed decisions in the context of the introduction of new and underutilized vaccines [32], and the more recent SIVAC (Supporting Independent Immunization and Vaccine Advisory Committees) Initiative [48]. The objective of this latter Initiative is to assist in the establishment or strengthening of functional, sustainable independent NITAGs in GAVI-eligible and middle income countries in making recommendations for program improvements and vaccine introductions through technical assistance, training, development of tools and information sharing. More information and link to these resources can be found at: http://www.who.int/immunization/sage/national_advisory_committees/en/index.html.

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Conflict of interest

Philippe Duclos has no financial interests relevant to this paper.

References

[1] World Health Organization and UNICEF. GIVS global immunization vision and strategy 2006–2015. Geneva: World Health Organization, WHO/IVB/05.05; 2005. ⟨http://www.who.int/vaccines-documents/DocsPDF05/GIVS_Final_EN.pdf⟩ [accessed 05.02.2010].
[2] Meeting of the immunization Strategic Advisory Group of Experts, November 2006—conclusions and recommendations. Weekly Epidemiol Rec 2007;82:1–16.
[3] GAVI Alliance. [Online] Available from: URL:http://www.gavialliance.org/.
[4] IFFim Supporting GAVI. [Online] Available from: URL: http://www.iff-immunisation.org/.
[5] Piso B, Wild C. Decision support in vaccination policies. Vaccine 2009;27:5923–8.
[6] Bryson M, Duclos P, Jolly A, Cakmak N. A Global Look at National Immunization Technical Advisory Groups. Vaccine 2010;28(Suppl. 1):A13–7.
[7] Kamiya H, Okabe N. Leadership in immunization: the relevance to Japan of the U.S.A. experience of the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP). Vaccine 2009;27(11):1724–8.
[8] Berger P, Micallef J, Barrau K, Manuel C, Auquier P. Vaccination anti-hépatite B: après la décision du Secrétaire d'Etat à la Santé. La Presse médicale 1999;28(31):1702–6.
[9] Guidelines for National Interagency Coordinating Committees. Brazzaville: World Health Organization, AFRO/EPI; 1998.
[10] Indian Academy of Pediatrics Committee on Immunization (IAPCOI) Consensus recommendations on immunization, 2008. Indian Pediatrics 2008;45:635–48.
[11] Red Book Online; 2009. ⟨http://aapredbook.aappublications.org/resources/⟩ [accessed 05.02.2010].
[12] Smith JC, Snider DE, Pickering LK. Immunization policy development in the United States: the role of the Advisory Committee on immunization practices. Ann Inter Med 2009;250:45–9.
[13] Salisbury DM. Development of immunization policy and its implementation in the United Kingdom. Health Aff 2005;24(3):744–54.
[14] Ismail S, Langley J, Harris T, Warshawsky B, Desai S, FarhangMehr M. Canada's National Advisory Committee on Immunization (NACI): evidence-based decision making on vaccines and immunization. Vaccine 2010;28(Suppl. 1):A58–63.
[15] Freed GL. The structure and function of immunization advisory committees in Western Europe. Child Health Hum Vacc 2008;4(4):292–7.
[16] Andreae MC, Switalski K, Abraham L, Freed GL. National immunization advisory committees of the World Health Organization's European Region. Vaccine 2009;27(24):3131–6.
[17] Bryson M, Duclos P, Jolly A, Bryson J. A systematic review of national immunization policy making processes. Vaccine 2010;28(Suppl. 1):A6–12.
[18] Leclerc C. Comprendre et construire le groupe. Chronique Sociale, Les presses de l'université Laval. Quebec, Canada; 1999.
[19] Mucchielli R. La dynamique des groupes: connaissance du problème, applications pratiques Formation permanente en sciences humaines. Paris: ESF; 1992.
[20] Hunt J. Core concepts of organizational behaviors. The Nature of Groups PowerPoint presentation for a course delivered at the Texas Tech University; 1999 [Chapter 9].
[21] Amado G, Guittet A. La Dynamique des communications dans les groupes. Paris: Armand Colin; 1997.
[22] Wikipedia definition of Ex officio member; 2009. ⟨http://en.wikipedia.org/wiki/Ex_officio_member⟩ [accessed 05.02.2010].
[23] Wikipedia definition of Liaison officer; 2009. ⟨http://en.wikipedia.org/wiki/Liaison_officer⟩ [accessed 05.02.2010].
[24] Bertók J. Managing conflict of interest in the public service: OECD guidelines and Country Experiences. Paris: Organisation for Economic Co-operation and Development (OECD) Publications; 2003.
[25] Lurie P, Almeida CM, Stine N, Stine AR, Wolfe SM. Financial conflict of interest disclosure and voting patterns at Food and Drug Administration Drug Advisory Committee meetings. JAMA 2006;295(16):1921–8.
[26] The UK DOH, Joint Committee on Vaccination and Immunisation, Members' Code of Practice; 2009. ⟨http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_098495.pdf⟩ [accessed 05.02.2010].
[27] Council of Europe. Recommendation No. R (2000) 10 of the Committee of Ministers to Member states on codes of conduct for public officials; 2008. ⟨http://www.coe.int/t/dghl/monitoring/greco/documents/Rec%282000%2910_EN.pdf⟩ [accessed 05.02.2010].
[28] Floret D. Immunization: process of elaborating guidelines and their evolution in France. Annals Pharmaceutiques Françaises 2009;67:219–23.
[29] Kimman T, Boot H, Berbers G, Vermeer-de Bondt PE, Ardine de Wit G, de Melker HE. Developing a vaccination evaluation model to support evidence-based decision making on national immunization programs. Vaccine 2006;24:4769–78.
[30] Erickson LJ, De Wals P, Farand L. An analytical framework for immunization programs in Canada. Vaccine 2005;23(19):2470–6.
[31] Evidence-based recommendations for immunization—methods of the National Advisory Committee on Immunization. An Advisory Committee Statement (ACS). Can Commun Dis Rep 2009;35(ACS-1):1–10.
[32] Andrus JK, Toscano CM, Lewis M, Oliveira L, Ropero AM, Dávila M, et al. A model for enhancing evidence-based capacity to make informed policy decisions on the introduction of new vaccines in the Americas: PAHO's ProVac initiative. Public Health Rep 2007;122(6):811–6.
[33] Zimmerman RK, Jackson RE. Vaccine policy decisions: tension between science, cost-effectiveness and consensus? Am Fam Phys 2001;63(10):1919–23.
[34] Morrato EH, Elias M, Gericke CA. Using population-based routine data for evidence-based health policy decisions: lessons from three examples of setting and evaluating national health policy in Australia, the UK and the USA. J Public Health (Oxf) 2007;29(4):463–71.

[35] Iglesias CP, Drummond MF, Rovira J, NEVALAT Project Group. Health-care decision-making processes in Latin America: problems and prospects for the use of economic evaluation. Int J Technol Assess Health Care 2005;21(1): 1–14.
[36] Hoffmann C, Graf von der Schulenburg JM. The influence of economic evaluation studies on decision making. A European survey. Health Pol 2000;52(3):179–92.
[37] National Health and Medical Research Council. How to use the evidence: assessment and application of scientific evidence. Canberra: NHMRC; 2000.
[38] Velasco M, Perleth M, Drummond M, Gürtner F, Jørgensen T, Jovell A, et al. Best practice in undertaking and reporting health technology assessments. Working group 4 report. Int J Technol Assess Health Care 2002;18:361–422.
[39] Higgins J, Green S, editors. Cochrane handbook for systematic reviews of interventions. Version 4.2.6. The Cochrane Library (Issue 4). Chichester, UK: John Wiley & Sons, Ltd.; 2006.
[40] Centre for Reviews and Dissemination. Undertaking systematic review of research on effectiveness: CRD's guidance for those carrying out or commissioning reviews. York, UK: CRD; 2001.
[41] Quorom Group.Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of reporting of meta-analyses. Lancet 1999;354:1896–900.
[42] Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. JAMA 1995;273:408–12.
[43] Greenhalgh T. Assessing the methodological quality of published papers. BMJ 1997;315:305–8.
[44] Hailey D. Towards transparency in health technology assessment: a checklist for HTA reports. Int J Technol Assess Health Care 2003;19:1–7.
[45] Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924–6.
[46] Petherick ES, Villanueva EV, Dumville J, Bryan EJ, Dharmage S. An evaluation of methods used in health technology assessments produced for the Medical Services Advisory Committee. Med J Aust 2008;188(8):495.
[47] Duclos P, Okwo-Bele JM. Recommandations et politiques vaccinales mondiales: Le rôle de l'OMS. Médecine/Sciences 2007;23:409–16.
[48] SIVAC website; 2009. ⟨http://www.sivacinitiative.org⟩ [accessed 05.02.2010].