



# The National Committee for Vaccines Regulation and Surveillance of Vaccine-Preventable Diseases in the Sultanate of Oman: Evidence-based approach and consensus decision-making

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## ABSTRACT

The National Committee for Vaccines Regulation and Surveillance of Vaccine-Preventable Diseases serves as the National Immunization Technical Advisory Group (NITAG) in the Sultanate of Oman. It is the only advisory body to assist the Government in establishing policies and strategies and in evaluating new vaccines with respect to technology, quality and safety. It has six to eight core members as well *ex officio* members. Committee members are appointed for a period of 3 years by the Minister of Health and committee members declare their potential conflicts of interests and sign a confidentiality agreement. The cost of vaccines and the overall immunization program are considered when the committee makes its recommendations. Evidence-based decision-making could be facilitated by introducing more economic expertise to the committee.

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## 1. Description and background

The National Committee for Vaccines Regulation and Surveillance of Vaccine-Preventable Diseases was established by Ministerial Decree No. 18/2000 [1]. Within the Sultanate of Oman it functions as a National Immunization Technical Group (NITAG) and is the National Committee advising on policy analysis, strategy formulation and the regulation of vaccines. Its objective is to assist and inform the Government of Oman's Ministry of Health (MOH) in establishing policies and strategies. As well as evaluating new vaccines in terms of technology, quality and safety, it considers latest scientific advancements and recommendations, alongside a situation analysis of all vaccine-preventable diseases. Prior to the committee's establishment, the Department of Communicable Disease Surveillance and Control aided the MoH with these decisions.

The committee's decisions are evidence-based and take into account all the important factors pertaining to vaccines and immunization policy. Only the most reputable sources of information are

used and decision-making is consensus based, dependent upon the evaluation and grading of evidence as provided for in the Terms of Reference. There are six core members, as well as *ex officio* members, giving a total membership of ten (Table 1).

## 2. Terms of reference and process of meetings

The Ministerial Decree no. 18/2000, then revised 134/2008, established the committee as an advisory body to aid senior decision-makers of the Sultanate. The committee is thus the only national advisory body charged with developing national policy on these issues. The committee Chair gives a summary of recommendations to the highest level of decision-makers, such as the Minister of Health, who has the final say on the matter. Decisions and recommendations taken by the committee enjoy the highest level of credibility among the various bodies concerned, including the Ministry of Health, non-health government ministries and the private sector.

The official terms of reference for the committee include: advising on the technical specifications for vaccines; advising on the standards and regulations for prescribing, providing, transporting and storing vaccines, both in the public and private health sectors; advising on the documents and types of data to be collected on adverse events; and taking measures to avoid preventable, adverse events. They also specify that the committee advise on the significance of epidemiological or clinical studies submitted in support of these vaccines at their registration and thereafter, recommending policies for regulating the use of these vaccines in the Sultanate.

**Abbreviations:** CDC, Centers for Disease Control and Prevention; DCDC, Department of Communicable Disease Surveillance and Control; DGHA, Director General for Health Affairs; ECDC, European Centre for Disease Control and Prevention; EMRO, World Health Organization's Eastern Mediterranean Regional Office; EPI, Extended Program of Immunization; GCC, Gulf Cooperation Council; MOH, Ministry of Health; NITAG, National Immunization Technical Advisory Group; WHO, World Health Organization.

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**Table 1**  
Committee member.

• Current Chairman: Dean, Oman Medical College (Paediatrician)	
• Secretary: Director, Department of Communicable Disease Surveillance and Control (Public Health), Ministry of Health (MoH)	
• Members:	Director, Public Health Laboratories, MoH(Virologist) Head, Child Health Dept., Royal Hospital, MoH (Infectious Disease Paediatrician) Head of Internal Medicine, Royal Hospital, MoH (Adult Infectious Disease) Head of Immunology division, SQU Please add name in full (Immunologist expert from the university)
• <i>Ex officio</i> members:	Director Drug Control Dept. (Pharmaceutical Affairs and Drug Control), MoH Director, Drug test Central Laboratory (Pharmaceutical Affairs and Drug Control), MoH Director, Specification and Supplies Department (Medical Supply), MoH Director, Medical Stores (Medical Supply), MoH

The scope of the committee's activities extends to vaccines and immunization as well as to other infectious diseases. It addresses these issues within the parameters of the Terms of Reference. Within the area of vaccines and immunization, the committee decides on the use of new vaccines, most recently the seven-valent pneumococcal conjugate vaccine (PCV-7), the inactivated poliovirus vaccine (IPV) and the Haemophilus influenzae type b conjugate-hepatitis-B-DTwP (pentavalent) vaccine. It has also recommended vaccination schedules for these vaccines and has furthermore made recommendations on vaccines for high-risk groups, including targeted immunization against seasonal influenza, meningococcal meningitis and rubella. Different formulations for the pentavalent vaccine have been considered, as have vaccines extending beyond infant schedules to all vaccine-preventable diseases. Finally, the committee has made recommendations on specific vaccines, commissioning to outside experts impact studies on hepatitis-B vaccination as well as cost-effectiveness studies on the rotavirus and PCV-7 vaccines.

Minutes of committee meetings and a record of their recommendations are summarized and publicized on a regular basis in a national newsletter distributed to all health sector professionals, including physicians, members of the Ministry of Health and university researchers. The meetings themselves are closed.

Committee members are appointed for a period of 3 years by the Minister of Health and may be re-appointed thereafter for another 3 years maximum. These appointments are made on the basis of nominations given by the Director General for Health Affairs (DGHA), the Director of the Department of Communicable Disease Surveillance and Control (DCDSC), the Chair and other committee members. There are also four *ex officio* members on the committee. They participate in the discussions that lead to the required consensus.

Conflicts of interest are avoided through committee members declaring their interests and signing confidentiality agreements. Each member is required to provide a written declaration of interest at each meeting as well as at the time of his or her appointment. Non-governmental members receive no travel cost reimbursement or any other form of payment.

Guidelines are currently being written to govern nominations to the committee, the mode of functioning of committee members and other issues. A rotation process for membership is also being considered.

Meetings are held at the Ministry of Health at least twice a year, with additional meetings as required on an *ad hoc* basis. There were three meetings in 2008 and six in 2009. In addition, informal meetings are held occasionally between the Chairman, the Executive Secretary and one or two committee members to discuss the general direction of the group.

The Secretary of the committee is responsible for preparing and circulating an updated agenda, along with proper background documents, articles, studies, etc., at least a month in advance of any meeting. The agenda is distributed to all the members for their approval and to obtain suggestions for additional items. After

the committee meetings, suggestions for the next agenda are also sought. In addition, items are proposed occasionally by the Sultanate's decision-makers, and by physicians directly via e-mails or dialogue with committee members. The pharmaceutical industry is not allowed to present topics to the committee. Within 2 weeks of the meeting, the Secretariat records and shares the minutes with NITAG members. The members have approximately 2 weeks to respond and clarify as well as endorse (no reply from any member within that allocated period affirms consent).

### 3. Development of recommendations and the basis for decision-making

The committee obtains technical data from a variety of sources: official communicable disease data published by the MOH (newsletter, annual statistical report); locally or internationally published studies; its own members; invited experts based within the Sultanate (e.g. WHO). For example, in developing recommendations on the introduction of rotavirus vaccine into the EPI, a rotavirus disease burden study was commissioned by external experts. The task force made use of WHO position papers and other position statements such as those from the US Centers for Disease Control and Prevention (CDC), as well as Internet sites of the WHO, CDC and the European Centre for Disease Control and Prevention (ECDC).

A significant source of information is obtained from working groups set up by the Committee to address specific topics, with one working group for each topic. These groups are *ad hoc*, existing as long as they are needed to provide the necessary scientific evidence to inform decision-making. The committee members decide upon the composition of the task force, selected from within the MoH, university and the private sector, with the Chairperson giving final approval. The working group produces a paper to be submitted to the committee, who reviews and assesses it. The working groups may also make use of outside experts but are not permitted to involve the pharmaceutical industry. Sometimes WHO representatives may also participate in the working groups.

After assessing all available data, the committee will reach consensus and recommendations will be made. If consensus proves impossible, the matter will be sent to the MoH, to make the final decision. Agreed recommendations are forwarded to the ultimate decision-makers within the MoH and then widely circulated via circulars and newsletters. It should be noted that to date the committee has always followed official WHO recommendations for vaccine use.

Formal contact between the committee members and similar NITAGs in the Gulf Cooperation Council (GCC) countries is facilitated through an annual inter-country meeting on communicable diseases that includes all the countries of the GCC. This comprises Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates and Yemen. Half of the meeting each year is devoted to discussing issues concerning the Expanded Programme on Immunization (EPI), including the introduction of new vaccines and

immunization issues. In 2007, it was recommended that GCC countries would have a common EPI schedule, a decision validated by all NITAGs in GCC countries and then approved by the relevant Ministers. As of 1 January 2008, the decision was implemented.

#### **4. The role played by economic evaluations and other financial issues in decision-making**

The cost of vaccines, as well as that of the overall immunization program, is considered when the committee decides on its recommendations. Formal economic evaluations are made (cost-effectiveness, cost-benefit and cost-utility) and both affordability and sustainability are assessed. Subcommittees, with the assistance of health economic experts from within the MoH, assist in making these evaluations—for example, an economic evaluation of rotavirus vaccine disease burden was undertaken. They are currently assessing the human papillomavirus (HPV) disease burden from an economic perspective. Additionally, assessments made regionally are taken into account, particularly when provided by WHO's Eastern Mediterranean Regional Office (EMRO) or from other GCC countries, such as in the case of cost-effectiveness studies on HPV.

#### **5. The role of the committee in the ultimate decision-making process**

Recommendations are circulated to all members to receive their comments, after which they are sent to decision-makers for final approval. The Government is obliged to implement committee recommendations. The Ministry of Finance and other government departments play no part in decision-making.

A good example of how decisions are made can be found in the case of the introduction of PCV-7 into the EPI schedule in Oman. At the time, there was very strong demand from the vaccine committee members and paediatricians to introduce the vaccine. As a result, the committee recommended forming a task force to study the disease burden and the vaccine's cost-effectiveness. Ultimately all the necessary information was generated and studied, with a recommendation then made to introduce PCV-7 into EPI.

It should be noted that in the Sultanate of Oman, there is no role for the pharmaceutical industry, insurers, and lobby groups in the committee's decision-making process.

#### **6. Communications activities and training practices**

The committee disseminates data and information in letters to public health officials, letters to physicians and through its quarterly newsletter. Members communicate with each other at meetings and via email. Information is shared with NITAGs in other Gulf countries, where most of them already have their own committees.

There is no specific training for members *per se*, but when a new member joins, a detailed discussion and orientation with the Secretary follows about the scope of the committee's work. In addition, the Secretary regularly circulates updated information to the whole committee.

To maintain their level of competence and awareness of current issues, members attend WHO meetings, national EPI meetings and other health congresses. This enables members to meet other health professionals in their field and to keep abreast of new knowledge.

#### **7. Conclusion: problems encountered, limitations and further developments**

The Sultanate of Oman is a small country, therefore it is difficult to find and maintain a sufficiently large number of experts in immunization and immunization-related fields. There is, for example, only one immunologist in the entire country. The few existing experts work either for the MoH (90%) or for the university (10%). In some cases this results in a lack of sufficient expertise to address specific questions—an example being that the committee's health economist is often so busy with other activities that he is not always available for committee work.

The Sultanate's evidence-based decision-making process could be improved by making sure that the committee is updated regularly on immunization issues. To achieve this, the Secretary sends updated information from WHO and other EPI sources to all members, doing his best to ensure they understand and digest the information. This is not always easy to accomplish, given the fact that the members are very busy. The Secretary is investigating ways of overcoming these obstacles.

Evidence-based decision-making could also be improved by bringing more expertise onto the committee, either by training existing members or by bringing new members on board. The University, for example, could provide committee members with training in health economics so that they would be able to deal with economic questions at a higher level than at present. Likewise, generalists with specific expertise could be brought in to help the committee with its deliberations, even though they might not be experts in the field. For instance, a statistician could be included on the committee to provide some perspective on economic issues, even if he or she is not an expert in health economics.

#### **Conflict of interest statement**

The authors state that they have no conflict of interest.

#### **Reference**

- [1] Ministerial Decree no. 18/2000, The Sultanate of Oman; 2000.