



The National Advisory Group on Immunization (NAGI) of the Republic of South Africa

Barry D. Schoub^{a,*}, Ntombenhle J. Ngcobo^b, Shabir Madhi^c

^a National Institute for Communicable Diseases, Private Bag X4, Sandringham 2131, South Africa

^b Expanded Program on Immunization: National Department of Health, Pretoria, South Africa

^c DST/NRF: Vaccine Preventable Diseases, University of the Witwatersrand, South Africa

ARTICLE INFO

Keywords:
Immunization
Advisory committee
Evidence
Decision making
South Africa

ABSTRACT

The National Immunization Technical Advisory Group (NITAG) in South Africa, known as the National Advisory Group on Immunization (NAGI), was established in 1993 to advise the National Department of Health (DoH) on issues related to vaccination. Meetings are held as needed but at least twice a year. The scope includes vaccines and immunization and other relevant infectious disease issues. NAGI also makes recommendations on vaccine schedules and formulations. Agendas are set by DoH and the Chairman of NAGI. NAGI brings together experts from a range of different fields relevant to vaccines and vaccinations and has been an important resource for guiding the Expanded Program of Immunization (EPI) in South Africa.

© 2010 Elsevier Ltd. All rights reserved.

1. Introduction

The National Immunization Technical Advisory Group (NITAG) in the Republic of South Africa is the National Advisory Group on Immunization (NAGI). This committee was established in 1993 to advise the Department of Health (DoH) on issues related to vaccination. Prior to that time no committee had existed, so decisions concerning vaccines and immunization had been taken on the basis of *ad hoc* consultations or discussions with local experts and WHO.

The first NAGI was established in the dying days of the apartheid government when the country was largely isolated from the international community and when scientific and academic contacts were substantially restricted. Following on the first democratically elected government, NAGI enjoyed greatly enhanced access to international expertise during the rest of its first 5-year term as well as seeing a strengthening of the immunization program.

The South African NAGI consists of 9 regular members representing disciplines of paediatrics, vaccinology, community health, virology, microbiology, infectious diseases, neurology, pulmonology and medicines regulation. In addition there is also *ex officio* representation from the DoH and the country offices of the WHO and UNICEF – making a total of 14 participants (Table 1).

2. Terms of reference and process of meetings

NAGI was established by a letter of appointment from the Ministry of Health (MoH) that included a brief outline of the committee's mission. There are terms of reference [1] that were attached to the letter of appointment. These spell out clearly what inputs the MoH expects from NAGI and the process through which NAGI recommendations should be communicated to the ministry.

The documents produced by the committee are not public. Recommendations and other documents such as rationales for introducing new vaccines (including assessments of disease burdens and cost-benefit analyses) are sent to the DoH. NAGI minutes are sent to the Director General of Health for perusal who liaises with the MoH on a need basis, or vice versa.

The MoH appoints all the members to the committee, based on expertise and merit. Appointment to NAGI is made via a letter from the MoH. No contract is drawn up since members serve in honorary, non-remunerative capacities and each member is appointed to a five-year term that is renewable. Vacancies created by resignation may be filled by the MoH.

The five *ex officio* members, one each from WHO and UNICEF along with three from the DoH, are not allowed to participate in formal voting but are otherwise full participants in committee deliberations.

DoH members act only as the secretariat for NAGI, which helps ensure that the committee is in touch with what is happening with the program at a practical level and also facilitates communication between NAGI and the Department. The DoH members generally come from the Department's Expanded Program on Immunization (EPI) Unit, occasionally joined by other senior officials who

Abbreviations: EPI, Expanded Program of Immunization; NAGI, National Advisory Group on Immunization; TFI, Task Force on Immunization; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

* Corresponding author. Tel.: +27 11 3866137; fax: +27 11 8821872.

E-mail address: barrys@nicd.ac.za (B.D. Schoub).

Table 1
NAGI committee members.

Chairman: NICD Community Health Specialist, University of Pretoria Professor of Microbiology, University of Pretoria Professor of Paediatrics, Director Institute of Infectious Disease and Molecular Medicine, Director South African Tuberculosis Vaccine Initiative University of Cape Town Professor of Pulmonology, N R Mandela School of Medicine, University of Kwa-Zulu-Natal Professor of Neurology, University of Pretoria Professor of Infectious Diseases, University of Stellenbosch Consultant to Medicines Regulatory Authority, South Africa Professor of Vaccinology, DST/NRF: Vaccine Preventable Diseases, University of the Witwatersrand Department of Health, Expanded Programme on Immunization (EPI) (<i>ex-officio</i>) Department of Health, Expanded Programme on Immunization (<i>ex-officio</i>) Department of Health, Expanded Programme on Immunization (<i>ex-officio</i>) UNICEF Representative, Pretoria (<i>ex-officio</i>) WHO Representative, WHO Country Office (<i>ex-officio</i>)
--

attend the meetings. Outside experts make presentations to the committee as needed, and the DoH is encouraging the presence of senior experts from WHO and UNICEF, especially these organizations' country representatives. Non-government members do not receive any regular payment but have their travel reimbursed and may receive honoraria for their time.

There is no obligatory written declaration of interest demanded of NAGI members either at the time of each meeting or when new members are appointed, nor are members required to sign confidentiality agreements. Nevertheless, members are expected to declare interests when these exist. NAGI is currently looking into this issue and the question has recently been brought up by the DoH.

Meetings are prepared by the DoH, acting in its capacity as NAGI Secretariat, whose EPI Unit relays issues to the Chairman for inclusion in the meeting agenda. The Secretariat has a budget for its expenses. Meetings are hosted by the National Institute for Communicable Diseases (NICD). The costs related to meeting attendance and logistics (arranging transport, reimbursing expenses and paying nominal honoraria) are managed by an EPI administrator. This administrator is also responsible for taking minutes at the meeting. The operational budget for NAGI comes from the EPI program.

Meetings are held at the NICD in Johannesburg on an "as needed" basis but at least twice a year, supplemented by electronic consultations. In addition, the Chair of NAGI may call an emergency meeting if the need arises. Meetings are closed, but on occasion outside persons may be invited to attend, including representatives of the pharmaceutical industry and non-member academics. In 2008 there were two in-person meetings and two meetings via teleconference and in 2009 there were the same.

3. Development of recommendations and the basis for decision making

The scope of the committee's work includes vaccines and immunization as well as other infectious disease issues where relevant. Within the area of vaccines and immunization, it makes yes/no decisions concerning the use of new vaccines. For example, NAGI has recommended the introduction of rotavirus and pneumococcal vaccines in South Africa and has recently seen these recommendations implemented [2]. Earlier it had recommended the introduction of Hib vaccine into the EPI [3].

NAGI makes recommendations on vaccine schedules and has been considering the timing of the measles vaccine as well

as advising that three doses of pneumococcal conjugate vaccine (PCV) be given spaced at six and fourteen weeks and at nine months. Additionally, it recommends vaccines such as for pandemic H1N1 influenza for high-risk groups and makes recommendations on vaccines beyond infant schedules and for all vaccine-preventable diseases. The committee is presently considering human papillomavirus (HPV) vaccine in this context, having previously considered those for rubella and tetanus/diphtheria.

NAGI also makes recommendations concerning vaccine formulations while also recommending specific vaccines for the same disease, e.g. inactivated poliovirus vaccine (IPV) and oral poliovirus vaccine (OPV) were considered along with combination vaccines. When required, it also asks for further studies to be made. In the case of the HPV vaccine, for instance, NAGI decided that more studies were needed concerning the effectiveness of the vaccine under conditions of high human immunodeficiency virus (HIV) disease burden such as exists in the local environment.

The committee has a variety of sources of information and technical expertise, beginning with its official and *ex officio* membership and including invited *ad hoc* experts from both inside and outside South Africa. It makes use of experts from the NICD and from university departments as well. Expertise is provided by WHO and UNICEF members participating in NAGI and is also obtained from WHO position statements. Industry representatives are either invited by NAGI or approach the committee requesting to be heard on specific issues.

When deciding on recommendations, the committee takes the following vaccine-preventable health outcomes into account, listed in descending order of importance: mortality, disability-adjusted life years or quality-adjusted life years lost, hospitalizations, equity, overall morbidity and epidemic potential. The committee assesses these factors as an ensemble, based on an overall portfolio of data.

Recommendations are decided upon by consensus of NAGI members, excluding *ex officio* participants and have always been done so. There have never been instances where voting was required or to record dissenting opinions, although provision has been made for doing so if the need arises. A report is then sent to the relevant officials in the DoH.

Minutes of meetings record the deliberations and highlight specific recommendations. These minutes and recommendations are sent to the Director General of Health for executive action. As NAGI reports directly and exclusively to the National DoH, the deliberations and specific formal recommendations are not published but are kept confidential. Discussions between the DoH and NAGI could, however, result in making information available to the public when there is a need, depending on the sensitivity of the matter under consideration. This situation has not occurred up until now.

The committee generally follows WHO recommendations in its decision making, but there have been exceptions to this. For example, WHO recommends that the measles vaccine be given only at nine months [4], whereas South Africa provides vaccination at both nine and eighteen months. Likewise, the country has shifted to providing IPV at six, ten, and fourteen weeks, with OPV given at birth and at six weeks, all of which is not consistent with WHO policy [5]. Additionally, the PCV immunization schedules of six and fourteen weeks and then again at nine months (as opposed to WHO policy of 6-10-14 weeks or 2-4-6 months [6]), as well as the rotavirus scheduled dose at fourteen weeks (as opposed to WHO policy of six and ten weeks [7]), indicate an occasional independence from WHO directives. When decisions taken by NAGI at variance with WHO recommendations, these take into account local disease programmatic factors as well as the fact that that South Africa has a Public Private Partnership (PPP) agreement on vaccine supplies. The PPP agreement is with the Biovac Institute which has a research and a development function and is developing local capacity for the production of vaccines. NAGI has no formal ties with NITAGs in other

Download English Version:

<https://daneshyari.com/en/article/10970144>

Download Persian Version:

<https://daneshyari.com/article/10970144>

[Daneshyari.com](https://daneshyari.com)