



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



The National Advisory Group on Immunisation (NAGI)

Proposed Revision: Terms of Reference and Conditions for NAGI

February 2020

1. INTRODUCTION

- 1.1. The National Immunisation Technical Advisory Group (NITAG) in the Republic of South Africa is known as the National Advisory group on Immunisation (NAGI). NAGI was first established in 1994, following on recommendations of a review of the National Expanded Programme on Immunisation in South Africa (EPI-SA) conducted by the National Department of Health (NDOH) in conjunction with the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO).
- 1.2. It was envisaged that NAGI would comprise of members with expertise on vaccines, epidemiology of vaccine preventable disease, control of vaccine preventable diseases (VPD) and operational issues with regard to immunisation. NAGI membership expertise should include but is not limited to specialists in paediatrics/child health, public health, infectious/communicable disease control, microbiology, virology, immunology/ vaccinology, epidemiology, health economics, evidence-based health care, and medicinal product regulation. The NAGI members are likely to be experts conducting research and or teaching in their specific fields.

2. MANDATE

- 2.1. The overall aim of NAGI is to bring together experts from different fields involved in vaccinology and immunisation, who will advise and guide the NDOH of South Africa to implement an effective immunisation programme in keeping with current international standards and development. NAGI will provide the NDOH with ongoing and timely medical, scientific and public health advice relating to vaccines and immunisation strategy. This work may relate to the use of new and established vaccines in humans, vaccine evaluation, and the implementation of vaccine schedules including in response to VPD outbreaks or threats.

3. ROLES AND RESPONSIBILITIES

- 3.1. To advise the Minister of Health and the NDOH on strategies relating to currently in-use vaccines or new vaccine introduction.
- 3.2. To advise the Minister of Health and NDOH on off label use of currently in-use or new vaccines.
- 3.3. To facilitate the collation/assembly and synthesis of necessary literature required for decision making on policy issues (e.g. disease burden, cost benefit analysis of a vaccine before new vaccine introduction)
- 3.4. To review and update the chapter on Immunisations that is contained in the Primary Health Care Essential Medicines List (EML) Standard Treatment Guidelines.
- 3.5. To help identify critical research needs around immunisation.
- 3.6. To be instrumental in the development of innovative measures in relation to vaccine use, for VPD control that will promote and protect the health of all South Africans.
- 3.7. To commission special projects or studies to address critical gaps in immunisation related practices.
- 3.8. To regularly review progress of the EPI-SA programme including vaccine coverage and challenges in relation thereto.
- 3.9. To present an annual report to the Minister of Health on their area of work.

4. CONDITIONS FOR NAGI

- 4.1. NAGI will be an independent advisory body of experts that does not form part of the structures that relate to the NDOH.
- 4.2. NAGI will advise the Minister of Health and the NDOH on matters related to vaccines and immunisation.
- 4.3. NAGI members are nominated for appointment by the Minister of Health based on their field of expertise and on merit.

- 4.4. NAGI members will serve a four-year term which is renewable to a maximum of two consecutive terms.
- 4.5. Once constituted, NAGI will appoint its own chairperson, deputy chairperson and secretary.
- 4.6. The Minister retains the right to appoint additional members or replace any member who can no longer serve for any reasons e.g. relocation, poor performance, resignation, death, etc.
- 4.7. NAGI has the privilege to communicate directly (through the chairperson and the Chief Director: Child, Youth and School Health) with the Deputy Director-General responsible for EPI, and where necessary with the Director-General or Minister of Health.
- 4.8. A two-thirds presence of members shall constitute a quorum for making decisions and recommendations that are presented to the NDOH through the Deputy Director-General.
- 4.9. Where possible NAGI recommendations should be based on consensus. Should NAGI members fail to agree on a matter, a majority of a quorate meeting is needed for a decision to be adopted.
- 4.10. NAGI members not employed by Government, are eligible to receive remuneration for their participation in the meetings, the level of which will be determined by the Minister of Health in accordance with Public Finance Policies.
- 4.11. NAGI members are expected to declare potential conflict of interest that may arise out of their position as NAGI members and their other activities, sponsorship, employment, affiliation, etc.

5. MEMBERSHIP

5.1. Chair

The Chair will be elected by a simple majority of a quorate NAGI meeting. The Chair is a non-voting member, except when there is a tie vote.

5.2. Vice-Chair

A Vice-Chair will be elected by a majority of a quorate NAGI meeting. The Vice-Chair will act only when the Chair is unavailable as an alternate acting Chair.

5.3. Secretariat

The EPI Specialist, the National EPI Manager and other officials in the EPI sub-directorate will form the secretariat of NAGI and will work closely with the Chair.

5.4. Members

- 5.4.1 Membership will consist of twelve to fifteen voting members (i.e. excluding the Chair) who are knowledgeable in the field of immunisation practices, have multidisciplinary expertise in public health and paediatrics, and have expertise in the use of vaccines and prophylaxis agents for the prevention of VPD.
- 5.4.2 Membership may also include one or more members with expertise in pharmaceuticals specifically biological medicines. There will be at least one representative from the private sector, as well as a representative of the National Essential Medicines List Committee (NEMLC). Members are expected to express their personal opinions as informed by their professional expertise. Appointments should reflect the Republic of South Africa's policy that committee membership be fairly balanced in terms of points of view represented, diverse demographic and geographic areas, and the committee's function.
- 5.4.3 The membership will be reviewed on a regular basis by the Chair in consultation with the NDOH. Suggestions will be sought from current and former NAGI members. Selection will be based on expertise and public advertisement. When a member is unable to complete his or her term, a letter of resignation should be submitted to the Chair of the committee and the Minister of Health via the Executive Secretariat. Membership will automatically terminate following non-attendance of three consecutive scheduled meetings even if reasons have been offered.

5.4.4 All new members will be expected to comply with NAGI's conflict of interest policy and guidelines and should have signed a declaration of interest statement prior to taking office, and which will be supplemented with any new declarations before each meeting. The Chair (or attending committee members in the event of the Chair's declaration) will make the final decision on whether or not a COI exists, and the action required to address this.

5.4.5 A new member will be appointed for the full four-year term.

5.5. Ex-officio Members

The NDOH can assign ex-officio non-voting members. The role of the Ex-officio members is to support the work of NAGI by providing additional knowledge and expertise. Ex-officio members include individuals from liaison Departments and Structures, and development partners such as UNICEF and WHO.

5.6. NAGI Working Groups

NAGI may, from time-to-time, establish time-bound working groups to deal with specific immunisation-related issues. The working group may comprise NAGI and non-NAGI members but must be chaired by a NAGI member who will provide feedback at NAGI meetings. Working group members will be expected to sign both Declarations of Interest and Non-Disclosure agreements as required.

5.7. Representation of the NDOH at NAGI

Representatives of NDOH will attend NAGI meetings to facilitate functioning of NAGI. In addition to the EPI specialist and National EPI manager who are part of the secretariat, the Chief Director: Child, Youth and School Health and the EPI Pharmaceutical Policy Specialist will attend meetings to enable clarification of Departmental and programmatic matters.

6. VOTING AND QUORUM

6.1. NAGI decisions will ideally be reached by consensus. Voting if required, will be restricted to the voting members only. A two thirds majority of current members is required to authenticate a vote and in the case of a meeting, two thirds of a quorate meeting. Members who have been absent for all discussions and not able to review all background documentation will be encouraged to abstain if they are not in a position to form an objective opinion. An abstention will count as a neutral vote. Where there is a tie, the Chair can cast the deciding vote. Representatives of the NDOH and Ex-officio members will not be permitted to vote.

7. RESOURCES AND SUPPORT

7.1. The NDOH will cover all expenses related to the functioning of NAGI, including travel and subsistence, venue and catering. Secretariat functions to the committee (or working group) will be provided by the NDOH via the office of the Senior EPI Specialist and the National EPI Manager. Scientific, research, policy, monitoring, and other technical support will be provided and/or funded by NDOH. The members' travel expenses to participate at regular and ad hoc NAGI meetings will be paid by the NDOH in accordance with Public Finance Policies.

7.2. Ex-officio members will be expected to pay for their travel expenses.

8. MEETINGS

8.1. NAGI meets four times a year (face-to-face) and by teleconference as needed.

8.2. The chairperson of NAGI will call for additional meetings as need arises.

8.3. The venues of the meetings will be arranged by the NDOH and will be mutually agreed upon with the Chair.

8.4. Attendance

Members of NAGI assume the responsibility for attending all meetings. If a meeting is missed, background material will be provided on issues discussed and the member will be expected to be prepared for the next meeting.

8.5. Record of Decisions

For each meeting, minutes of discussions will be prepared by the Executive Secretariat within two weeks of the meeting. Once reviewed by the Chair, these will be distributed to members and Ex-officio members for comments within one month following the meeting. Once approved by all NAGI members, the minutes will be adopted at the next meeting and signed by the Chair as a reflection of the proceedings.

8.6. Invitees

Experts, including representatives from manufacturers, may be invited to make presentation on a need basis, but should not be involved in formulating the recommendations.

8.7. Selection of topics (on a needs basis)

8.7.1 A minimum of two weeks before each meeting, agenda items will be requested, and a list of current agenda items will be distributed. Those suggesting new agenda items are asked to specify the topic, issues of concern, and specific questions to be addressed by NAGI. Agenda items are accepted for presentation by the Executive Secretary, in consultation with the Chair. In addition, urgent agenda items or matters arising from the previous minutes or as raised by committee members may be included at the start of the NAGI meeting.

8.7.2 NAGI will review each major VPD at least once every 4 years, to consider whether a revised recommendation is needed.

9. PRIVACY OF INFORMATION

9.1. Matters discussed at the meeting are confidential and should not be discussed by members in public. Reports to respective associations by liaison members should be in general terms only and should be maintained in confidence by that member's organization. All members are required to sign confidentiality agreements. In the event that it would be useful to share a draft statement with specific groups for feedback, the Chair and Executive Secretary should be consulted.

10. MEDIA INTERACTION

10.1. All media requests related to NAGI statements or activities should be directed to the NDOH who will coordinate all external communications. When appropriate, the NDOH in consultation with the Chair, may appoint a member of the committee to act as its spokesperson.

11. DECLARATION OF INTEREST

11.1. Members, representatives and invited external experts are expected to conduct themselves in an appropriate manner and in accordance with the NAGI conflict of interest guidelines. They must declare all interests which may constitute a conflict of interest (COI), real or perceived on an annual basis to the Executive Secretary and disclose any circumstances that may place or be seen to place the member in a real, apparent or potential COI. Prior to each meeting, members will be given an opportunity to advise on any potential COI. The chair of NAGI or of a working group will decide after discussion with the member, whether or not this constitutes a COI. It will be incumbent upon the member to update their disclosure in writing, should their personal situation change.

- 11.2. Members, ex-officio members and external experts are expected to protect and maintain as confidential any trade secret or privileged information divulged during the work of the committee. They must not discuss or divulge information obtained from the work of the committee, including its recommendations, until such time as this information has been officially released by NDOH for public distribution.

12. RECOMMENDATIONS

12.1. Development Process

- 12.1.1 NAGI members may take the lead for drafting recommendations on behalf of the working group. The working group is responsible for consolidating the relevant data including research data and presenting a summary with recommendations where relevant, to the full committee. Documents should be submitted in a timely manner for members to have time (minimum of two weeks before the issue is to be discussed) to analyse the information prior to discussion and decision making.
- 12.1.2 Smaller working groups will be established to deal with specific vaccine-related issues. Working group chairs should be members of NAGI or as deemed appropriate by the Committee Chair. Members will be asked to volunteer to participate in working groups based on their expertise. A working group membership list will be maintained by the Secretariat and reviewed on a regular basis. Working groups will review technical aspects and prepare recommendations to be discussed by the full committee. Working groups must include one or more regular voting members but may also include ex-officio members or other experts. External experts, including representatives from manufacturers, may be invited to present to the group but may not join the group or participate in group discussions. Other stakeholders will be consulted before the recommendation is finalised.
- 12.1.3. The process of developing NAGI recommendations may include but is not limited to:
- a. Review of the recommendations of other groups such as World Health Organisation recommendations and inputs from the Strategic Advisory Group of Experts on Immunisation (SAGE) and the AFRO Regional Immunisation Technical Advisory Group (RITAG).
 - b. Review of product monograph;
 - c. Review of registration status with South African Health Products Regulatory Authority(SAHPRA), other recognised medical regulatory authorities and through WHO pre-qualification;
 - d. Review of the scientific literature on the burden of disease (morbidity, mortality) in the population in general and in specific risk groups, vaccine characteristics (e.g. safety, efficacy, effectiveness). Consideration will be given to the relevance, quality and quantity of published and unpublished data, and emphasis on local or regional data.
- 12.1.4. The evidence supporting the NAGI recommendations will be explicit.

12.2. Submission of Recommendations from NAGI

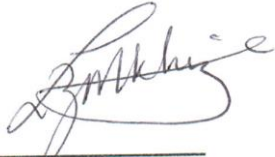
- 12.2.1. Each working group leading the recommendation will draft the recommendation for adoption by the whole committee and signed by the Chair for presentation to the NDOH.
- 12.2.2. The Chief Director: Child, Youth and School Health and the EPI unit will present all the recommendations and matters brought up by NAGI to the Deputy Director-General or Director-General: Health for further consideration and action.
- 12.2.3. The Deputy Director-General or Director-General: Health will take up the recommendations with the relevant structures e.g. the Minister, the Senior Management Team, the provincial Heads of Health, the National Health Council and other similar structures.
- 12.2.4. The National and the Provincial EPI units or other relevant units will embark on the implementation of recommendations once these have been considered and agreed upon by the Deputy Director-General or Director-General: Health and the Heads of Health.
- 12.2.5. It is the responsibility of the NDOH to work out details of implementation of the NAGI recommendations.

- 12.2.6. The NDOH under the leadership of the Deputy Director-General or Director-General: Health will take reasonable measures to facilitate the implementation of the recommendations of NAGI, taking into account the constraints of limited resources.
- 12.2.7. After a decision is made on a recommendation, the NDOH will formally inform the Chair of NAGI of the decision for feedback to the whole committee.
- 12.2.8. All recommendations made by NAGI will be tracked by the Secretariat and be regularly reviewed by NAGI.

13. REVIEW OF TERMS OF REFERENCE

- 13.1. The Terms of Reference will be reviewed once a year, amendments will be agreed upon by consensus or vote; and submitted to the Minister of Health for consideration.

Signed by the Minister of Health



DR ZL MKHIZE, MP
MINISTER OF HEALTH

15/07/2020
DATE