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Development of a concept paper on the establishment and functioning of a National Immunization Technical Advisory Group

Guidance document

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TABLE OF CONTENTS

TABLE OF CONTENTS	1
INTRODUCTION	2
PURPOSE OF A CONCEPT PAPER	3
STEPS FOR PREPARING A CONCEPT PAPER	4
DRAFT VERSION	4
VALIDATION	4
SECTIONS OF THE CONCEPT PAPER	5
1. NATIONAL CONTEXT IN IMMUNIZATION	5
1.1. CURRENT SITUATION OF VACCINE-PREVENTABLE DISEASES AND VACCINE PROGRAMMES	5
1.2. THE NATIONAL IMMUNIZATION PROGRAMME (NIP)	5
1.3. THE DECISION-MAKING PROCESS IN THE NIP	5
2. CONTRIBUTION OF A NITAG TO THE NATIONAL IMMUNIZATION DECISION-MAKING PROCESS	6
2.1. EXISTING COMMITTEES IN IMMUNIZATION AND POTENTIAL STRUCTURE OF THE NITAG	6
2.2. MAPPING OF INFLUENCES	7
2.3. NATIONAL INSTITUTIONS WHICH WILL BE INVOLVED IN THE ESTABLISHMENT AND FUNCTIONING OF THE NITAG	7
2.4. MAPPING OF TOPICS	7
3. PROPOSAL FOR ESTABLISHING A NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUP	7
3.1. PROPOSED TERMS OF REFERENCE OF THE NITAG	7
3.2. FUNCTIONING CONSIDERATIONS	7
3.3. CHALLENGES AND SUCCESS FACTORS	8
APPENDIX 1: WHO GUIDANCE ON THE ESTABLISHMENT OF NITAGS	9

INTRODUCTION

THE SIVAC INITIATIVE

The SIVAC Initiative is implemented in strong collaboration with WHO and other partners. It is a program of the Health Policy and Institutional Development unit of the Agence de Médecine Préventive (AMP), which is a WHO Collaborating Center for evidence-informed immunization policymaking (www.sivacinitiative.org).

The Initiative aims to assist countries in the establishment or strengthening of functional, sustainable National Immunization Technical Advisory Groups (NITAGs).

The SIVAC Initiative conducts the following activities:

- ✦ Support the creation of NITAGs in middle income and GAVI-eligible countries worldwide. In Western-Africa, a regional approach is developed in collaboration with the West Africa Health Organization (WAHO).
- ✦ Strengthen new and existing NITAGs, in order to improve their functioning and their capacity to issue recommendations based on evidence.
 - Develop and share knowledge about NITAGs and evidence-based decision making :
 - Development of tools to facilitate the functioning of the NITAGs
 - Organization of workshops
 - Creation of a NITAG resource center to provide information, tools, and training to NITAGs and to the global immunization community to improve the evidence-based decision making process

NATIONAL IMMUNISATION TECHNICAL ADVISORY GROUPS

NITAGs aim to provide National Authorities with evidence-based recommendations for national immunization programs and policies.

NITAGs are composed of national experts from various disciplines (e.g. pharmacologist, pediatrician, clinician, epidemiologist, infectious diseases specialist, health economist...) who examine the existing evidence at local, regional and international levels to provide their Ministers of Health with specific technical and scientific recommendations on all areas of immunization (modification of immunization schedules, introduction of new vaccines, improvement of routine immunization coverage...).

Guidance on the establishment and the functioning of the NITAGs has been issued by WHO (Appendix 1).

This document builds on WHO guidance; it presents the steps for developing a concept paper for the establishment of a NITAG and the key points to be addressed.

PURPOSE OF A CONCEPT PAPER

The objective of a concept paper is to describe the role and functioning of the future NITAG and its place in a country decision-making system.

The concept paper should:

- 1) Describe the current situation regarding vaccine preventable diseases, immunization programmes, decision-making processes,
- 2) Describe the principles that will guide the establishment and *modus operandi* (procedures, terms of reference, etc.) of the future NITAG taking into consideration the local specificities;

It is also recommended to refer to the WHO Guidelines “National Immunization Technical Advisory Group (NITAG) Guidance for their establishment and functioning” (Appendix 1)

STEPS FOR PREPARING A CONCEPT PAPER

Draft version

It is recommended that a small team of experts (3 – 8 members) is designated by the Ministry of Health and develops this concept paper. The working group should include at least one senior pediatrician, one senior epidemiologist, one staff of the National Immunization Program (NIP). Other experts with experience in infectious diseases and in immunization could be associated. The team should prepare a draft document based on their knowledge and on the consultations of other experts for specific questions.

Validation

Once the draft concept paper is ready the country could organize a consensus workshop to review the document with the wider immunisation stakeholders community and get their buy-in. Representatives from the following institutions are important to involve in the process

- ✦ The different units of the Ministry of Health (Immunization, Child and Health, Occupational Health, School and University health...)
- ✦ Other ministries (e.g. Ministry of Finance, Ministry of Education...)
- ✦ National Public Health Services
- ✦ Private health sector
- ✦ Professional health associations
- ✦ Research Institutes
- ✦ Universities (pediatrics, infectious diseases, epidemiology, health sociology and anthropology, health economy, microbiology, virology...)
- ✦ Immunization Inter-Agency Coordination Committee (ICC)
- ✦ National Regulation Authority
- ✦ WHO and UNICEF
- ✦ NGOs involved in immunization programs
- ✦ Civil Society Organizations (Red Cross, patient association, religious groups...)
- ✦ Health Military Medical services
- ✦ Health system coverage (social security...)

It is recommended that the length of the concept paper does not exceed 15 pages.

SECTIONS OF THE CONCEPT PAPER

We suggest that the concept paper is presented as follows.

1. National context in immunization

1.1. Current situation of vaccine-preventable diseases and vaccine programmes

Please describe (3 pages max) key relevant points about

- ✦ Socio-demographic situation of the country (short paragraph)
- ✦ Vaccine Preventable Diseases- mortality and morbidity
- ✦ Current organization of the Extended Programme in Immunization (EPI) (schedules, coverage, success and weaknesses...)
- ✦ The financing of the national immunization programmes
- ✦ Immunization activities carried out outside the EPI
- ✦ The organization of the immunization services (public and private sector)

1.2. The national immunization programme (NIP)

Describe the structure of the Ministry of Health (MoH) and its services/programmes. Elaborate on the NIP.

1.3. The decision-making process in the NIP

Please describe:

- ✦ Other ministries and their respective services/programmes involved in immunization decision-making
- ✦ National Regulatory Bodies in immunization.
- ✦ The groups or committees currently involved in making decisions about the national immunization programmes (MoH committees, ICC, etc.);
 - Their mandates
 - The institution to which these groups belong (or where their secretariat is located)
- ✦ The types of information used in decision making (research papers, national data, WHO recommendations, etc.);
- ✦ The process for making decisions (e.g., the formation of working groups to study the specific issue being discussed) and the ultimate decision-makers. Refer to recently introduced vaccines or new immunisation policy/strategy
 - If recommendations are already used in any phase of the decision-making process, please elaborate:
 - + Who issues recommendations? When are they taken in consideration?
 - + Are they confidential? Available publicly?

- + Are they binding?
- + How the process for the final approval by the MOH is made;
- + All other relevant information concerning decision-making for the NIP.

2. Contribution of a NITAG to the national immunization decision-making process

To complete this section, please liaise with the legal adviser of the MoH.

2.1. Existing committees in immunization and potential structure of the NITAG

The objective of this section is to see which possibilities do the legal framework and the organization of the MoH and public institutions offer to create committees, and the type of committees that can be created under this framework.

Please start with a description of existing committees in immunization mentioned in section 1.2 above. For each of them, describe:

- + Legal framework
 - o What are the ministries / institutions involved in the creation of such committee?
 - + Type of legal document establishing the committee (provide a copy if possible)
 - + Signatories of the document (Ministry of Health, Prime Minister, President...)?
- + What are the areas covered and the mandate / attributions of the committee?
 - o Is the committee focusing on immunization only or is it also working on other topics?
 - o What is its remit (consultative, executive, advisory)?
- + Functioning characteristics
 - o How and for how long are members designated?
 - o What are the frequency and the type of meetings?
 - o How does the committee make decisions (voting, consensus, etc.)?
 - o Which institution is in charge of the secretariat or coordinates the committee?
 - o What is the budget and what expenses does it cover?
- + What kind of outputs does it issue (decisions, recommendations, others...)?
 - o If recommendations: are they binding?
- + Who are the recipients of the committee's outputs (recommendations, decisions, others)?
 - o Are recommendations / decisions made public?
- + Are there other specificities?

Once you have described the existing committees, elaborate clearly on the benefit of the NITAG as it compares to existing committees. It is crucial to show that there will be not duplication of mandate or scope between NITAG and existing committees. Finally, building on what you describe on the functioning of the existing committees, please elaborate on the structure that the NITAG could have.

2.2. Mapping of influences

Based on recent vaccine introduction/immunization experiences in the country, please describe the various bodies that can influence immunization policy decisions:

- + Key opinion leaders
- + Civil society and religious groups
- + Others

2.3. National institutions which will be involved in the establishment and functioning of the NITAG

Please list and describe the institutions involved in immunisation policies and programme implementation or working in immunisation related disciplines

- + Technical agencies
- + Universities
- + Research institutes
- + Departments of MoH
- + Other...

2.4. Mapping of topics

Please describe the technical topics related to immunizations that are on the MoH agenda for the next 2-5 years (introduction of new vaccines, modification of schedules, coverage improvement...) and will be submitted to the NITAG.

3. Proposal for establishing a national immunization technical advisory group

For guidance on this section, please refer to WHO Guidelines (Appendix 1).

3.1. Proposed terms of reference of the NITAG

3.2. Functioning considerations

3.2.1. Membership

- ✦ Describe the disciplines and types of members (core member, ex-officio and liaison member) of the future NITAG
- ✦ Describe the terms and procedures for the selection of committee members:
 - The selection procedures should be adapted to the country context (proposal to the MoH submitted by the EPI? Call for expression of interest? Selection from existing committees?)
 - Number of members, duration of mandate, possibility and procedures for the renewal/extension of membership...
 - Rotation of chairmanship...

3.2.2. Operating procedures

Describe the proposed procedures and rules of the committee (including frequency of meetings, setting-up working groups to study specific issues, development of annual work plans, procedures to avoid conflicts of interest, dissemination of recommendations to the MoH, etc.).

Indicate that detailed operating procedures will be described in a manual once the NITAG is established; the manual will describe roles and responsibilities of each category of membership, of the secretariat, methods of work for development of recommendations, preparation and dissemination of reports.

3.2.3. Legal framework

Describe the legal / administrative requirements for establishing the NITAG (new law or decree from the government, and steps necessary for obtaining this legal basis).

For this section, also seek advice from the legal adviser of the MoH.

3.2.4. Resources

Describe the proposed institution or agency that will coordinate and serve as the technical and scientific secretariat of the committee. Describe the human resources that will be allocated to this task.

Describe the budget and the human resources that will be planned to ensure that the NITAG is working properly. Please also indicate in which budget line this will be included.

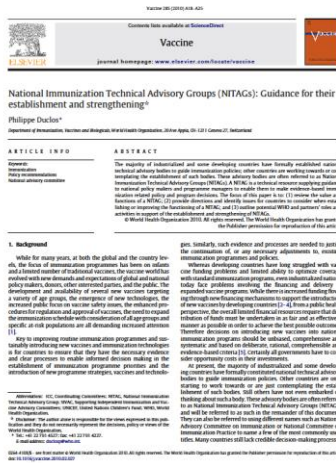
3.3. Challenges and success factors

Please describe:

- ✦ What will facilitate the establishment and the functioning of the NITAG
- ✦ The weaknesses and the gaps the country needs to address to have a fully functional NITAG (e.g. lack of expertise in specific areas, human resources for a functional secretariat, sustainability...).

APPENDIX 1: WHO GUIDANCE ON THE ESTABLISHMENT OF NITAGS

Click on the document below:



Or access it online here: http://www.nitag-resource.org/medias/librairie/260_1-20101227-094653.PDF