



SIVAC

Supporting Independent
Immunization and Vaccine
Advisory Committees

February 2016

Key findings of Armenian NITAG evaluation

Key points for consideration in the
development of the work plan

Version 2.0

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Agence de Médecine Préventive

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1. Introduction

In November 2015, in the framework of its collaboration with WHO-EURO for strengthening immunization decision-making in the European region, the Health Policy and Institutional Development Center supported Armenian NITAG performance evaluation. Key findings presented in this document should be discussed / adjusted with the NITAG, and inform the development of an annual NITAG work plan

Three aspects that were evaluated:

- ✦ Functioning: Do the NITAG structure and operations foster the timely generation of recommendations?
- ✦ Quality and Evidence Based Recommendation Making: Has the NITAG developed, formalized and implemented processes to ensure quality recommendation?
- ✦ Institutional positioning: Is the NITAG fully integrated into the national immunization decision-making system?

2. Results

2.1. Functioning

LEGAL STRUCTURE AND OPERATING DOCUMENTS

- ✦ Decree establishing the NITAG (2013 – replacing former committee set in 2009)
- ✦ Decree includes some information on the running of the committee
 - Most observed elements are actually compliant with the decree (e.g. circulation of agenda...)
 - Some elements are not compliant (e.g. no actual Conflicts of Interest management policy), partially compliant (e.g. number of meetings, that depends on years and that depends whether extraordinary meetings are considered) or quite different to the decree (e.g. decisions are actually taken by consensus, while the decree mentions they are taken at simple majority)
 - Some elements are not considered in the decree (e.g. rotation of members)
- ✦ No other reference documents to guide the functioning of the NITAG (e.g. Standard Operating Procedures – SOP)

MEMBERSHIP

- ✦ There are 12 core-members, including the Executive Secretary of the NITAG, covering 4 medical disciplines
- ✦ A need of two additional experts within the committee was mentioned by NITAG members (one immunologist, one health economist)
- ✦ There is no liaison nor ex-officio members (note that a few members are affiliated with other organizations, such as National Regulatory Agency and Paediatrician Association)
- ✦ Executive Secretary of the NITAG is senior advisor to the head of NCDC in charge of the management of the NIP

PLANNING AND AGENDA SETTING

- ✦ The agenda is set up meeting by meeting
- ✦ NIP receives request from MoH (Deputy Minister in charge of Public Health, department of Public Health, Child and Maternal Health Inspectorate...) and Head of NCDC. These requests are not formal. Some of these questions initially addressed to the NIP are “transferred” to the NITAG agenda
- ✦ No direct requests are sent from the MoH to the NITAG.
- ✦ There is no annual agenda setting in consultation with national stakeholders.

ORGANISATION OF MEETINGS

- ✦ Secretariat is in charge of organizing meetings. Four persons are involved in the Secretariat activities, all within the NIP (without formal assignment for this, but as a part of their regular duties).
- ✦ In addition to ordinary meetings, many extraordinary meetings are organized
 - Extraordinary meetings seem to be mostly following-up with ordinary meetings
 - There is no circulated reports for extraordinary meetings.

CONFLICT OF INTEREST

- ✦ The decree mentions that members should present a written declaration on possible conflict of interest before each meeting.
- ✦ Not done, no conflict of interest management policy reported (such policies are unusual in Armenia).
- ✦ Members met during the evaluation were not reluctant to speak about the activities / links they had with other organizations, and none of them had conflict of interest with vaccine manufacturers.

FUNDING

- ✦ The MoH does not allocate a budget for the NITAG.
- ✦ Each institution pays for human resources out of their own budget (e.g. NIP budget for secretariat).
- ✦ The sole other expenses are related to coffee breaks, and are covered by the institution hosting the meeting. There is no available funding for conducting studies or other scientific activities.
- ✦ GAVI transition plan should include some resources for NITAG capacity building (source : joint appraisal report).

2.2. Evidence Based Recommendation Making

FRAMEWORK FOR THE CONSIDERATION OF THE QUESTION

- ✦ The role of the NITAG in handling the overall policy question is limited. In details, assuming it is topics-based, it is not fully clear:
 - Whether the question asked to the NITAG is quite broad or more focused and specific
 - What is the role of the NITAG in the definition of the research questions
- ✦ The NITAG does not build a recommendation framework to guide its work, and does not apply a systematic process to prepare the recommendation.
- ✦ Type of data used are quite consistent and aspects most usually considered are:
 - Clinical aspects (of disease and of AEFI)
 - Safety of vaccines
 - Epidemiology (but it is not reported in meeting minutes).

PREPARATION OF THE RECOMMENDATION (BACKGROUND DOCUMENTS)

- ✦ Secretariat staff in charge of preparing NITAG meetings is motivated and skilled in medical disciplines. The staff has received none to limited training related to the process to issue evidence based recommendations (e.g. literature search or evidence appraisal).
- ✦ Literature search are mostly conducted by the Executive Secretary herself, in collaboration with the Head of the VPD Department.
- ✦ Access to data and literature for the preparation of meetings:
 - Access to national data is easy (but availability of data is varying – e.g. there is data (screening) for cervical cancer but there is no data for pneumonia).
 - Literature considered includes WHO documents (position papers, weekly epidemiologic review...), recommendations from the ACIP and NACI (and when available recommendations from European NITAGs provided by WHO), publications on Russian National Library of Medicine and to a lower extent on PubMed.
 - Access to literature is also limited because the NITAG cannot purchase publications.
- ✦ Background documents are circulated to members one week before meeting.
- ✦ Some members contribute in searching and providing evidence to feed the discussions (which illustrates strong motivation of members, but may also imply duplication of work) :
 - By searching individually prior to the meetings
 - By searching individually after the meeting, when members are asked to send their opinion

CONSIDERATION OF THE EVIDENCE IN THE RECOMMENDATION MAKING PROCESS

- ✦ For some topics the Secretariat provides a synthesis of the evidence gathered. Even if they may be the result of a hard and good work, these documents are not named as such, the presentation of the evidence is not done in a standardized format, and there is no reference to sources.
- ✦ External experts on specific topics are sometimes invited to NITAG meetings to present data and feed the discussion.
- ✦ Even though some evidence is considered, some interviewees raised the concern that recommendations may be more based on “experts opinions” than evidence.
- ✦ Overall, it is difficult to follow the process and the evidence considered, as it is not fully reported in the meeting minutes (see next section).
- ✦ It can be noted that data related to AEFI and contraindications are important topics for the NITAG:
 - A “permanent” working group on AEFI present declared rates of AEFI at the beginning of each meeting, and severe cases are individually discussed during NITAG meetings.
 - As the NITAG gathers high level clinicians expert in immunization, it is an opportunity to discuss such topics with most relevant persons
 - On the other side, these topics (and the related clinical approach) may take a prominent place compared to broader policy issues.

MEETING REPORT AND RECOMMENDATIONS

- ✦ Meeting minutes are not detailed and do not allow to fully understand the evidence considered, the discussions, the process for making recommendations or for defining needs for additional analysis, and, if any, what the recommendation is based on.
- ✦ There are no recommendation notes as such.
 - Recommendations are stated in the end of meeting minutes

- They are not put ahead, and there is no formal difference between organizational recommendations (e.g. about the continuation of the work on a topic) and final recommendations of the NITAG.

2.3. Integration into the immunization decision-making system

NITAG'S INDIVIDUALS VERSUS NITAG AS A BODY

- ✦ NITAG members (including Executive Secretary) are very well known for their expertise. They are some of the most renowned experts in the field and some have some links with the highest decision making level. The high expertise and reputation of these members is a great asset for the NITAG.
- ✦ However, the NITAG as a body is not very visible. As an illustration, 3 out of 5 of the stakeholders interviewed during the evaluation (within and outside of the MoH) said they were not aware about the existence of the committee, or only very vaguely (but knew very well the individuals). It can be noted that 2 of them were at the “professional” level, and that the head of their department (who was not available for meeting during the evaluation) was reported to be very aware of the existence and role of NITAG.

NITAG POSITIONING TOWARDS MOH

- ✦ There is no formal interactions between the NITAG (as a body) and the decision-making level. As said before:
 - Interactions rely on individuals
 - Requests from decision-makers are addressed to the NIP (as the NIP, not as the NITAG Secretariat).
 - Recommendations are not formally communicated to the decision-making level
- ✦ After the NITAG recommended to replace DTaP by Pentavalent (booster dose), the MoH consulted with other bodies (Pediatic Association and public health organizations) before making the related decision (i.e. the MoH did not fully rely on NITAG recommendation).
- ✦ Minister of Health is interested in evidence based approach which provides an opportunity for the NITAG.

NITAG VISIBILITY TOWARDS OTHER NATIONAL STAKEHOLDERS

- ✦ NITAG (as a body) visibility is limited
- ✦ Recommendations of NITAG are not widely disseminated

3. Key Recommendations

3.1. On NITAG functioning

DEVELOP ANNUAL AGENDA IN COLLABORATION WITH NATIONAL STAKEHOLDERS

The development of an annual agenda, in collaboration between the MoH, the Chair and the NIP (Executive Secretary of the NITAG) should facilitate the agenda setting of each meeting (leaving more time to prepare the background documents) and position better the NITAG to tackle policy issues. Thus, it should also reinforce the visibility of the NITAG (see section on institutional positioning of the committee). It does not prevent to have topics added in the agenda along the year, depending on the needs.

With same perspective of better activities planning and positioning of the NITAG, a list of the topics to be addressed in the 2-3 years horizon could be developed every year.

DEVELOP STANDARD OPERATING PROCEDURES (SOP)

A set of SOP can be developed:

- ✦ It can facilitate the functioning of the committee, by standardizing some of the tasks (NITAG, Secretariat) and formalizing some communication circuits.
- ✦ It can address some points that are not considered in the decree (or make them more accurate), such as the rotation of members
- ✦ Similarly, generic documents (templates) can be developed (see also next section).

IMPLEMENT A CONFLICT OF INTEREST (COI) MANAGEMENT POLICY

While it is well noted that it is not common to have a CoI management policy in Armenia, it is recommended to implement such a policy (which is a basic WHO indicator on NITAG performance, reported in the JRF). If so, because it is unusual, such a policy should be thoroughly explained and discussed with all NITAG members (a SIVAC / WHO document is being developed for this purpose).

CAREFULLY CONSIDER THE EXPANSION OF MEMBERSHIP

As addition of other members (immunologist, health economist) is put on the table by some members, this question should be carefully considered (assessment of their role and added value – possible consideration of other expertise). Adding ex-officio and liaison members can also be an opportunity to get formal links with stakeholders. This question of membership can be considered together with the mapping of stakeholders and experts (see next sections).

3.2. On Evidence Based Recommendation Making

STRUCTURE THE PROCESS FOR DEVELOPING RECOMMENDATIONS

The process for the development of the recommendation should be strengthened. The topic is broad, and two points can be implemented quite easily and help structure the whole process:

- ✦ For each topic addressed to the NITAG, develop a recommendation framework that will guide the work of the NITAG.
- ✦ Use the NITAG Resource Center (NRC) to get access to further literature.

STANDARDIZE DOCUMENTS

Besides the process, it is recommended to have some more structured and standardized documents. It can be done quite “easily”, and such documents can:

- ✦ Foster the strengthening and standardization of the process.
- ✦ Facilitate the work of the NITAG at different levels (writing / reading the document)
- ✦ Increase the credibility / visibility of the NITAG activities

It concerns (amongst possibly others):

- ✦ Background documents that present a synthesis of the evidence gathered (and possibly other, such as the missing information, some specific questions asked to the NITAG members...)
- ✦ Meeting reports
- ✦ Recommendation notes, to be disseminated as appropriate, and stating the recommendation of the NITAG, with a reference to the evidence.

SET-UP WORKING GROUPS TO DEVELOP BACKGROUND DOCUMENTS AND PREPARE RECOMMENDATIONS, IN LIAISON WITH THE SECRETARIAT

Establishment of working group to prepare specific recommendations, in liaison with the Secretariat, would allow to bring more experts on a specific topic, who will focus more on the preparation of a topic, leaving more time for the Secretariat for other tasks (e.g. preparation of reports, preparation of other topics..). It may also limit the number of extraordinary meetings. It should overall increase efficiency of the NITAG.

In order to mobilize appropriate experts in the working groups, a mapping of national experts can be conducted.

It can be noted that decree mentions the establishment of working groups.

In order to address these points, a training for the whole Secretariat and the whole NITAG on the development of evidence based recommendation should be very useful (SIVAC training available). In addition, some specific and targeted trainings may be useful (e.g. training on literature search).

3.3. On integration into the immunization decision-making system

Strengthening the functioning and the recommendation making process (see previous sections) would also indirectly foster the strengthening of the integration of the NITAG.

FORMALIZE COMMUNICATION WITH MOH (DECISION MAKING LEVEL)

Formalisation of communication with the MoH should help increasing the visibility of the NITAG, and position it as an “unescapable” body for immunization policy making. It can include

- + Definition / clarification of communication channels
- + Standardization of documents (e.g. recommendation notes)

DISSEMINATE MORE THE NITAG RECOMMENDATIONS TO EXTERNAL STAKEHOLDERS

NITAG recommendations can be more widely disseminated (MoH website which is quite popular, other website being developed with the support of UNICEF – to be confirmed). Evidence underlying the recommendation should be included.

More widely, links with professional associations and other stakeholders can be reinforced, so as to increase visibility of NITAG amongst health professionals (other forms of collaboration with such stakeholders can also be developed, for instance for the preparation of background documents)

DEVELOP A COMMUNICATION PLAN TO INCREASE OVERALL NITAG VISIBILITY

More communication should be made on the NITAG (role, activity) and its recommendations to respond to the lack of the visibility of the NITAG – towards the MoH and external stakeholders and the general population – should be elaborated. The two recommendations above will be part of this communication plan.

NITAG should build upon the reputation and professional network of the members to increase its visibility. When appropriate, members are invited to communicate more in their capacity of NITAG members (instead of their “regular” capacity).

CONDUCT A MAPPING OF STAKEHOLDERS

A stakeholder’s mapping and analysis can help address the above points (refining of communication strategy and development of possible collaborations).