



The Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative: A country-driven, multi-partner program to support evidence-based decision making

Kamel Senouci^{a,*}, Julia Blau^a, Batmunkh Nyambat^b, Papa Coumba Faye^a, Lara Gautier^a, Alfred Da Silva^a, Michael O. Favorov^b, John D. Clemens^b, Philippe Stoeckel^a, Brad D. Gessner^a

^a Agence de Médecine Préventive (AMP), Paris, France

^b International Vaccine Institute (IVI), Seoul, South Korea

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ABSTRACT

Multiple health priorities, limited human resources and logistical capacities, as well as expensive vaccines with limited funds available increase the need for evidence-based decision making in immunization programs. The aim of the Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative is to support countries in the establishment or strengthening of National Immunization Technical Advisory Groups (NITAGs) that provide recommendations on immunization policies and programs (e.g., vaccination schedules, improvements of routine immunization coverage, new vaccine introduction, etc.). SIVAC, a program funded by the Bill & Melinda Gates Foundation, is based on a country-driven, step-by-step process that ensures its support is tailored to country needs and emphasizes NITAG sustainability. SIVAC supports countries by reinforcing the capacities of the NITAG scientific and technical secretariat and by providing specific support activities established in consultation with the country and other international partners. Additionally, SIVAC and partners have built an electronic platform, the NITAG Resource Center, that provides information, tools, and briefings to NITAGs and the immunization community.

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1. Introduction

The need for evidence-based decision making in immunization programs has become crucial in light of multiple health priorities, limited human resources and logistical capacities, as well as the high cost of vaccines relative to limited public funds that are available. Evidence-based decision making can provide support for immunization programs compared to other health interventions, and within immunization programs, can inform decisions related to new vaccine introduction, vaccine priorities, vaccine schedules, target groups and other issues.

An important step that countries can take to encourage well-informed decision making regarding immunization is to establish a group of national experts to advise the Ministry of Health. So far, most industrialized countries and some developing countries

have already constituted National Immunization Technical Advisory Groups (NITAGs) to guide immunization policies [1], while other countries are currently working towards the establishment of NITAGs.

2. What is SIVAC?

The aim of the Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative is to help countries establish or strengthen NITAGs. This support is provided in middle-income countries and in countries that are eligible for support from the Global Alliance for Vaccines and Immunization (GAVI). The main role of NITAGs is to help health authorities formulate immunization policies according to the specific needs of their country, while taking into account the regional and international context. In addition to supporting countries directly, SIVAC also contributes to activities and products that can benefit a wider range of countries.

This project, funded by the Bill & Melinda Gates Foundation, is led by the French agency Agence de Médecine Préventive (AMP), in partnership with the International Vaccine Institute (IVI) of Seoul, Republic of Korea (Table 1), and in collaboration with the World Health Organization (WHO) through its headquarters and regional and country offices.

Abbreviations: NITAG, National Immunization Technical Advisory Group; SIVAC, Supporting Independent Immunization and Vaccine Advisory Committees; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

* Corresponding author at: Agence de Médecine Préventive (AMP), c/o Institut Pasteur, 25-28 rue du Docteur Roux, 75724 Paris Cedex 15, France.
Tel.: +33 1 53 86 89 20; fax: +33 1 53 86 89 39.

E-mail address: ksenouci@aamp.org (K. Senouci).

Table 1
Who implements the SIVAC initiative?

<p>Agence de Médecine Préventive (AMP): Created in 1972, AMP is a non-profit organization that links and mobilizes scientific, biological, technical, human and financial resources to address the needs of developing countries in the area of infectious diseases. To achieve this goal, AMP provides technical consultancy and international health expertise in various areas such as applied epidemiology, laboratory technology, health economics, health logistics, instructional system design, biostatistics and ethics. Website: www.aamp.org</p> <p>International Vaccine Institute (IVI): Located in Seoul, Republic of Korea, IVI was originally established at the initiative of the United Nations Development Program (UNDP). IVI is an international research, development and technical assistance organization exclusively devoted to bringing new vaccines to poor populations of the developing world. Its mission is to combat infectious diseases through innovations in vaccine design, development and introduction, addressing the needs of people in developing countries. Website: www.ivi.int</p>

The SIVAC team is composed of a program director, a program manager and a program officer based in Paris, France; a coordinator for Asia based in Seoul, Republic of Korea; and a coordinator for West Africa based in Abidjan, Cote d'Ivoire. The principal investigator of the SIVAC Initiative is AMP's scientific director. There are many other contributors to the project, including technical staff from AMP with specialties in epidemiology, training and communications, health economics, immunization logistics, and vaccine cold chain, as well as IVI staff and consultants with expertise in translational research and epidemiology. The SIVAC Initiative also benefits from the input of the members of its External Technical Advisory Panel (ETAP). This advisory panel is composed of eleven members, all from different countries, who were selected for their expertise and for their active participation in the establishment and implementation of immunization policies and programs at the national, regional, and international level. Their roles are to advise the SIVAC team and to provide input concerning strategic directions for the project.

Initiated in April 2008, the project is planned to end in April 2015. Initially, SIVAC's objective was to assist in establishing NITAGs in six GAVI-eligible countries in Africa and six GAVI-eligible countries in Asia. However, after the first few months of activities, which included an in-depth situational analysis and a review of the accomplishments of WHO regional offices in facilitating the establishment of NITAGs in Asia, the SIVAC team decided to enlarge its mandate. This enlarged mandate includes assisting in the establishment of NITAGs in GAVI-eligible and middle-income countries in Asia and Africa, as well as in Europe and the Middle East, and supporting the functioning of existing NITAGs. The enlarged mandate also includes establishing strong collaborations with the WHO and other partners in the global immunization community.

The project is evaluated on a regular basis to adjust to the changing needs of the countries involved and adapt to contextual changes. Two formal evaluations will be carried out, one in 2012 and one at the end of the project in 2015. The ultimate measures of SIVAC's success will be the establishment of NITAGs in countries where none had previously existed, active evidence-based decision making by existing and newly created NITAGs, use of NITAGs' decisions by the Ministries of Health and Finance, and the long-term sustainability of NITAGs after the SIVAC Initiative ends.

3. What are the activities of SIVAC?

3.1. Overview

The SIVAC initiative includes country activities, inter-country activities, and crosscutting activities.

Two types of country support can be distinguished:

- The creation of at least seven NITAGs in GAVI-eligible and middle-income countries worldwide.
- The reinforcement of at least six existing NITAGs to improve their evidence-based decision-making processes in developing recommendations.

Selection of the countries to receive SIVAC assistance is in progress. Based on pre-defined selection criteria (including geographic representativeness, routine immunization coverage rates, political stability, and others), a list of potential countries was established based on a literature review, a review of the WHO and UNICEF immunization data [2], and consultations with WHO regional offices. This pre-selection process is being followed by visits to several candidate countries to evaluate the feasibility of the project and the willingness of national health authorities to participate in this program.

3.2. Creation of NITAGs

The SIVAC approach for the creation of NITAGs is based on a country-driven, step-by-step process aimed at ensuring that SIVAC support is tailored to country needs and that the emphasis is on NITAG sustainability. SIVAC's step-by-step approach (Fig. 1) starts with the pre-selection process detailed above, followed by a visit to the country to evaluate project feasibility and the willingness of national health authorities to establish a NITAG. During the country visit, SIVAC meets with national health authorities, describes the WHO guidelines on the functioning and composition of a NITAG and gives examples of other existing NITAGs. SIVAC also consults with national experts, WHO, UNICEF, and others to ensure that expertise is available and that the country is ready to implement a NITAG.

If results from the initial visit prove to be positive and the national authorities express a willingness to establish a NITAG through a letter of interest, SIVAC makes a second country visit to initiate development of a concept paper. The concept paper describes the current situation of immunization policies and programs, gives examples on how they are established, lists potential partners, describes the envisioned NITAG composition, delineates the proposed NITAG's terms of reference, and proposes priority topics to be put on the NITAG agenda. Ideally, the concept paper is developed by a small group consisting of members of the Ministry of Health and external experts, and is then submitted to a large number of experts for discussion and consensus during a national workshop. At this stage, SIVAC mainly provides technical support by helping with the development of the concept paper. Based on the final version of the concept paper, the national authorities develop the legal documents related to the establishment of the NITAG, and sign an agreement with SIVAC that clearly defines the type of support that SIVAC will provide to the country.

Once the NITAG is legally established in the country, the next steps are to appoint the committee members, identify specific agenda topics, organize formal committee meetings, develop recommendations, and have recommendations adopted by the Ministry of Health. The key elements for rapid implementation of a NITAG are the availability of national experts in immunization, a strong willingness by the national authorities to support the NITAG process, a country-driven process, a collaborative approach that involves international partners, and an extensive national consultation process to reach consensus.

SIVAC mainly provides support to the country by reinforcing the scientific and technical capacities of the NITAG's secretariat. Detailed support activities provided by SIVAC are tailored to the country, and are established annually in consultation with the NITAG. These activities can include organizing a visit to a

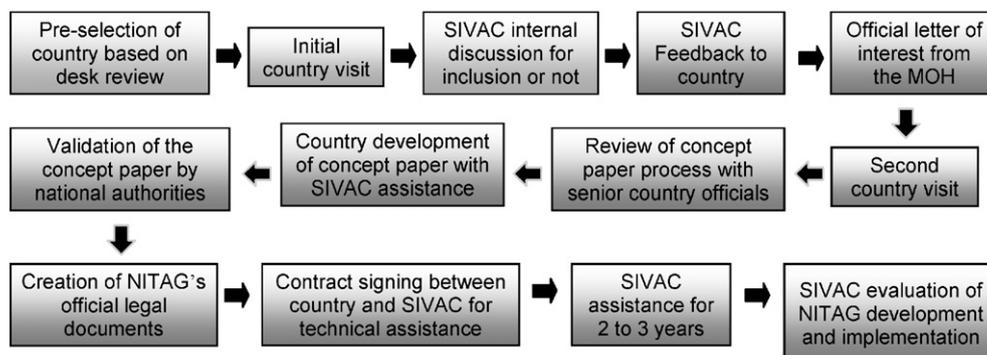


Fig. 1. A step-by-step approach.

well-established NITAG, hiring a national consultant to prepare background documents in areas where the secretariat is weak, briefing on specific issues, participating in the analysis, or other activities. The expected duration of SIVAC support to a country ranges from 2 to 3 years, but this may vary from country to country, keeping in mind that support should be consistent with long-term sustainability. SIVAC also continuously monitors the NITAG's progress and adjusts its support on as-needed basis. At the end of SIVAC's assistance, a comprehensive evaluation on the NITAG's development and implementation is conducted.

3.3. Reinforcement of NITAGs

Recently, several NITAGs have been established in GAVI-eligible and middle-income countries but many of these committees have limitations in implementation and have requested support for improvement. These countries have asked SIVAC and partners to help them to strengthen their functioning (e.g., organization of the NITAG, selection of members, or management of possible competing interests) or to respond to specific technical issues (e.g., lack of expertise in some area or insufficient technical data to reach decisions). For example, an existing NITAG may be required to give advice about the introduction of a new vaccine, such as the rotavirus vaccine. In this case, SIVAC would provide support to the country to help them identify available data on disease burden, health economics, and vaccine safety, as well as data on logistical and cold chain issues. SIVAC would also help in the analyses of the decision-making process related to rotavirus vaccine introduction in other countries; participate in evaluating the implications of the introduction of the vaccine in terms of organization, infrastructure and finances; and define the target population. The expected duration for the provision of SIVAC support and evaluation is about one and a half years per country, but this may vary depending on the circumstances of each specific case.

SIVAC focuses on making this process sustainable in order to facilitate the country's future decision-making process. Therefore, SIVAC concentrates on mobilizing expertise at the country or sub-regional level, in concert with other international initiatives and organizations. This process is reviewed with each country, and recommendations for improving the functioning of the NITAG are developed. As with the creation of NITAGs, SIVAC aims to promote a country-driven process.

The assistance provided can take various forms and depends on the countries' needs and states of advancement in the creation of their committees (Table 2). SIVAC assists NITAGs in both process and structural changes. Two forms of SIVAC assistance are provided:

- Scientific and technical assistance to committee members. This can be country-specific, e.g., a national health economist providing input and training for economic analyses and including these analyses in the evidence-based decision-making process. It can also be more global, e.g., providing training to all committee members on economic analyses or providing training to committee members on the process of decision making by bringing them to other countries where NITAGs are already functioning well.
- Direct support to the secretariat. This can be scientific, e.g., helping the secretariat respond to a call for tender to obtain funding for a study. Alternatively, this can be administrative, e.g., sending invitations to proposed committee members.

3.4. Inter-country ITAG

In West Africa, several countries may not have the capacity to establish NITAGs for various reasons (e.g., lack of expertise, recent conflicts, budget issues, and others). SIVAC has proposed that, as an intermediate step before establishing NITAGs in these countries, support could be provided to establish an inter-country Immunization Technical Advisory Group (ITAG) that would include several or all of the countries of West Africa. The host for this inter-country ITAG could be the West African Health Organisation (WAHO), which is the technical health agency of the Economic Community of West African States (ECOWAS) and has responsibility for health matters for the 15 signatory countries in West Africa.

This committee's mandate would be advisory rather than binding upon member states. Suggestions have been made regarding its focus (e.g., common health problems such as meningitis, pneumonia or malaria); its composition (e.g., the inclusion of only some countries within the WAHO umbrella); and its mode of functioning (e.g., it might provide technical support to some countries using expertise available in neighboring countries). The feasibility and

Table 2
Possible areas of assistance from SIVAC to existing NITAGs.

<ul style="list-style-type: none"> • Support in reviewing important issues facing countries • Support in reviewing existing tools and partners available for responding to country needs • Support in mobilizing national and sub-regional expertise to ensure sustainability • Support in collecting, analyzing and generating information • Help in establishing the country's action plan • Help in achieving a decision and a set of NITAG recommendations • Help in formulating an action plan for disseminating the recommendations • Support in identifying funding (e.g., for additional studies, to support NITAG functioning) • Support in publishing NITAG decisions • Collaboration with other partners and initiatives

Table 3

A selection of products of the NITAG Resource Center.

- *NITAG observatory*: map of the status of NITAG activities in the world
- *Digital library*: position papers, manuscripts, and WHO guidelines
- *NITAG organization and management tools*: templates and guidelines
- *Evidence-based decision-making tools*: tools in the fields of disease burden, health economics, health financing, and logistics
- *Training/Briefing programs*: courses designed for multimedia, interactive training on topics such as curriculum development, e-tutoring, and coaching trainees
- *Forums*

relevance of such an exploratory approach is being assessed by SIVAC in collaboration with WAHO. A collaborative decision will be made by WAHO, individual countries, and partners on whether to proceed with the inter-country ITAG as suggested. If the decision is positive, work on creating this committee would start immediately.

3.5. Crosscutting activities

Sharing information and experiences is a key element in enhancing evidence-based national decision making in immunization and in ensuring the sustainability of the process at the country level. From this perspective, SIVAC is conducting crosscutting activities to facilitate the evidence-based decision-making process in all NITAGs. These activities are conducted according to an analysis of the work being done by national, regional, and international partners.

Recognizing that publications about NITAGs are scarce, SIVAC has actively encouraged countries to document their experiences concerning their established NITAGs. This activity, known as “The Role of National Advisory Committees in Supporting Evidence-based Decision Making for National Immunization Programs,” is published in the current supplement to *Vaccine*. The published manuscripts aim to provide information to countries new to implementing NITAGs on possible NITAG design and functioning, as well as on particular problems that may occur. 20 countries with well-established NITAGs were selected by SIVAC, with support from the WHO, based on their representativeness in terms of geography and level of development. Fifteen of the solicited countries responded positively to the exercise and are included in the supplement [3].

Additionally, SIVAC administered a questionnaire-based survey in conjunction with all of the WHO regional offices. This survey aimed at identifying the needs of existing and future NITAGs in terms of materials, training/briefing and tools. Results were completed in January 2010 during a workshop convened by SIVAC that gathered current and future NITAG members, as well as international partners.

These two activities form the basis of the development of one of SIVAC's major activities, the NITAG Resource Center. The aim of this electronic platform is to provide information, tools, and training to NITAGs and to the global immunization community to improve evidence-based decision-making processes. SIVAC recognizes that there are many existing tools in the field of immunization but has noticed that few are easily accessible by NITAG members. The NITAG Resource Center contains a comprehensive collection of materials and services that support NITAGs in establishing evidence-based recommendations. Materials come from secondary sources or are specifically developed by SIVAC and partners (Table 3). Most of the services provided are Web-based, with CD-ROMs developed and disseminated to users who have limited access to the Internet. In addition to Web-based services, sub-regional workshops are planned for some particular topics and the use of some tools.

The NITAG Resource Center's services will be evaluated periodically by SIVAC. According to the evaluation of users' needs and an

Table 4

The partners of the SIVAC Initiative.

- World Health Organization (WHO) headquarters, regional offices, and country offices
- United Nations Children's Fund (UNICEF)
- The Global Alliance for Vaccines and Immunizations (GAVI)
- The Sabin Vaccine Institute
- The Program for Appropriate Technology in Health (PATH)
- National technical agencies (e.g., US Centers for Disease Control and Prevention (CDC))
- Regional political organizations (e.g., West African Health Organisation (WAHO))
- Pasteur Institutes
- Public health schools
- Professional societies
- Existing NITAGs
- Ministries of Health in participating countries

assessment of their evolution, SIVAC will develop additional tools, training courses, information, and other services.

4. Who participates in the SIVAC partner network?

Collaborating with key stakeholders in the field of vaccines and immunization is a priority for SIVAC. SIVAC has been informing, meeting and collaborating with many national and international partners including WHO (headquarters, regional and country offices), the United Nations Children's Fund (UNICEF), the Program for Appropriate Technology in Health (PATH), the US Centers for Disease Control and Prevention (CDC), and many other national and international organizations (Table 4).

Meetings with different partners have provided SIVAC with a clear picture of various ongoing activities, particularly with the aim of integrating the SIVAC Initiative into existing programs and specifying joint actions. For example, SIVAC has met regularly with the Immunizations, Vaccines, and Biologicals unit at WHO headquarters, as well as with WHO regional offices. SIVAC has participated in the WHO project on Immunization Schedules Optimization [4] and has been included in some of the WHO regional strategies. Additionally, SIVAC has held a number of information meetings for partners (e.g., GAVI and UNICEF) and participated in several strategic regional and international meetings. Finally, SIVAC ensured that NITAG chairs or members could participate at meetings and work shops to build bridges amongst the immunization community.

5. Conclusion

To make the best-informed decisions in the field of immunization, countries are encouraged by WHO to establish technical groups of national experts. The SIVAC Initiative, a 7-year-long project funded by the Bill & Melinda Gates Foundation, aims to help countries establish or strengthen their NITAGs by providing them with the best available evidence on the functioning and experiences of these groups.

The SIVAC approach is a step-by-step, country-driven process that provides sustainable support to a selection of countries to help them create their own NITAGs or to reinforce existing NITAGs. In this process, countries are encouraged to consider WHO guidelines and to make use of SIVAC's resources, including the expertise of its staff and of its numerous partners, the current supplement to *Vaccine*, and the NITAG Resource Center.

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Conflict of interest statement

The authors state that they have no conflict of interest.

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