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# Chile's National Advisory Committee on Immunization (CAVEI): Evidence-based recommendations for public policy decision-making on vaccines and immunization

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ABSTRACT

A National Immunization Technical Advisory Group (NITAG) provides independent, evidence–based recommendations to the Ministry of Health for immunization programmes and policy formulation. In this article, we describe the structure, functioning and work processes of Chile's NITAG (CAVEI) and assess its functionality, quality of work processes and outputs, and integration of the committee into the Ministry of Health policy process using the *Assessment tool for National Immunization Technical Advisory Groups*. Among its strengths, CAVEI's administrative and work plasticity allows it to respond in a timely manner to the Ministry of Health's requests and proactively raise subjects for review. Representation of multiple areas of expertise within the committee makes CAVEI a robust and balanced entity for the development of evidence–based comprehensive recommendations. High ranking profile of the Secretariat structure furthers CAVEI's competences in policymaking and serves as a bridge between the committee and international initiatives in the field of immunizations.


## 1. Introduction

National Immunization Technical Advisory Groups (NITAGs) are multidisciplinary groups of national experts responsible for providing independent, evidence–based advice to policy makers and programme managers on policy issues related to immunization and vaccines. The Global Vaccine Action Plan (GVAP) calls for all Member States to establish or have access to such a NITAG by 2020 [1] In 2017, an increased number of NITAGs met GVAP functionality criteria with respect to 2016 (64% vs. 73%). These criteria consist of six process indicators: (i) legislative or administrative

*Abbreviations:* NITAG, National Immunization Technical Advisory Group; CAVEI, Comité Asesor en Vacunas y Estrategias de Inmunización; PAHO, Pan American Health Organization; WHO, World Health Organization; CDC, United States Centers for Disease Control and Prevention; GVAP, Global Vaccine Action Plan; GNN, Global NITAG Network; MoH, Ministry of Health; BCG, Bacillus Calmette–Guérin vaccine; DTP3, Diphtheria-tetanus-pertussis vaccine third dose; MMR1, Measles–mumps–rubella vaccine first dose; ToR, Terms of reference; SOP, Standard operating procedures; NIPH, National Institute of Public Health; SAGE, Strategic Advisory Group of Experts on Immunization; FDA, United States Food and Drug Administration, EMA, European Medicines Agency; EVIPNET, Evidence informed policy networks.

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basis for the advisory group; (ii) formal written terms of reference; (iii) at least five different areas of expertise represented among core members, (iv) at least one meeting per year; (v) circulation of the agenda and background documents at least one week prior to meetings; and (vi) mandatory disclosure of any conflict of interest [2].

The improvement in advisory groups capacity to meet the functionality criteria reflects the dynamic nature of the NITAG community and the support offered by the Global NITAG Network (GNN) and WHO Regional Offices to build national sustainable capacities through the provision of training material, training and evaluation sessions and the facilitation of peer–to–peer support meetings [2].

The Chilean NITAG, CAVEI, is mandated by decree to provide the Ministry of Health (MoH) with advice on immunization programmes, strategies and policy formulation. CAVEI can provide advice on the use of any vaccine across de life span for routine immunization or mass vaccination campaigns. Ultimate decisions made by the MoH may fully, partially, or not take CAVEI's recommendations into account.

CAVEI meets the GVAP functionality criteria and sets it own agenda taking into consideration MoH requests.

## 2. Description and background

Establishment of CAVEI was first promulgated in December 2009 by ministerial decree N° 2028 [3], however, advisory group on vaccines activity in Chile dates back to the 1990s. Currently, the committee operates under the mandate of the ministerial decree N° 16 promulgated in April 2013 [4].

As an advisory committee to the MoH, CAVEI came to join a solid and long tradition of public health administration, planning, and health service delivery both in general and regarding immunization policy in particular (Fig. 1).

By the time CAVEI was established, Chile had a population of approximately 17,000,000 inhabitants, all-cause mortality rate was 5.6 per 1000 inhabitants, infant mortality 8.3 per 1000 live births and vaccination coverage for BCG, DTP3 and MMR1 was 99.1%, 94.9% and 91.9%, respectively [5].

The composition of a NITAG consists of core and non-core members. Core members are independent and credible experts who serve in the panel of experts in their own capacity and who do not represent the interests of a particular group or stakeholder. Non-core members are further divided into ex-officio members, who hold immunization-related key positions within government entities, and liaison members, who represent professional societies or associations, other national advisory committees, and key technical partners and thus serve as intermediary [7].

Since 2009, CAVEI's panel of experts has been composed of seven to twelve unpaid members from different regions of the country with expertise in a wide range of areas, including immunization, epidemiology, public health, virology, immunology, infectious diseases, primary health care, immunization services delivery, law and bioethics. The MoH conducts the calls for application to join the committee and the subsequent selection process. The chairperson is elected among core members. A recent update of the committee's standard operating procedures (SOP)– currently under legislation process– establishes that experts serve for a three-year term with the possibility of a renewal for one additional term. After the sixth year of service, a three-year gap is required for new application submissions.

The Secretariat of CAVEI is composed of ex-officio members. These are the heads of the MoH Immunization and Epidemiology

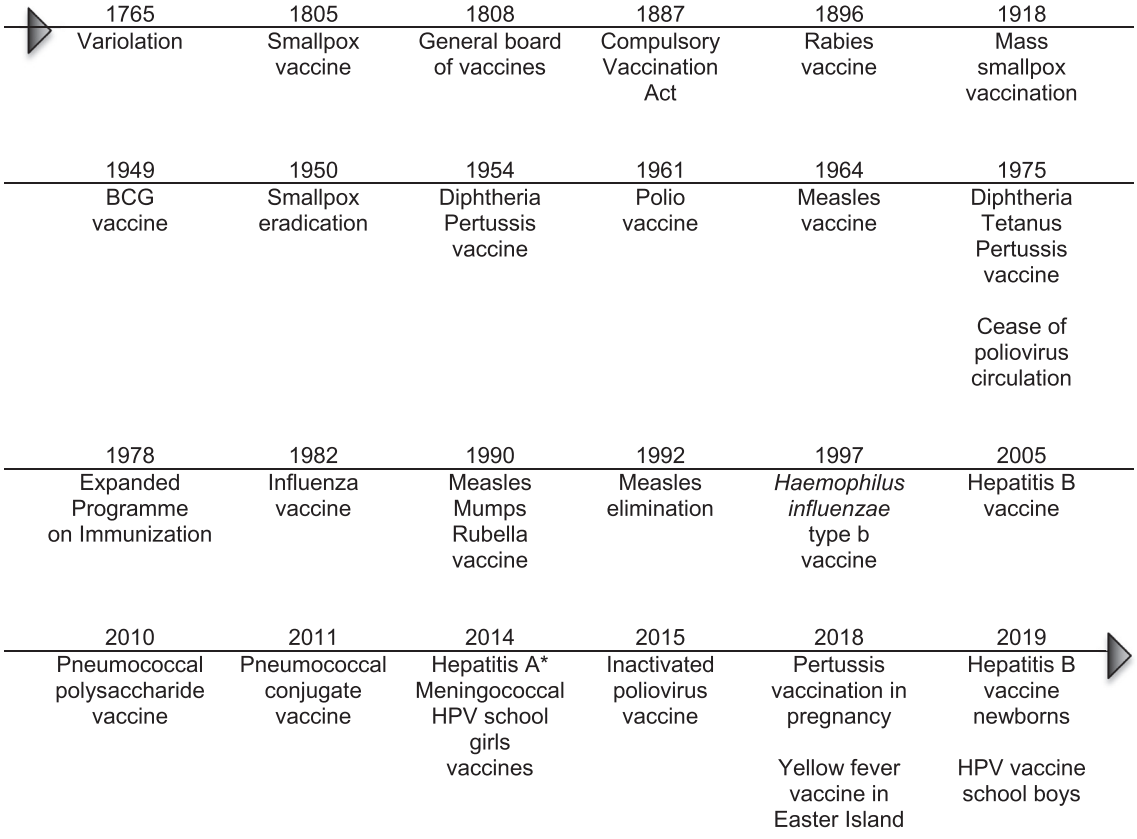


**Fig. 1. Chile's vaccination history timeline.** *Regions of Arica y Parinacota and Biobío. Extended to the whole country in 2018. Source: Immunization Department, Ministry of Health [6].

departments and a representative of the National Regulatory Authority, Institute of Public Health (IPH). To date, ex-officio members have contributed to the committee with their expertise in public policy, public administration, immunizations, paediatric infectious diseases, epidemiology, pharmacy, and vaccine pharmacovigilance. Liaison membership has recently been adopted by CAVEI and a representative of the Chilean Society of Infectious Diseases was appointed as a member of the committee in 2017.

## 3. Functioning and working dynamics

The Terms of reference (ToR) of CAVEI were first stated in 2009, shortly followed by the first version of the SOP. As complementary guidance documents, ToR and SOP have defined the committee operation mode, regulating its composition, members' nomination process, core member's rotation, code of conduct, declaration of conflict of interest, plenary meetings frequency, composition of working groups or subcommittees, evidence-based recommendation process, basis for decision making, financial support from the MoH for elementary functioning, communication with authorities, report of activities (meeting minutes) and work dissemination.

CAVEI's plenary meetings are held monthly and supplementary meetings are scheduled as needed. A quorum of two thirds of core members and two ex-officio members are required to start a plenary session. Declaration of interest must precede the start of each session. Recommendations are voted by core members only. Core members with declared interests are asked to recuse themselves from participating in the discussion and decision making of the issues relating to that interest.

Expenses associated with CAVEI meetings (location, food and travel) and one salary for the executive secretary position are funded by the MoH. The executive secretary's duties entail administration, management, evidence search, and manuscript drafting. Communication flow within CAVEI and with other parties centralizes in the Executive Secretariat.

The current panel of experts has established a *petit comité* for early processing of MoH inputs requests, prompt coordination before emergency consultations (e.g immunization strategies in natural disasters and disease outbreaks), and quick response to minor to moderate tasks including last-minute calls for meetings with health authorities, and drafts approval for circulation within the committee. The *petit comité* is composed of CAVEI's chairperson, one core or liaison member and the executive secretary. This group holds work meetings every two weeks and monthly meetings with the chief of the Immunization Department to foster communication and collaboration, and to ensure that the committee's work aligns with MoH interests. For the development of recommendations, one to two core or liaison members plus the executive secretary form working groups to lead the review of evidence and recommendation crafting.

Interaction with the pharmaceutical industry is regulated by the SOP. Until October 2018, CAVEI met with industry representatives following an audience request; from November 2018 onwards, the committee only accepts scientific evidence submitted for review. CAVEI members decline to participate in industry-sponsored conferences, workshops and gatherings.

## 4. Evidence–based recommendations

CAVEI recommendations respond to requests from the Under Secretary of Public Health, the Immunization Department or the Department of Epidemiology of the MoH, or issues identified as important by CAVEI members. Since its establishment, CAVEI has issued twenty-seven recommendations.

The overall development of recommendations takes into consideration various scientific, epidemiologic, surveillance, public policy, economic, programmatic, and social and behavioural factors for decision-making. The process for crafting recommendations and committee's positions requires the assessment of current available evidence and other elements that include:

- Published scientific literature from indexed journals.
- Unpublished work, including epidemiological information and national laboratory surveillance from the Institute of Public Health and independent laboratories, and adverse events following immunization from the National Regulatory Authority.
- Reports and bulletins issued by widely respected national and international entities including WHO, PAHO, SAGE, FDA, CDC, EMA, and other NITAGs.
- Unpublished data provided by vaccine manufacturers on safety, immunogenicity and efficacy of vaccines.
- Reports from scientific, professional, or civil organizations.
- Correspondence with experts.
- Policy briefs issued by EVIPNET Chile [8].
- Communication with Legal Office of MoH.

Evidence search and early analysis leads to the generation of a comprehensive body of evidence that helps working groups in addressing questions raised and also in identifying the weight of information gaps relative to the topic under study. CAVEI completes a ten–step process for recommendation development, as follows:

1. Understanding the context of the question raised.
2. Study of the epidemiological situation.
3. Identification of target population or risk groups.
4. Referential framework: current available recommendations.
5. Evidence search and critical assessment.
6. Generation of a comprehensive body of evidence.
7. Recommendation drafting and first circulation for members review.
8. Discussion, consensus and closure of the recommendation in plenary session, extraordinary session or by electronic mail if under time constraints.
9. Communication of the recommendation to the Immunization Department and public dissemination.
10. Feedback from the Immunization Department stating acceptance or decline of the recommendation.

The MoH makes ultimate decisions based on the recommendations submitted by CAVEI, along with other information such as manufacturing of vaccines, product registration and required legislative changes. The Immunization Department is in charge of publishing CAVEI's work on its website https://vacunas.minsal.cl/cavei/recomendaciones-cavei, including accepted and declined recommendations, minutes, and position papers. To date, there is 88% acceptance of CAVEI's recommendations.

## 5. CAVEI's evaluation

Stemming from WHO and GNN recommendations, the evaluation of a NITAG's performance helps advisory groups assess how their intended purpose is being met and identify strengths and opportunities for growth. From a networks perspective, the assessment of NITAGs helps countries know where they stand and allows for monitoring of progress at the regional or global levels [7,9].

Once the six NITAG criteria are satisfied, the opportunity for NITAGs to assess their performance by incorporating various perspectives and interests is at hand. Tools for a more complete eval-

uation are the *Indicators to assess National Immunization Technical Advisory Groups (NITAGs)* by Blau et al. [9] and the *SIVAC Evaluation Tool for National Immunization Technical Advisory Groups (NITAGs)* [10], both available for download at the NITAG Resource Centre website (http://www.nitag-resource.org). Countries may review the indicators annually to evaluate their progress toward achieving and institutionalizing more standardized and evidence-based processes for immunization policymaking.

Recently, the US-CDC, in collaboration with WHO and other Global NITAG partners, and upon request from the Global NITAGs Network, developed a simplified *Assessment tool for National Immunization Technical Advisory Groups* [11] that considered three areas of performance: functionality, quality of work processes and outputs, and integration of the committee into the MoH policy process. The tool was adapted from SIVAC material and incorporated information from NITAG-related publications and field experience of partners.

Previous to the application of evaluation tools, CAVEI assessed its structure and functioning using *National Immunization Technical Advisory Groups (NITAGs): Guidance for their establishment and strengthening* by Phillipe Duclos [7]. This pre-evaluation analysis shed light on CAVEI's growth in the past years and, consequently, on the need to update the committee's SOP. The new version of the standard operating procedures provides more detail on core-members' rotation, development of recommendations, working groups' formation, and communications with authorities.

In 2018, CAVEI underwent two evaluations. The first was a self-assessment using the *Indicators to assess National Immunization Technical Advisory Groups (NITAGs)* [9], which consists of 17 process, output, and outcome indicators. The application of this tool provided CAVEI with a broad picture of satisfactory performance.

The second evaluation was the pilot test of the *Assessment tool for National Immunization Technical Advisory Groups*. It evaluates functionality, quality of work processes and outputs, and integration of a NITAG into the MoH policy process. It was conducted over three days. An external consultant coordinated the assessment, which involved individual interviews with all NITAG members/secretariat followed by a group discussion on the last day. An expert in qualitative studies conducted the interviews using an open-ended questionnaire that was adapted to the profile and role of each interviewee. During the group session that lasted two hours, NITAG members and the secretariat jointly filled the NITAG assessment tool. The individual interviews were crucial to prompt the discussions and facilitate the application of the tool. For the purpose of piloting the NITAG assessment tool, interviews were limited to CAVEI members only. However, future applications of this tool may consider including immunization stakeholders, scientific and professional organizations.

Results show that CAVEI is an independent and credible advisory group with a solid administrative basis, clear conflict of interest policy, and practices that serve transparency purposes. CAVEI members are highly committed, which allows regular monthly meetings and supplementary meetings as needed, timely response to MoH requests, and public support of the authorities in times of crisis or questioning of immunization policies.

CAVEI has a robust technical composition of highly qualified professionals who are well recognized in their fields of expertise. Within the committee, the inclusion of the Immunization and Epidemiology Departments, and one representative of the National Institute of Public Health on the Secretariat ensures full participation of high rank governmental authorities involved in immunization policy. The representative of the NIPH being a specialist in vaccine safety is an asset. The Executive Secretary is trained in research epidemiology and public health, and is highly proactive.

Potential challenges to CAVEI's functionality include ensuring the continuity of work dynamics after membership renewal, procedure that could be arranged in such a way that membership terms do not end simultaneously. Also, the expansion of profile expertise on the expert panel to include additional specialties such as social scientists and civil society representatives is desirable.

Visibility and public awareness of CAVEI's work are to be reinforced, together with promoting the sharing of resources, experiences, strategies, and lessons learned with other NITAGs in international or regional meetings and networks.

## 6. Summary and conclusions

Since its establishment, CAVEI has served as a convergence platform for experts enrolled from multiple backgrounds to contribute jointly to immunization policymaking in Chile. CAVEI is an independent and credible advisory group with a solid administrative basis, clear conflict of interest management policy, and practices that serve transparency purposes. These qualities allow CAVEI to publicly support authorities in times of crisis or questioning of immunization policies, and position papers of the committee are examples of this.

As an advisory body to the Ministry of Health, it is essential for CAVEI to maintain its independence and credibility, as well as the quality of its work processes and the soundness of its recommendations. The continuity of CAVEI's intended purpose lies in the permanent alignment with the needs and priorities of health authorities.

CAVEI's organizational flexibility in addressing inputs requests from the health authorities is a remarkable strength. In addition to the monthly frequency of meetings, supplementary meetings and the formation of a subcommittee comprised of a few members to respond to emergency consultations illustrates CAVEI members' commitment to respond to the needs of the MoH in particular and to the population's health needs, overall. Also, CAVEI's working dynamics has allowed the committee to increase productivity in terms of number of recommendations issued per year.

The composition of CAVEI provides the committee with outstanding technical quality, both on the panel of experts and on the Secretariat. The expansion of profiles within the committee could be implemented incorporating new core, liaison or ex-officio members.

CAVEI seems to find itself in an advanced stage of NITAG development, possibly one near consolidation. However, functionality challenges are always to be foreseen and proactive planning and action shall never cease. The health authorities must continue funding CAVEI's essential functioning and encourage its engagement in technical exchanges with other NITAGs and immunization networks.

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## Declaration of Competing Interest

JD has no conflicts of interests. CG has no conflicts of interests. JC has no conflicts of interests. JA has no conflicts of interests. MC has no conflicts of interests. ED has no conflicts of interests. ME works as immunization coordinator for a private hospital that purchases vaccines from different manufacturers and declares to have no conflicts of interests relevant to this paper. JI has no conflicts of interests. JR has no conflicts of interests. AS has no conflicts of interests. SS has no conflicts of interests. NE has no conflicts of interests. MB has no conflicts of interests.

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