Brief report

National Immunization Commission: Strengthening evidence-based decision making in Argentina

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ABSTRACT

In Argentina, the National Technical Advisory Group on Immunizations is represented by the National Immunization Commission (CoNaNl), an organization created by the Ministry of Health in 2000. Recently, the Argentine government has decided to prioritize vaccination as a state policy, emphasizing this strategy as a sign of social equity so CoNaNl was restructured to increase its capacity to formulate sound and evidence-based recommendations. The commission shall consist of a group of immunization experts, representatives of scientific societies, the immunization program and the Ministry of Health. Its functions include the formulation of recommendations on the introduction of vaccines into the immunization program. The recommendations are based on technical, programmatic and social criteria. This decision-making process transparent with the support and advice of experts and scientific societies and guided by available evidence decisions help strengthen the Ministry of Health immunization policy generating greater confidence and support from the population and health professionals.

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1. Introduction

The establishment of national immunization programs is one of the strategies with the greatest impact on disease prevention. In order to ensure success, having expert advice to guide the formulation of evidence-based recommendations that prioritize aspects such as burden of disease, vaccine efficacy and safety, and cost benefit, among others, is fundamental. In this endeavor, technical advisory groups on immunizations play a key role. Some examples are the Advisory Committee on Immunization Practices (ACIP) [1] in the United States and the World Health Organization’s (WHO) Strategic Advisory Group of Experts on Immunizations (SAGE) [2–4]. The Pan-American Health Organization’s (PAHO) ProVac initiative has encouraged the establishment and strengthening of these advisory groups in Latin American and Caribbean countries [5].

In Argentina, National Immunization Technical Advisory Groups (NITAG) is represented by the National Immunization Commission (CoNaNl), an organization created by the Ministry of Health in 2000. CoNaNl has provided advisory services and recommendations on immunization that are reflected in the introduction of different vaccines into the immunization schedule. The lessons learned over the last 12 years of work, along with recommendations from PAHO ProVac Initiative, have led to a proposal to restructure the organization and functions of CoNaNl.

This article describes the historical evolution, characteristics and achievements of CoNaNl in Argentina. This process and the current scientific developments, as well as the complexity of evidence and the prioritization process, have led to the formulation of a proposal on a new operating model for CoNaNl according to the current characteristics of the National Vaccine-Preventable Disease Control Program of Argentina.

1.1. Historical background

Argentina is a country with a population of 40,000,000 and an annual birth rate of approximately 750,000 [6]. The National Vaccine-Preventable Disease Control Program (ProNaCEI) is the Ministry of Health’s Agency responsible for vaccination policies,

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as well as procurement and distribution of the immunobiologics required to fulfil its objectives.

In 2000, the Ministry of Health decided to establish CoNaIn for the purpose of strengthening the actions of the National Immunization Program through a technical resource in immunization in order to advise national authorities in making evidence-based decisions and formulation of recommendations on matters related to vaccine and immunization, in order to achieve control, elimination and, whenever possible, eradication of vaccine-preventable diseases [7].

From 2000 to 2012, CoNaIn advised the Ministry of Health on the following situations, among others:

- Single-dose vaccination strategy for the introduction of the hepatitis A vaccine into the schedule [8,9].
- Implementation of contingency and vaccination plans to control the H1N1 influenza epidemic in 2009 [10].
- Introduction of the 13-valent pneumococcal conjugate vaccine into the immunization program in 2012 [11,12].
- Introduction of the human papilloma virus vaccine into the schedule in 2011 [13,14].
- Recommendation that pregnant women receive the dTap vaccine [15].
- Universal vaccination of adults against hepatitis B [16].

The contribution of the Ministry of Health, which consisted of providing support on studies conducted for evidence-based decision-making, was fundamental to carrying out this task. A key aspect of CoNaIn’s advisory role was that, by using the scientific evidence and the local epidemiological situation as tools, its recommendations strengthened the Ministry of Health’s decision-making process. In addition, the fact that the members of CoNaIn were representatives of scientific societies and regulatory bodies increased trust in national immunization policy among the general public and health professionals alike.

1.2. Evolution of CoNaIn

In recent years, the Argentine government has decided to prioritize vaccination as a State policy, emphasizing this strategy as a sign of social equity. This entails evaluating the need to introduce new vaccines not currently included in the program, such as chicken pox and rotavirus, update immunization policies (such as the plan to replace the attenuated polio vaccine with the inactivated vaccine) or to provide rapid response to epidemiological situations that affect the population (for example, imported measles cases), among other interventions. Therefore, it was deemed necessary to restructure CoNaIn to increase its capacity to formulate new sound and evidence-based recommendations. For this purpose, technical exchange between CoNaIn and the U.S. ACIP was organized with support from the PAHO ProVac Initiative and the Centers for Disease Control (CDC). In June 2012, a working meeting was held at CDC headquarters in Atlanta, with the participation of both organizations, representatives of the Ministry of Health, and members of CoNaIn.

The purpose of restructuring was to give CoNaIn a structure and regulations that would make it possible to formalize the formulation of recommendations, giving them the greatest possible transparency and soundness according to the previous experience of similar organizations like ACIP and SAGE.

Through this initiative, CoNaIn’s strength will be based on the following aspects:

1. Decision-making based on evidence and local epidemiological data.
2. Trust in and adherence to its recommendations by the population, healthcare workers and the media, as the result of a transparent decision-making process conducted with support and advice from experts and scientific societies guided by available evidence.
3. Evaluation of the impact of strategies proposed by CoNaIn through monitoring and surveillance reports produced by ProNaCEI.

According to WHO recommendations, CoNaIn will have the three key characteristic of a NITAG: formal (establish by a ministerial decree), technical (the terms of reference specify only a technical advisory role), and independent (member signed a declaration of interest and neither supervises nor reports to the Ministry of Health) [3,4].

2. New proposal for CoNaIn

In this new structure the commission was provided with a regulation which was lacking in the previous version. The main features introduced are new definitions about members, declaration of conflict of interest and mechanism of decision.

2.1. Purpose

CoNaIn is an independent technical body that advises national policy-makers on decision making on matters related to immunization based on evidence and local epidemiology. As it is an advisory body, it does not have decision-making, implementation, coordination or regulatory responsibilities regarding activities related to immunization.

2.2. Functions

Its functions include the formulation of recommendations on the introduction of vaccines into the immunization program, administration schedules, vaccine safety, vaccination policies, vaccine development, surveillance of vaccine-preventable diseases and any other matter on which ProNaCEI requires advice.

2.3. Composition

1. Core members: a group of experts on the matter (members), one of whom will serve as the chair of CoNaIn. The experts may be from the following fields or areas of expertise: infectious diseases, immunization, internal medicine, family medicine, microbiology and nursing. They will carry out their functions for a two-year period, with the possibility of being reelected for an additional period.
2. Associate members: representatives of scientific societies, technical bodies, national laboratories or national Ministry of Health programs, and guest experts or advisors.
3. A representative responsible for the immunization program per region.
4. Members of the Secretariat: the secretary (head of ProNaCEI) and a technical expert to provide status reports and consolidate recommendations.

Core members will be selected by ProNaCEI. The representatives of scientific societies and technical bodies will be appointed by the same. All of them will perform their functions ad honorem and must declare any conflicts of interest. No one matching the following descriptions may be a member: a. employee or advisor to a vaccine company that produces vaccines or related products; b. shareholder of a vaccine company. Anyone who has participated in the development of a product or on an advisory committee on a product discussed by CoNaIn may not participate in the formulation of recommendations on that particular product.
2.4. Working methodology

CoNaN will base its decisions on technical (efficacy, safety, burden of disease and cost-effectiveness), programmatic (supply, infrastructure and financing) and social criteria (acceptability, risk perception, political will and social equity) [17].

Working groups will be established to provide evidence-based information and options for consideration by CoNaN experts.

In order to evaluate the degree of evidence objectively, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system will be employed [18, 19].

2.5. Administrative and financial support

ProNaCEI will be responsible for providing administrative support. Regarding funding, costs will be limited to expenses related to holding meetings, administrative expenses and studies requested by the commission.

3. Discussion

The existence of a national advisory committee has enhanced the process of decision making related to immunization strategies in the countries that have established one.

The experience gained by CoNaN over twelve years of work has demonstrated the importance of having advisory committees composed of experts who make evidence-based recommendations to national immunization programs. As a result of the CoNaN recommendations which have been adopted by the Ministry of Health so far, significant achievements in the area of immunization were obtained. Examples of these achievements are: a national immunization schedule with sixteen vaccines [20], an important reduction of liver transplant due to hepatitis A [8, 9] and a high vaccination rate with influenza in risk group [10].

This new structure took ACIP as a model. Support was received from the PAHO ProVacc Initiative and the CDC through a working meeting held at CDC headquarters in Atlanta, with the participation of both organizations, representatives of the Ministry of Health, and members of CoNaN. As a result of this meeting, regulation for the CoNaN was developed. In Argentina as in other countries, expert opinion and the participation of representatives of scientific societies are considered important and are of high value for general public and health professionals. This increases the trust and response to the recommendations of the Ministry of Health.

Among the lessons learned, the importance of knowing the local epidemiological situation, the burden of disease, the use of cost-effectiveness studies and evidence-based decision making agreed upon by members of the commission are worth mentioning. Examples of these lessons include the previously mentioned experience with influenza and hepatitis A immunization.

In this new phase, the aim is to increase the results obtained in terms of number of recommendations and strengthen the role of a national advisory committee through a sound organic structure with operating regulations in line with the growing complexity of immunization. This operation will be supported by three lines of action: decision-making based on evidence and local epidemiology, building trust in the committee’s recommendations derived from the participation of experts and scientific societies and measurement of the impact of recommended strategies based on surveillance system data.

4. Conclusions

National advisory groups have proven to be a highly important tool in the implementation of immunization programs, as they strengthen them significantly. In Argentina, CoNaN has fulfilled this role over the last twelve years, with significant achievements in the introduction of vaccines into the national vaccination program and the formulation of evidence-based recommendations, with a strong impact on population’s health improvement. The new structure of the commission and joint work with PAHO ProVacc Initiative and the CDC will make it possible to strengthen this strategy. The experience gained through CoNaN’s work to date and that to be obtained following its restructuring could be useful to healthcare authorities in other countries working toward a more transparent, evidence-based decision making framework.

References

[18] New framework (GRADE) for development of evidence-based recommendations by the advisory committee on immunization practices. MMWR 2012;61(18):327.