



## Brief report

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



Daniel Stecher<sup>a,\*</sup>, Alejandra Gaiano<sup>a</sup>, Cristián Biscayart<sup>a</sup>, Angela Gentile<sup>b</sup>,  
Silvia Gonzalez Ayala<sup>c</sup>, Eduardo López<sup>c</sup>, Pablo Bonvehí<sup>d</sup>, Pablo Yedlin<sup>e</sup>,  
Cara Janusz<sup>f</sup>, Carla Vizzotti<sup>a</sup>

<sup>a</sup> Programa Nacional de Control de Enfermedades Immunoprevenibles, Ministerio de Salud, Buenos Aires, Argentina

<sup>b</sup> Sociedad Argentina de Pediatría, Buenos Aires, Argentina

<sup>c</sup> Sociedad Argentina de Infectología Pediátrica, Buenos Aires, Argentina

<sup>d</sup> Sociedad Argentina de Infectología, Buenos Aires, Argentina

<sup>e</sup> Ministro de Salud de Tucumán, Tucumán, Argentina

<sup>f</sup> Comprehensive Family Immunization Project, The ProVac Initiative, Pan American Health Organization, Washington, DC, USA

## ARTICLE INFO

## Article history:

Received 10 July 2013

Received in revised form 25 January 2014

Accepted 30 January 2014

Available online 13 February 2014

## Keywords:

Immunization

Decision making

Evidence based decisions

National advisory committee

## ABSTRACT

In Argentina, the National Technical Advisory Group on Immunizations is represented by the National Immunization Commission (CoNaIn), 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 CoNaIn 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.

© 2014 Elsevier Ltd. All rights reserved.

### 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 (CoNaIn), an organization created by the Ministry of Health in 2000. CoNaIn 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 CoNaIn.

This article describes the historical evolution, characteristics and achievements of CoNaIn 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 CoNaIn 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,

\* Corresponding author at: Programa Nacional de Control de Enfermedades Immunoprevenibles, Ministerio de Salud, Av. 9 de julio 1925 (C1073ABA), Buenos Aires, Argentina. Tel.: +54 1143799018.

E-mail address: [dstecher@intramed.net](mailto:dstecher@intramed.net) (D. Stecher).

as well as procurement and distribution of the immunobiologicals 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 a 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 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 Diseases and 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 with the previous experience of similar organisms 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

CoNaIn 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 CoNaIn 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 CoNaIn 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 CoNaIn 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 ProVac 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 CoNaIn. As a result of this meeting, regulation for the CoNaIn was developed. In Argentina as in others 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, CoNaIn 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 ProVac Initiative and the CDC will make it possible to continue strengthening this strategy. The experience gained through CoNaIn'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

- [1] Smith JC. The structure, role and procedures of the Advisory Committee on Immunization Practices (ACIP). *Vaccine* 2010;258:A68–75.
- [2] Strategic Advisory Group of Experts (SAGE) on immunization. WHO; 2014. Available at: <http://www.who.int/immunization/sage/en/> [accessed July 2012].
- [3] Duclos P. National Immunization Technical Advisory Groups (NITAGs): guidance for their establishment and strengthening. *Vaccine* 2010;28(Suppl. 1):A18–25. <http://www.sciencedirect.com/science/article/pii/S0264410X10001957> [accessed June 2013].
- [4] Improving evidence-based decision-making in immunization programmes. Regional Action Plan 2008–2010. World Health Organization, Regional Office for Eastern Mediterranean; 2009. <http://www.who.int/immunization/sage/RegionalActionPlanforImprovingDecisionMaking.UpdatedDec2009.pdf> [accessed June 2013].
- [5] Jauregui B, Sinha A, Clark A, Bolanos B, Resch S, Toscano C, et al. Strengthening the technical capacity at country-level to make informed policy decisions on new vaccine introduction: lesson learned by PAHO's ProVac initiative. *Vaccine* 2011;29:1099–106.
- [6] República Argentina. Censo; 2010. Available at: [http://www.censo2010.indec.gov.ar/resultadosdefinitivos\\_totalpais.asp](http://www.censo2010.indec.gov.ar/resultadosdefinitivos_totalpais.asp) [accessed July 2012].
- [7] Resolución Ministerio de Salud número 941. Expediente número 2002-11144/00-6. República Argentina.
- [8] Vizzotti C, Rearte A, Gentile A, González J, Ramonet M, Cañero M, et al. Vacunación universal con monodosis contra hepatitis A en argentina: impacto de la intervención. In: XII Congreso de la Sociedad Argentina de Infectología. 2012.
- [9] Hepatitis A vaccine WHO position paper; 2012. Available at: [http://www.who.int/wer/2012/wer8728\\_29.pdf](http://www.who.int/wer/2012/wer8728_29.pdf) [accessed September 2012].
- [10] Vizzotti C, Biscayart C, Carlino O, Gaiano A, Rearte A, Gentile A, et al. Influenza pandemic in Argentina: impact and control measures. In: VII Options for the control of Influenza. 2010.
- [11] Lineamientos técnicos para la introducción de la vacuna conjugada contra el neumococo en el calendario nacional de inmunizaciones de la República Argentina. Ministerio de Salud; 2012. Available at: <http://www.msal.gov.ar/images/stories/epidemiologia/inmunizaciones/lineamientos-neumococo-25-11-2011.pdf> [accessed September 2012].
- [12] Urueña A, Pippo P, Betelu MS, Virgilio F, Giglio N, Gentile A, et al. Cost-effectiveness analysis of the 10- and 13-valent pneumococcal conjugate vaccines in Argentina. *Vaccine* 2011;29(31):4963–5497.
- [13] Lineamientos técnicos para la introducción de vacuna contra el virus de papiloma humano. Argentina: Ministerio de Salud; 2011. Available at: <http://www.msal.gov.ar/images/stories/epidemiologia/inmunizaciones/equipos-de-salud/lineamientos-tecnicos-vph-2011.pdf> [accessed July 2012].
- [14] Ciapponi A, Bardach A, Glujovsky D, Gibbons L, Picconi MA. Type-specific HPV prevalence in cervical cancer and high-grade lesions in Latin America and the Caribbean: systematic review and meta-analysis. *PLoS ONE* 2011;6(10):e25493.
- [15] Alerta epidemiológica: tos convulsa. Argentina: Ministerio de Salud; 2012. Available at: <http://www.msal.gov.ar/images/stories/alertas/epidemiologia/2012/alerta-1-tos-convulsa-2012.pdf> [accessed July 2012].
- [16] Vacunación universal contra el virus de la hepatitis B. Argentina: Ministerio de Salud; 2012. Available at: <http://www.msal.gov.ar/images/stories/epidemiologia/inmunizaciones/2012/lineamientos-vacunacion-universal-hepatitis-b.pdf> [acceso setiembre 2012].
- [17] Andrus JK, Toscano CM, Lewis M, Oliveira L, Roper AM, Davila M. A model for enhancing evidence-based capacity to make informed policy decisions on the introduction of new vaccines in the Americas: PAHO's ProVac initiative. *Public Health Rep* 2007;122:811–6.
- [18] New framework (GRADE) for development of evidence-based recommendations by the advisory committee on immunization practices. *MMWR* 2012;61(18):327.
- [19] Grade Working Group. Available at: <http://www.gradeworkinggroup.org/> [accessed July 2012].
- [20] National immunization schedule. Argentina: Ministerio de Salud; 2013. Available at: <http://www.msal.gov.ar/index.php/component/content/article/46/184-calendario-nacional-de-vacunacion-2012>