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An overview of the National Consultative Council of Immunization in Honduras

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abstract

The State of Honduras instituted its technical advisory committee on immunization in response to recommendations made by the Pan-American Health Organization (PAHO) and the National Extended Program of Immunization (EPI). On 9 October 1999, the “National Consultative Council of Immunization” (NCCI) was established to provide support and recommendations to the EPI program for the eradication, elimination and control of vaccine-preventable diseases. The seven permanent members of the Council are all paediatricians. Additionally, there are liaison members (from PAHO, the national EPI team, and others) who participate in NCCI meetings when required. Meetings take place three times per year. The high quality of Council recommendations is demonstrated by the fact that the health authorities have adopted all of them.

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1. Introduction

In every country in the region, irrespective of income levels, the Pan-American Health Organization (PAHO) has for many years promoted the development of national committees on immunization practices (NCIP). Since 2006, within the framework of its Global Immunization Vision and Strategy, the World Health Organization (WHO), along with UNICEF, has officially and actively supported policy-making structures for vaccines and immunization, encouraging the creation of committees to bring relevant expertise in both intermediate and low-income countries. Indeed, implementing this strategy has enabled countries to make evidence-based decisions concerning the introduction of new vaccines and new immunization program strategies. The process considerably validates public institutions in charge of health-related issues and facilitates the assessment of immunization interventions and strategies.

Abbreviations: ACIP, Advisory Committee for Immunization Practices; AEFI, Adverse Events Following Immunization; CDC, Centers for Disease Control and Prevention; CONSUMI, Superior Ministerial Council; EPI, Extended Program of Immunization; NCCI, National Consultative Council of Immunization; NCIP, national committees on immunization practices; PAHO, Pan-American Health Organization; TAG, Technical Advisory Group; UNAH, National Autonomous University of Honduras; UNICEF, United Nations Children’s Fund; VPD, vaccine-preventable diseases; WHO, World Health Organization.

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2. Genesis of the Council

The State of Honduras implemented its technical advisory committee on immunization in response to recommendations made by the PAHO Technical Advisory Group (TAG) for vaccine-preventable diseases (VPD) and by WHO. In each member state, the individual national governments create and implement their own policies for vaccination programs, often following the guidelines set by WHO’s global office. WHO regional offices also participate in adapting recommendations to apply the global Expanded Program on Immunizations (EPI), providing publications and advice to the member states.

However, in addition to incorporating formal global recommendations, the creation of the Council reflected local specific needs. In 1979 the Health Secretary of Honduras created the National EPI with the objective of contributing to the control of VPD through a permanent program of free vaccination with emphasis on children [1]. For almost two decades the Honduras EPI offered only five vaccines, but in 1994 it began introducing new and under-used vaccines. The need then arose for a national consultative authority within the EPI to provide technical support on the topic of immunization.

Moreover, once the global EPI programme was integrated in Honduras, its national EPI team developed strong links with national medical associations working on VPD-related activities. With the objective of eradicating poliomyelitis, a committee entitled the “National Commission for the Eradication of Poliomyelitis” was created in 1988, representing the first step towards creating a Technical Advisory Group on immunization. This committee provided advice on other aspects of the EPI with the support of

professors from the National Autonomous University of Honduras (UNAH) and other identified national EPI experts. In 1994 another committee was created, the “National Commission for the Certification and Eradication of Poliomyelitis”, with a strengthened role and position.

Finally, on 9 October 1999, the Health Secretariat of Honduras established the “National Consultative Council of Immunization” (NCCI), by means of Ministerial Agreement number 3205, published in the official journal *La Gaceta* [2]. The creation of the Council made official the technical and scientific support received from recognized health experts in Honduras.

3. Structure and operating rules of the NCCI

3.1. General overview

The objectives, as stated in the NCCI’s official terms of reference, are the following: to “provide support and recommendations to the EPI for succeeding in the eradication, elimination and control of vaccine-preventable diseases through the definition and implementation of standardization, research, epidemiological monitoring, communication, resource mobilization and cold chain strategies, and other related aspects that enable achievement of goals and commitments for the control, elimination and eradication of vaccine-preventable diseases”.

The NCCI’s core activities are financed from part of the funding allocated by PAHO to the Health Secretariat of Honduras for the EPI team under the EPI Five-year Plan of Action [3]. Meeting expenditures (refreshments, documents, printing, copying, etc.) are covered on an annual basis to facilitate the work of the members.

The seven permanent members are all paediatricians, sharing therefore the same expertise and thus able to relate to each other on an equal basis. Each member works in a public or private hospital or at the Honduras Institute of Social Security. They are all active members of the Honduran Pediatrics Association (Table 1).

PAHO’s Immunization Bulletin of October 2007 describes the development, structure and functioning of this advisory committee. The publication states that “it is composed of members of scientific societies, professional associations and universities who meet four-to-six times a year. They issue recommendations on the immunization schedule and provide technical support. The NCCI also plays an important role for program advocacy” [4].

Meetings take place at the National Biologics Center located at EPI headquarters. These meetings are closed. Regular meetings are scheduled a year in advance but generally the next meeting’s date and key topics are agreed upon at each meeting. Additionally, extraordinary meetings are called in cases of emergency. Regular meetings occur approximately three times per year. The meetings are prepared by the institution that serves as the Secretariat of the Council, in this case the EPI as part of the Health Secretariat.

Table 1
Members, affiliations and expertise.

Chairman: Paediatrician, Professor of the College of Medical Sciences (National Autonomous University of Honduras), active member of the Honduran Pediatric Association.
Secretariat: EPI Executive Director, Public Health Doctor and member of the Honduras Public Health Doctors Association.
Members: Paediatricians, working in public/private hospitals or at the Honduras Institute of Social Security, active members of the Honduran Pediatric Association.
Liaison officers: PAHO National and International Consultant, EPI technical team, General Administrator for Health Promotion, General Administrator of Health Surveillance.

3.2. Membership rules

Initially NCCI members were appointed by the Secretariat of Health through the EPI. The selection of new members is now carried out by the NCCI itself according to needs it identifies [5]. Before a selection is made, a medical association (e.g. the Honduran Pediatric Association) presents its candidate to the EPI in response to the solicited profile. The NCCI subsequently examines the proposal and confirms the selection of the candidate by notifying the association. The successful candidate is eventually asked to formally meet with the Superior Ministerial Council (CONSUMI) of the Health Secretariat.

NCCI members do not receive any salary for the activities they carry out for the Council and are appointed for 2 years. A member can be asked to stay on for a longer period of time, however, in the event of another member resigning and the Council not wanting to look outside for a replacement. If a member resigns, he or she presents a letter of resignation to the board of directors. The resignation is then discussed by all the members gathered in a Council meeting, to decide whether it will be accepted, or not. Once accepted, the resignation procedure requires that the association, to which the resigning person belongs, appoint another person. If the person resigning is not part of any association, the EPI itself will identify another candidate, perhaps a member whose term is ending. If a member resigns for a temporary period of time, he or she can be reappointed.

There are no ex officio members. However, there is opportunity for external individuals (PAHO, industry experts, and others) to participate in NCCI meetings when required. These persons are considered “liaison members”.

4. Process for development of NCCI recommendations

As mentioned earlier, Council discussions are closed. Recommendations are reached through consensus. If the experts do not agree, they have to provide a scientific basis for discussing the matter further or they may vote and accept the decision of the majority. Recommendations are made on the following topics: the use of new vaccines, vaccine schedules, VPDs (mainly those in the process of eradication or elimination), support of the EPI Health Promotion Plan, Adverse Events Following Immunization (AEFI), and other topics.

Besides relying on their own expertise, members make use of the following sources of external data: official reports; WHO position statements; reports and recommendations from international meetings; positions of invited *ad hoc* experts; publications; and Internet websites (USA’s Advisory Committee for Immunization Practices – ACIP: <http://www.cdc.gov/vaccines/recs/acip/default.htm>, USA’s Centers for Disease Control and Prevention – CDC: www.cdc.gov and PAHO: www.paho.org). In general, the NCCI follows official WHO recommendations for vaccine use.

The primary vaccine-preventable outcomes that the NCCI uses to generate recommendations are the following: mortality; hospitalizations; epidemic potential; resource availability; and affordability. Other outcomes are also taken into account: overall morbidity; disability-adjusted life years (DALYs) or quality-adjusted life years (QALYs) lost; and equity. However it is important to note that the NCCI itself does not conduct economic evaluations. The outcomes are derived from the information generated at national and international levels for decision-making.

Recommendations are transmitted by the Council directly to decision-makers through notes and approved minutes of meetings. Other documents produced by the NCCI are published as meeting minutes, notes to superior authorities of the Health Secretariat and

position reports stating an opinion on new vaccine implications, classification of AEFI, and other topics. Minutes are made available to anyone working at the Secretariat or the Council who might need specific information [6]. Position reports and notes transmitted to the Health Secretariat are not accessible to the public.

In case of the introduction of new vaccines, once the technical decision in favour of introduction is made, an analysis of financial sustainability is required. This process is undertaken by the administrative department of the Health Secretariat and the Analysis Unit of the Finance Secretary.

5. The independence of the NCCI members

Because the impact of introducing a new vaccine involves major public health and financing issues, decisions on implementing new vaccines in national immunization programs should be impartial and based on rational, evidence-based criteria. Therefore it is very important that the Council members are independent. In the case of the NCCI of Honduras there are three concerns that emerge: the impact of the linkage to medical associations, the presence of EPI staff and potential conflicts of interest.

5.1. The impact of the linkage to medical associations

As noted earlier, NCCI members are strongly linked to medical associations (notably the Honduran Pediatric Association). This may have an impact on the recommendations taken by the Council for the Health Secretariat. However, this should not be considered a serious threat to the independence of the Council members. Even if medical associations present candidates for NCCI membership, they do not provide any financial support for the council's operating activities.

NCCI members are themselves also members of these associations, and the Council was originally built on this specificity. The Council is moving to enhance the presence of medical associations while at the same time aiming for more diversity. The NCCI also plans to increase the number of its staff members by integrating representatives of the Gynecology and Obstetrics Association, along with representatives of the Honduran Allergy, Immunology and Infectious Diseases Society.

5.2. The presence of EPI

Whereas developing countries generally struggle with problems involving the funding of vaccines and the extent of coverage of standard immunization programs, industrialized nations face problems involving the financing of expanded programs. Honduras, however, like most of the other Latin-American countries, already has extensive vaccine coverage due to active promotion of immunization by PAHO. The global EPI has been integrated in the country for many years and its national team has a relatively strong influence. Thus countries like Honduras tend to have an industrialized-country profile, i.e. their legislation facilitates and guarantees the financing of both current and new vaccines in compliance with the national EPI.

The Council meetings are held at the national EPI headquarters. This alone denotes the close relation existing between EPI and the NCCI. Also, the fact that one of the senior members of the NCCI is the EPI Executive Director is significant in this regard. Officially the EPI, being part of the Health Secretariat, appoints new members. Any candidates for NCCI membership presented by the medical associations are selected by the EPI technical team according to the solicited profile. In addition, the agenda of Council activities is exclusively based on lists of key issues elaborated yearly according to the needs identified by the EPI.

The close bond between the EPI and the NCCI could have an impact on the impartiality required for recommendations taken

by the Council. However, as in the case of medical associations, this relationship must be understood as historically specific to this country even though it might be considered a source of potential bias if it were the case for committees in industrialized countries. This bond is part of the Council's identity and it has no influence on the decision-making process. The high quality of the Council's recommendations is demonstrated by the fact that to date, the health authorities have implemented all recommendations.

5.3. Measures to prevent conflicts of interests

The NCCI, acknowledging the importance of preventing conflicts of interests, has developed a strategy for avoiding such conflicts among Council members. If a member, for private or professional reasons, appears to have any specific interest in a topic under discussion, he or she will be required to resign temporarily and will be prohibited from voting on the matter. The fact that the authorities of Honduras have implemented this procedure adds legitimacy to the decision-making process. This process of temporary suspension of members has been used on two occasions. However, currently there is no requirement for an official written declaration of interest prior to each meeting or when a new member is appointed.

5.4. Potential role of other external public and private institutions

As described above, medical associations and EPI staff members play an important role in the recommendation process. PAHO and pharmaceutical industries also play a role in the formulation of recommendations but their presence is not as influential as that of the EPI and the medical associations. They nonetheless occasionally act as external experts at Council discussions. Both are considered providers of information, but they can neither participate in deliberations nor vote during meetings. They are not directly involved, therefore, when a recommendation is decided upon by the Council.

The Council pays considerable attention to avoiding any close links with the pharmaceutical industry. However, members occasionally participate in the revision of regulatory aspects related to vaccines that come from the private sector including pharmaceutical companies, giving recommendations to institutional proposals.

The role of PAHO is more significant, especially in the first stage of the work carried out by the Council members. This is historically based on the role PAHO played in initiating national committees on immunization practices in the region. Some PAHO national and international consultants are considered liaison officers. Furthermore, PAHO is the only external organization that can have a say in the agenda by transmitting its own recommendations. Also, together with the EPI staff, PAHO members help prepare working papers and related documentation for the meetings.

6. The NCCI areas of expertise and future directions

Most NCCI recommendations are based upon scientific data, particularly clinical trials. Use of an evidence-based process, regulated by ethical rules, allows the NCCI to develop what health authorities consider as important technical documents and gives the decision-making process greater legitimacy. Indeed, the NCCI provides a scientific basis for decisions that otherwise might be based primarily on political or economic concerns.

All Council members are doctors and do not have skills in health economics. However, economic evaluations have been taken into account when considering the introduction of new vaccines or changes that would increase costs (e.g. pentavalent vaccine DTP-Hib-hepatitis B, rotavirus vaccine and influenza vaccine). These formal economic evaluations have been undertaken in the country with the support of PAHO and WHO. In addition the Council accepts the results of economic evaluations done internationally

or regionally. Economic evaluations done by manufacturers are reviewed and analyzed, but at the moment they are not taken into consideration because of potential conflicts of interest.

The evidenced-based decision-making process of the Council could be further improved by increasing the number of meetings that would enable members to cover more material and enable recommendations to be made in a more timely fashion. Exchanging successful experiences with other committees in the region should also be considered. These are two strategies that have been suggested by the NCCI members themselves [7]. Another way to enhance the decision-making process would be to train the members in basics of health economics in order for them to develop some skills in economic evaluation and rely on their own knowledge and interpretations instead of relying solely on external data.

The role that the NCCI plays in informing policy recommendations is currently not well appreciated by the general public and greater publicity of this should be considered by Health Secretariat.

7. Conclusion

NCCI recommendations are considered important to the introduction of new vaccines such as pentavalent (DTP-Hib-hepatitis B) and rotavirus. These recommendations provide an evidence-based approach to the decision-making process. Moreover, they are taken by a group of experts whose professional and ethical trajectory is recognized. Facing the challenges of the accelerated introduction of new vaccines and the need to succeed in eradicating vaccine-preventable diseases, the Council acknowledges that it is necessary to review its operating rules and strengthen the continuous training of its members, especially in the field of health economics. Indeed, including data from economic assessments should be, as far as possible, part of the recommendation process.

At first glance, NCCI independence seemed to be jeopardized by the strong links the Council has developed with medical associa-

tions and with the EPI technical team. However, these bonds form part of the identity of the Council and part of the context of its creation.

All of the recommendations made by NCCI have been followed by the Health Secretariat of Honduras. This acknowledges the competence of the Council members and the quality of their work.

As far as the independence of Council members is concerned, care is taken to prevent conflicts of interest. Likewise, since the Council uses an evidence-based procedure to reach its recommendations (based on clinical trials), its legitimacy is ensured.

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Conflict of interest statement

The authors state that they have no conflict of interest.

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